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**VIRTUAL/TELECONFERENCE  
MIDWIFE ADVISORY COMMITTEE  
Virtual, 4822 Madison Yards Way, Madison  
Contact: Tom Ryan (608) 266-2112  
July 15, 2025**

*The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Committee.*

**AGENDA**

**12:00 P.M.**

**OPEN SESSION – CALL TO ORDER – ROLL CALL**

**A. Adoption of Agenda (1-2)**

**B. Approval of Minutes of May 13, 2025 (3)**

**C. Administrative Matters – Discussion and Consideration**

1. Department, Staff and Committee Updates
2. Committee Members
  - a) Abitz, Leslie C.
  - b) Bauer, Korina M.
  - c) Guzzardo, Angela I.
  - d) Scherer, Kelsey A.
  - e) Stevenson, Kaycie Marie

**D. Administrative Rule Matters – Discussion and Consideration (4-65)**

1. Drafting Proposals: SPS 180 to 183, Relating to Licensed Midwives Comprehensive Review
2. Pending and Possible Rulemaking Projects

**E. Licensed Midwives – Informed Consent Form – Discussion and Consideration (66-80)**

**F. Legislative and Policy Matters – Discussion and Consideration**

**G. Discussion and Consideration of Items Added After Preparation of Agenda:**

1. Introductions, Announcements and Recognition
2. Administrative Matters
3. Election of Officers
4. Education and Examination Matters
5. Credentialing Matters
6. Legislative and Policy Matters
7. Administrative Rule Matters

8. Committee Liaison Training and Appointment of Mentors
9. Informational Items

## **H. Public Comments**

## **ADJOURNMENT**

**NEXT MEETING: SEPTEMBER 23, 2025**

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED  
WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at <https://dsps.wi.gov>. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.



**VIRTUAL/TELECONFERENCE  
MIDWIFE ADVISORY COMMITTEE  
MEETING MINUTES  
MAY 13, 2025**

**PRESENT:** Leslie Abitz, Korina Bauer, Angela Guzzardo (*arrived at 12:09 p.m.*), Kayci Marie Stevenson, Kelsey Scherer

**STAFF:** Tom Ryan, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Tracy Drinkwater, Board Administration Specialist; and other DSPS Staff

**CALL TO ORDER**

Korina Bauer, Chairperson, called the meeting to order at 12:00 p.m. A quorum of four (4) members was confirmed.

**ADOPTION OF AGENDA**

**MOTION:** Leslie Abitz moved, seconded by Kayci Marie Stevenson, to adopt the agenda as published. Motion carried unanimously.

**APPROVAL OF MINUTES FROM MARCH 18, 2025**

**MOTION:** Leslie Abitz moved, seconded by Kayci Marie Stevenson, to approve the minutes of March 18, 2025, as published. Motion carried unanimously.

*Angela Guzzardo arrived at 12:09 p.m.*


**ADJOURNMENT**

**MOTION:** Korina Bauer moved, seconded by Leslie Abitz, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 2:01 p.m.

**State of Wisconsin  
Department of Safety & Professional Services**

**AGENDA REQUEST FORM**

<b>1) Name and title of person submitting the request:</b>  Nilajah Hardin Administrative Rules Coordinator		<b>2) Date when request submitted:</b> 07/02/25 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
<b>3) Name of Board, Committee, Council, Sections:</b> Midwife Advisory Committee			
<b>4) Meeting Date:</b> 07/15/25	<b>5) Attachments:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<b>6) How should the item be titled on the agenda page?</b>  Administrative Rule Matters – Discussion and Consideration 1. Drafting Proposals: SPS 180 to 183, Relating to Licensed Midwives Comprehensive Review 2. Pending or Possible Rulemaking Projects	
<b>7) Place Item in:</b> <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	<b>8) Is an appearance before the Board being scheduled?</b> <i>(If yes, please complete <a href="#">Appearance Request</a> for Non-DSPS Staff)</i>  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>9) Name of Case Advisor(s), if required:</b>  N/A	
<b>10) Describe the issue and action that should be addressed:</b> Attachments: 1. SPS 180 to 183 Redlined Code Text 2. FIGO Guideline on Misoprostol 3. ACOG Committee Opinions a. Ethical Decision Making in Obstetrics and Gynecology b. Informed Consent and Shared Decision Making in Obstetrics and Gynecology c. Refusal of Medically Recommended Treatment During Pregnancy 4. March of Dimes WI Maternity Care Desert 5. March of Dimes WI Report Card  Copies of current Department Rule Projects Can be Viewed Here: <a href="https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx">https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx</a>			
<b>11) Authorization</b> <div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="width: 60%;">             Signature of person making this request         </div> <div style="width: 35%; text-align: right;">           07/02/25            Date         </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="width: 60%;">           Supervisor (if required)         </div> <div style="width: 35%; text-align: right;">           Date         </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="width: 60%;">           Executive Director signature (indicates approval to add post agenda deadline item to agenda)         </div> <div style="width: 35%; text-align: right;">           Date         </div> </div>			
<b>Directions for including supporting documents:</b> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

## Chapter SPS 180

### AUTHORITY AND DEFINITIONS

SPS 180.01      Authority.      SPS 180.02      Definitions.

Note: Chapter RL 180 was renumbered chapter SPS 180 under s. 13.92 (4) (b) 1., Stats., Register November 2011 No. 671.

**SPS 180.01 Authority.** The rules in chs. SPS 180 to 183 are adopted under the authority of ss. 227.11 (2) and 440.08 (3), Stats., and subch. XIII of ch. 440, Stats.

**SPS 180.02 Definitions.** As used in chs. SPS 180 to 183 and in subch. XIII of ch. 440, Stats.:

- (1) “Administer” means the direct provision of a prescription drug or device, whether by injection, ingestion or any other means, to the body of a client.
- (1m) “Automated external defibrillator” has the meaning given in s. 440.01 (1) (ad), Stats.
- (2) “Client” means a woman who obtains maternity care provided by a licensed midwife.
- (3) “Consultation” means discussing the aspects of an individual client’s circumstance with other professionals to assure comprehensive and quality care for the client, consistent with the objectives in the client’s treatment plan or for purposes of making adjustments to the client’s treatment plan. Consultation may include history-taking, examination of the client, rendering an opinion concerning diagnosis or treatment, or offering service, assistance or advice.
- (3m) “Defibrillation” has the meaning given in s. 440.01 (1) (ag), Stats.
- (4) “Department” means the department of safety and professional services.
- (5) “Direct supervision” means immediate on-premises availability to continually coordinate, direct and inspect at first hand the practice of another.
- (7) “HIPAA” means the Health Insurance Portability and Accountability Act of 1996, 42 USC 1320d et seq.
- (8) “Licensed midwife” means a person who has been granted a license under subch. XIII of ch. 440, Stats., to engage in the practice of midwifery.
- (9) “Practice of midwifery” means providing maternity care during the antepartum, intrapartum, and postpartum periods consistent with the standards of practice set forth in ch. SPS 182.

- (10) “Temporary permit” means a credential granted under s. SPS 181.01 (4), to an individual to practice midwifery under the direct supervision of a licensed midwife pending successful completion of the requirements for a license under s. SPS 181.01 (1).
- (11) “Ventricular fibrillation” has the meaning given in s.440.01 (1) (i), Stats.

Chapter SPS 181

APPLICATIONS FOR LICENSURE, RENEWAL OF LICENSES AND TEMPORARY  
PERMITS

SPS 181.01 Applications.

Note: Chapter RL 181 was renumbered chapter SPS 181 under s. 13.92 (4) (b) 1., Stats., Register November 2011 No. 671.

**SPS 181.01 Applications. (1) LICENSES.** An individual who applies for a license as a midwife shall apply on a form provided by the department. An applicant who fails to comply with a request for information related to the application, or fails to meet all requirements for the license within 120 calendar days from the date of filing shall file a new application and fee if licensure is sought at a later date. The application shall include all of the following:

- (a) The fee specified in s. 440.03 (9), Stats.
- (b) Evidence satisfactory to the department of one of the following:
  - 1. That the applicant holds a valid certified professional midwife credential granted by the North American Registry of Midwives or a successor organization.
  - 2. That the applicant holds a valid certified nurse-midwife credential granted by the American College of Nurse Midwives or a successor organization.
  - 3. That the applicant holds a valid certified nurse-midwife or midwife credential granted by the American Midwifery Certification Board or a successor organization.
- (c) That the applicant, subject to ss. 111.321, 111.322 and 111.335, Stats., does not have an arrest or conviction record. An applicant who has a pending criminal charge or has been convicted of any crime or ordinance violation shall provide the department with all information requested relating to the applicant's pending criminal charge, conviction or other offense, as applicable. The department may not grant a midwife license to a person convicted of an offense under s. 940.22, 940.225, 944.06, 944.15, 944.17, 944.30, 944.31, 944.32, 944.33, 944.34, 948.02, 948.025, 948.06, 948.07, 948.075, 948.08, 948.09, 948.095, 948.10, 948.11 or 948.12, Stats.
- (d) Evidence satisfactory to the department that the applicant has current proficiency in the use of an automated external defibrillator achieved through instruction provided by an individual, organization, or institution of higher education approved under s. 46.03 (38), Stats., to provide the instruction.

**Note:** Instructions for applications ~~Applications~~ for licensure as a midwife are available ~~from the Department of Safety and Professional Services, Division of Professional Credential Processing, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708-8935, or from on~~ the department's website at: <http://dsps.wi.gov>.

**(1m) RECIPROCITY FOR SERVICE MEMBERS, FORMER SER- VICE MEMBERS, AND SPOUSES OF SERVICE MEMBERS OR FORMER SERVICE MEMBERS.** A reciprocal

midwife license shall be granted to an applicant who is a service member, former service member, or the spouse of a service member or former service member as defined in s. 440.09 (1), Stats., if the department determines that the applicant meets all of the requirements under s. 440.09 (2), Stats. Subject to s. 440.09 (2m), Stats., the department may request verification necessary to make a determination under this subsection.

**Note:** ~~Instructions for applications~~~~Application forms~~ are available on the department's website at <http://dsps.wi.gov> ~~https://dsps.wi.gov/pages/Home.aspx, or by request from the~~ Department of Safety and Professional Services, P.O. Box 8935, Madison, WI 53708, or call (608) 266-2112.

- (2) RENEWAL OF LICENSES. (a) Except for temporary permits granted under sub. (4), the renewal date for licenses granted under subch. XIII of ch. 440, Stats., is July 1 of each even-numbered year.
- (b) Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee specified in s. 440.08 (2) (a) 46w., Stats.
- (c) At the time of renewal of a license under par. (b), a licensed midwife shall submit proof satisfactory to the department of all of the following:
1. The licensee holds a valid certified professional midwife credential from the North American Registry of Midwives or a successor organization, or a valid certified nurse-midwife credential from the American College of Nurse Midwives or a successor organization.
  2. The licensee has current proficiency in the use of an automated external defibrillator achieved through instruction provided by an individual, organization, or institution of higher education approved under s. 46.03 (38), Stats., to provide the instruction.
- (3) LATE RENEWAL OF LICENSES. A licensed midwife who fails to renew a license by the renewal date may renew the license by submitting an application on a form provided by the department and satisfying the following requirements:
- (a) If applying less than 5 years after the renewal date, satisfy the requirements under sub. (2), and pay the late renewal fee specified in s. 440.08 (3), Stats.
- (b) If applying 5 years or more after the renewal date, satisfy the requirements under sub. (2); pay the late renewal fee specified in s. 440.08 (3), Stats., and submit proof of one or more of the following, as determined by the department to ensure protection of the public health, safety and welfare:
1. Successful completion of educational course work.
  2. Successful completion of the national examination required by the North American Registry of Midwives for certification as a certified professional midwife or successful completion of the national examination required by the American College of Nurse Midwives for certification as a certified nurse-midwife.

- (4) TEMPORARY PERMITS. (a) Application. An applicant seeking a temporary permit shall apply on a form provided by the department. An applicant who fails to comply with a request for information related to the application, or fails to meet all requirements for a permit within 120 calendar days from the date of filing shall submit a new application and fee if a permit is sought at a later date. The application shall include all of the following:
1. The fee specified in s. 440.05 (6), Stats.
  2. Evidence satisfactory to the department of all of the following:
    - a. The applicant is actively engaged as a candidate for certification with the North American Registry of Midwives or a successor organization; or is currently enrolled in the portfolio evaluation process program through the North American Registry of Midwives or a successor organization, or a certified professional midwife educational program accredited by the Midwifery Education Accreditation Council.
    - b. The applicant has received a written commitment from a licensed midwife to directly supervise the applicant's practice of midwifery during the duration of the temporary permit.
    - c. The applicant is currently certified by the American Red Cross or American Heart Association in neonatal resuscitation.
    - d. The applicant is currently certified by the American Red Cross or American Heart Association in adult cardiopulmonary resuscitation.
    - e. The applicant has attended at least 5 births as an observer.
    - f. The applicant, subject to ss. 111.321, 111.322 and 111.335, Stats., does not have an arrest or conviction record. An applicant who has a pending criminal charge or has been convicted of any crime or ordinance violation shall provide the department with all information requested relating to the applicant's pending criminal charge, conviction or other offense, as applicable. The department may not grant a temporary permit to a person convicted of an offense under s. 940.22, 940.225, 944.06, 944.15, 944.17, 944.30, 944.31, 944.32, 944.33, 944.34, 948.02, 948.025, 948.06, 948.07, 948.075, 948.08, 948.09, 948.095, 948.10, 948.11 or 948.12, Stats.

**Note:** ~~Instructions for applications~~ Applications are available ~~from the Department of Safety and Professional Services, Division of Professional Credential Processing, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708-8935, or from~~ on the department's website at: <http://dsps.wi.gov>.

- (b) Duration of permit. 1. The duration of a temporary permit is for a period of 3 years or until the permit holder ceases to be currently registered or actively engaged as a candidate for certification as specified in par. (a) 2., whichever is shorter.
2. A licensed midwife with a written commitment to supervise the holder of a temporary permit shall notify the department immediately of a termination of the supervisory relationship.

3. Upon termination of a supervisory relationship, the temporary permit shall be automatically suspended until the permit holder obtains another written supervisory commitment that complies with par. (a) 2. b.
4. The department may in its discretion grant renewal of a temporary permit. Renewal shall be granted only once and for a period of no more than 3 years. A permit holder seeking renewal of a temporary permit shall submit documentation that satisfies the requirements for an initial permit under par. (a).

**Note:** The North American Registry of Midwives may be contacted at ~~5257 Rosestone Dr., Lilburn, GA 30047~~ P.O. Box 420, Summertown, TN 38483, 1-888-842-4784, <https://narm.org/>. The American College of Nurse-Midwives may be contacted at ~~8402 Colesville Road, Suite 1550, silver spring, MD 20910~~ 409 12<sup>th</sup> Street SW, Suite 600, Washington, DC 20024-2188, (240) 485-1800, <https://www.midwife.org/>.



Chapter SPS 182

**STANDARDS OF PRACTICE**

SPS 182.01      Standards.      SPS 182.02      Informed consent.  
SPS 182.03      Practice.

**Note:** Chapter RL 182 was renumbered chapter SPS 182 under s. 13.92 (4) (b) 1., Stats., Register November 2011 No. 671.

**SPS 182.01 Standards.** Licensed midwives shall comply with the standards of practice of midwifery established by the National Association of Certified Professional Midwives.

**Note:** The standards of the National Association of Certified Professional Midwives are set forth in ch. SPS 183 Appendix I. The National Association of Certified Professional Midwives may be contacted at 234 Banning Road, Putney, VT 05346, (866) 704-9844, <https://www.nacpm.org/>.

**SPS 182.02 Informed consent. (1) DISCLOSURE OF INFORMATION TO CLIENT.** A licensed midwife shall, at an initial consultation with a client, provide a copy of the rules promulgated by the department under subch. XIII of ch. 440, Stats., and disclose to the client orally and in writing on a form provided by the department all of the following:

- (a) The licensed midwife's experience and training.
- (b) Whether the licensed midwife has malpractice liability insurance coverage and the policy limits of the coverage.
- (c) A protocol for medical emergencies, including transportation to a hospital, particular to each client.
- (d) A protocol for and disclosure of risks associated with vaginal birth after a cesarean section.
- (e) The number of babies delivered and the number of clients transferred to a hospital since the time the licensed midwife commenced practice of midwifery.
- (f) A statement that the licensed midwife does not have the equipment, drugs or personnel available to perform neonatal resuscitations that would normally be available in a hospital setting.

**Note:** Forms are available ~~from the Department of Safety and Professional Services, Division of Professional Credential Processing, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708-8935, or from on~~ the department's website at: <http://dsps.wi.gov>.

**(1m) DISCLOSURE OF INFORMATION BY TEMPORARY PERMIT HOLDER.** A temporary permit holder shall inform a client orally and in writing that the temporary permit holder may not engage in the practice of midwifery unless the temporary permit holder practices under the direct supervision of a licensed midwife.

**(2) ACKNOWLEDGEMENT BY CLIENT.** A licensed midwife shall, at an initial consultation with a client, provide a copy of the written disclosures required under sub. (1), to the client and obtain the client's signature acknowledging that she has been informed, orally and in writing, of the disclosures required under sub. (1).

**SPS 182.03 Practice. (1) TESTING, CARE AND SCREENING.** A licensed midwife shall:

- (a) Offer each client routine prenatal care and testing in accordance with current American College of Obstetricians and Gynecologists guidelines.
- (b) Provide all clients with a plan for 24 hour on-call availability by a licensed midwife, certified nurse-midwife or licensed physician throughout pregnancy, intrapartum, and 6 weeks postpartum.
- (c) Provide clients with labor support, fetal monitoring and routine assessment of vital signs once active labor is established.
- (d) Supervise delivery of infant and placenta, assess newborn and maternal well being in immediate postpartum, and perform Apgar scores.
- (e) Perform routine cord management and inspect for appropriate number of vessels.
- (f) Inspect the placenta and membranes for completeness.
- (g) Inspect the perineum and vagina postpartum for lacerations and stabilize.
- (h) Observe mother and newborn postpartum until stable condition is achieved, but in no event for less than 2 hours.
- (i) Instruct the mother, father and other support persons, both verbally and in writing, of the special care and precautions for both mother and newborn in the immediate postpartum period.
- (j) Reevaluate maternal and newborn well being within 36 hours of delivery.
- (k) Use universal precautions with all biohazard materials.
- (L) Ensure that a birth certificate is accurately completed and filed in accordance with state law.
- (m) Offer to obtain and submit a blood sample in accordance with the recommendations for metabolic screening of the newborn.
- (n) Offer an injection of vitamin K for the newborn in accordance with the indication, dose and administration route set forth in sub. (3).
- (o) Within one week of delivery, offer a newborn hearing screening to every newborn or refer the parents to a facility with a newborn hearing screening program.
- (p) Within 2 hours of the birth offer the administration of antibiotic ointment into the eyes of the newborn, in accordance with state law on the prevention of infant blindness.
- (q) Maintain adequate antenatal and perinatal records of each client and provide records to consulting licensed physicians and licensed certified nurse-midwives, in accordance with HIPAA regulations.

(2) PREScription DRUGS, DEvICES AND PROCEDUREs. A licensed midwife may administer the following during the practice of midwifery:

- (a) Oxygen for the treatment of fetal distress.
- (b) Eye prophylactics – 0.5% erythromycin ophthalmic ointment or 1% tetracycline ophthalmic ointment for the prevention of neonatal ophthalmia.
- (c) Oxytocin, or pitocin, as a postpartum antihemorrhagic agent.
- (d) Methyl-ergonovine, or methergine, for the treatment of postpartum hemorrhage.
- (dm) Misoprostol, or cytotec, for the prevention and treatment of postpartum hemorrhage.
- (d)(e) Vitamin K for the prophylaxis of hemorrhagic disease of the newborn.
- (e)(f) RHo (D) immune globulin for the prevention of RHo (D) sensitization in RHo (D)

Commented [NH1]: Other changes?

negative women.

~~(f)~~(g) Intravenous fluids for maternal stabilization —~~5% dextrose in lactated~~Lactated Ringer's solution—~~(D5LR)~~, unless unavailable or impractical in which case 0.9% sodium chloride may be administered.

~~(g)~~(h) In addition to the drugs, devices and procedures that are identified in pars. (a) to (g), a licensed midwife may administer any other prescription drug, use any other device or perform any other procedure as an authorized agent of a licensed practitioner with prescriptive authority.

**Note:** Licensed midwives do not possess prescriptive authority. A licensed midwife may legally administer prescription drugs or devices only as an authorized agent of a practitioner with prescriptive authority. For physicians, physician assistants, and advanced practice ~~nurses~~nurse prescribers, an agent may administer prescription drugs or devices pursuant to written standing orders and protocols.

**Note:** Medical oxygen, 0.5% erythromycin ophthalmic ointment, tetracycline ophthalmic ointment, oxytocin (pitocin), methyl-ergonovine (methergine), misoprostol (cytotec), injectable vitamin K and RHo (D) immune globulin are prescription drugs. See s. SPS 180.02 (1).

- (3) INDICATIONS, DOSE, ADMINISTRATION AND DURATION OF TREATMENT. The indications, dose, route of administration and duration of treatment relating to the administration of drugs and procedures identified under sub. (2) are as follows:

SPS 180 to 183 – Licensed Midwives Comprehensive Review  
Redlined Code Text

Medication	Indication	Dose	Route of Administration	Duration of Treatment
Oxygen	Fetal distress	Maternal: 6-8 L/minute Infant: 10-12 L/minute 2-4 L/minute	Mask  Bag and mask Mask	Until delivery or transfer to a hospital is complete 20 minutes or until transfer to a hospital is complete
0.5% Erythromycin Ophthalmic Ointment Or 1% Tetracycline Ophthalmic Ointment	Prophylaxis of Neonatal Ophthalmia	1 cm ribbon in each eye from unit dose package  1 cm ribbon in each eye from unit dose package	Topical  Topical	1 dose
Oxytocin (Pitocin) 10 units/ml	Postpartum hemorrhage only	10-20 units, 1-2 ml	Intramuscularly only	1-2 doses
Methyl-ergonovine (Methergine) 0.2 mg/ml or 0.2 mg tabs	Postpartum hemorrhage only	0.2 mg	Intramuscularly Orally	Single dose Every 6 hours, may repeat 3 times Contraindicated in hypertension and Raynaud's Disease
<del>Misoprostol (Cytotec) 800 mcg or 400-600 mcg</del>	<del>Prevention and Treatment of Postpartum hemorrhage only</del>	<del>800 mcg for treatment or 400-600 mcg for prevention</del>	<del>Sublingually or orally</del>	<del>1 dose</del>
Vitamin K 1.0 mg/0.5 ml	Prophylaxis of Hemorrhagic Disease of the Newborn	0.5-1.0 mg, 0.25-0.5 ml	Intramuscularly	Single dose
RHo (D) Immune Globulin	Prevention of RHo (D) sensitization in RHo (D) negative women	Unit dose	Intramuscularly only	Single dose at any gestation for RHo (D) negative, antibody negative women within 72 hours of spontaneous bleeding. Single dose at 26-28 weeks gestation for RHo (D) negative, antibody negative women and Single dose for RHo (D) negative, antibody negative women within 72 hours of delivery of RHo (D) positive infant, or infant with unknown blood type
<del>5% dextrose in lactated Ringer's solution (D5LR), unless unavailable or impractical in which case 0.9% sodium chloride may be administered</del>	To achieve maternal stabilization during uncontrolled post-partum hemorrhage or anytime blood loss is accompanied by tachycardia, hypotension, decreased level of consciousness, pallor or diaphoresis	<del>First liter run in at a wide-open rate, the second liter titrated to client's condition 125 mL/h or 250 mL/hr</del>	<del>IV catheter 18-gauge or greater (2 if hemorrhage is severe) Intravenously</del>	Until maternal stabilization is achieved or transfer to a hospital is complete

- (4) **CONSULTATION AND REFERRAL.** (a) A licensed midwife shall consult with a qualified licensed physician, licensed physician assistant, certified advanced practice nurse prescriber, or a licensed ~~certified~~ nurse-midwife providing obstetrical care, whenever there are significant deviations, including abnormal laboratory results, relative to a client's pregnancy or to a neonate. If a referral to a physician is needed, the licensed midwife shall refer the client to a physician and, if possible, remain in consultation with the physician until resolution of the concern.

Commented [NH2]: Other changes?

**Note:** Consultation does not preclude the possibility of an out-of-hospital birth. It is appropriate for the licensed midwife to maintain care of the client to the greatest degree possible, in accordance with the client's wishes, during the pregnancy and, if possible, during labor, birth and the postpartum period.

- (b) A licensed midwife shall consult with a qualified licensed physician, licensed physician assistant, certified advanced practice nurse prescriber, or ~~certified~~licensed nurse-midwife with regard to any mother who presents with or develops the following risk factors or presents with or develops other risk factors that in the judgment of the licensed midwife warrant consultation:
1. Antepartum.
    - a. Pregnancy induced hypertension, as evidenced by a blood pressure of 140/90 on 2 occasions greater than 6 hours apart.
    - b. Persistent, severe headaches, epigastric pain or visual disturbances.
    - c. Persistent symptoms of urinary tract infection.
    - d. Significant vaginal bleeding before the onset of labor not associated with uncomplicated spontaneous abortion.
    - e. Rupture of membranes prior to the 37th week gestation.
    - f. Noted abnormal decrease in or cessation of fetal movement.
    - g. Anemia resistant to supplemental therapy.
    - h. Fever of 102° F or 39° C or greater for more than 24 hours.
    - i. Non-vertex presentation after 38 weeks gestation.
    - j. Hyperemesis or significant dehydration.
    - k. Isoimmunization, Rh-negative sensitized, positive titers, or any other positive antibody titer, which may have a detrimental effect on mother or fetus.
    - L. Elevated blood glucose levels unresponsive to dietary management.
    - m. Positive HIV antibody test.
    - n. Primary genital herpes infection in pregnancy.
    - o. Symptoms of malnutrition or anorexia or protracted weight loss or failure to gain weight.
    - p. Suspected deep vein thrombosis.
    - q. Documented placental anomaly or previa.
    - r. Documented low lying placenta in woman with history of previous cesarean delivery.
    - s. Labor prior to the 37th week of gestation.

- t. History of prior uterine incision.
  - u. Lie other than vertex at term.
  - v. Multiple gestation.
  - w. Known fetal anomalies that may be affected by the site of birth.
  - x. Marked abnormal fetal heart tones.
  - y. Abnormal non-stress test or abnormal biophysical profile.
  - z. Marked or severe poly- or oligo-dydramnios.
  - za. Evidence of intrauterine growth restriction.
  - zb. Significant abnormal ultrasound findings.
  - zc. Gestation beyond 42 weeks by reliable confirmed dates.
2. Intrapartum.
- a. Rise in blood pressure above baseline, more than 30/15 points or greater than 140/90.
  - b. Persistent, severe headaches, epigastric pain or visual disturbances.
  - c. Significant proteinuria or ketonuria.
  - d. Fever over 100.6° F or 38° C in absence of environmental factors.
  - e. Ruptured membranes without onset of established labor after 18 hours.
  - f. Significant bleeding prior to delivery or any abnormal bleeding, with or without abdominal pain; or evidence of placental abruption.
  - g. Lie not compatible with spontaneous vaginal delivery or unstable fetal lie.
  - h. Failure to progress after 5 hours of active labor or following 2 hours of active second stage labor.
  - i. Signs or symptoms of maternal infection.
  - j. Active genital herpes at onset of labor.
  - k. Fetal heart tones with non-reassuring patterns.
  - L. Signs or symptoms of fetal distress.
  - m. Thick meconium or frank bleeding with birth not imminent.
  - n. Client or licensed midwife desires physician consultation or transfer.
3. Postpartum.
- a. Failure to void within 6 hours of birth.
  - b. Signs or symptoms of maternal shock.
  - c. Febrile: 102° F or 39° C and unresponsive to therapy for 12 hours.
  - d. Abnormal lochia or signs or symptoms of uterine sepsis.
  - e. Suspected deep vein thrombosis.
  - f. Signs of clinically significant depression.
- (c) A licensed midwife shall consult with a licensed physician or licensed certified nurse-midwife with regard to any neonate who is born with or develops the following risk factors:
- 1. Apgar score of 6 or less at 5 minutes without significant improvement by 10 minutes.
  - 2. Persistent grunting respirations or retractions.
  - 3. Persistent cardiac irregularities.
  - 4. Persistent central cyanosis or pallor.
  - 5. Persistent lethargy or poor muscle tone.

6. Abnormal cry.
7. Birth weight less than 2300 grams.
8. Jitteriness or seizures.
9. Jaundice occurring before 24 hours or outside of normal range.
10. Failure to urinate within 24 hours of birth.
11. Failure to pass meconium within 48 hours of birth.
12. Edema.
13. Prolonged temperature instability.
14. Significant signs or symptoms of infection.
15. Significant clinical evidence of glycemic instability.
16. Abnormal, bulging, or depressed fontanel.
17. Significant clinical evidence of prematurity.
18. Medically significant congenital anomalies.
19. Significant or suspected birth injury.
20. Persistent inability to suck.
21. Diminished consciousness.
22. Clinically significant abnormalities in vital signs, muscle tone or behavior.
23. Clinically significant color abnormality, cyanotic, or pale or abnormal perfusion.
24. Abdominal distension or projectile vomiting.
25. Signs of clinically significant dehydration or failure to thrive.

(5) TRANSFER. (a) Transport via private vehicle is an acceptable method of transport if it is the most expedient and safest method for accessing medical services. The licensed midwife shall initiate immediate transport according to the licensed midwife's emergency plan; provide emergency stabilization until emergency medical services arrive or transfer is completed; accompany the client or follow the client to a hospital in a timely fashion; provide pertinent information to the receiving facility and complete an emergency transport record. The following conditions shall require immediate physician notification and emergency transfer to a hospital:

1. Seizures or unconsciousness.
2. Respiratory distress or arrest.
3. Evidence of shock.
4. Psychosis.
5. Symptomatic chest pain or cardiac arrhythmias.
6. Prolapsed umbilical cord.
7. Shoulder dystocia not resolved by Advanced Life Support in Obstetrics (ALSO) protocol.
8. Symptoms of uterine rupture.
9. Preeclampsia or eclampsia.
10. Severe abdominal pain inconsistent with normal labor.
11. Chorioamnionitis.
12. Clinically significant fetal heart rate patterns or other manifestation of fetal distress.
13. Presentation not compatible with spontaneous vaginal delivery.

14. Laceration greater than second degree perineal or any cervical.
15. Hemorrhage non-responsive to therapy.
16. Uterine prolapse or inversion.
17. Persistent uterine atony.
18. Anaphylaxis.
19. Failure to deliver placenta after one hour if there is no bleeding and fundus is firm.
20. Sustained instability or persistent abnormal vital signs.
21. Other conditions or symptoms that could threaten the life of the mother, fetus or neonate.

(b) A licensed midwife may deliver a client with any of the complications or conditions set forth in par. (a), if no physician or other equivalent medical services are available and the situation presents immediate harm to the health and safety of the client; if the complication or condition entails extraordinary and unnecessary human suffering; or if delivery occurs during transport.

(6) **PROHIBITED PRACTICES.** A licensed midwife may not do any of the following:

- (a) Administer prescription pharmacological agents intended to induce or augment labor.
- (b) Administer prescription pharmacological agents to provide pain management.
- (c) Use vacuum extractors or forceps.
- (d) Prescribe medications.
- (e) **Provide out-of-hospital care to a woman who has had a vertical incision cesarean section.**
- (f) Perform surgical procedures including, but not limited to, cesarean sections and circumcisions.
- (g) Knowingly accept responsibility for prenatal or intrapartum care of a client with any of the following risk factors:
  1. Chronic significant maternal cardiac, pulmonary, renal or hepatic disease.
  2. Malignant disease in an active phase.
  3. Significant hematological disorders or coagulopathies, or pulmonary embolism.
  4. ~~Uncontrolled~~ ~~insulin~~ ~~insulin~~ requiring diabetes mellitus.
  5. Known maternal congenital ~~abnormalities~~ ~~conditions~~ affecting childbirth.
  6. Confirmed isoimmunization, Rh disease with positive titer.
  7. Active tuberculosis.
  8. Active syphilis or gonorrhea.
  9. Active genital herpes infection 2 weeks prior to labor or in labor.
  10. Pelvic or uterine ~~abnormalities~~ ~~conditions~~ affecting normal vaginal births, including tumors and malformations.
  11. ~~Alcoholism or abuse~~ ~~Alcohol use disorder~~.
  12. ~~Drug addiction or abuse~~ ~~Substance use disorder~~.
  13. ~~Confirmed AIDS status~~.
  14. ~~13.~~ Uncontrolled current serious ~~psychiatric illness~~ ~~psychological or behavioral condition or disorder~~.
  15. ~~Social or familial conditions unsatisfactory for out-of-hospital maternity care services~~.
  16. ~~14.~~ Fetus with suspected or diagnosed congenital ~~abnormalities~~ ~~conditions~~ that may

Commented [NH3]: Other changes?



require immediate medical intervention.

Chapter SPS 183  
GROUNDS FOR DISCIPLINE

SPS 183.01 Disciplinary proceedings and actions.

Note: Chapter RL 183 was renumbered chapter SPS 183 under s. 13.92 (4) (b) 1., Stats., Register November 2011 No. 671.

**SPS 183.01 Disciplinary proceedings and actions.**

(1) Subject to the rules promulgated under s. 440.03 (1), Stats., the department may reprimand a licensed midwife or deny, limit, suspend, or revoke a license or temporary permit granted under subch. XIII of ch. 440, Stats., if the department finds that the applicant, temporary permit holder, or licensed midwife has engaged in misconduct. Misconduct comprises any practice or behavior that violates the minimum standards of the profession necessary for the protection of the health, safety, or welfare of a client or the public. Misconduct includes the following:

- (a) Submitting fraudulent, deceptive or misleading information in conjunction with an application for a credential.
- (b) Violating, or aiding and abetting a violation, of any law or rule substantially related to practice as a midwife. A certified copy of a judgment of conviction is prima facie evidence of a violation.

Note: Pursuant to s. SPS 4.09, all credential holders licensed by the department need to report a criminal conviction within 48 hours after entry of a judgment against them. The department form for reporting convictions is available on the department's website at <http://dsps.wi.gov>.

- (c) Having a license, certificate, permit, registration, or other practice credential granted by another state or by any agency of the federal government to practice as a midwife, which the granting jurisdiction limits, restricts, suspends, or revokes, or having been subject to other adverse action by a licensing authority, any state agency or an agency of the federal government including the denial or limitation of an original credential, or the surrender of a credential, whether or not accompanied by findings of negligence or unprofessional conduct. A certified copy of a state or federal final agency decision is prima facie evidence of a violation of this provision.
- (d) Failing to notify the department that a license, certificate, or registration for the practice of any profession issued to the mid- wife has been revoked, suspended, limited or denied, or subject to any other disciplinary action by the authorities of any jurisdiction.
- (e) Violating or attempting to violate any term, provision, or condition of any order of the department.
- (f) Performing or offering to perform services for which the midwife is not qualified by education, training or experience.
- (g) Practicing or attempting to practice while the midwife is impaired as a result of any

condition that impairs the midwife's ability to appropriately carry out professional functions in a manner consistent with the safety of clients or the public.

- (h) Using alcohol or any drug to an extent that such use impairs the ability of the midwife to safely or reliably practice, or practicing or attempting to practice while the midwife is impaired due to the utilization of alcohol or other drugs.
- (i) Engaging in false, fraudulent, misleading, or deceptive behavior associated with the practice as a midwife including advertising, billing practices, or reporting, falsifying, or inappropriately altering patient records.
- (j) Discriminating in practice on the basis of age, race, color, sex, religion, creed, national origin, ancestry, disability or sexual orientation.
- (k) Revealing to other personnel not engaged in the care of a client or to members of the public information which concerns a client's condition unless release of the information is authorized by the client or required or authorized by law. This provision shall not be construed to prevent a credential holder from cooperating with the department in the investigation of complaints.
- (L) Abusing a client by any single or repeated act of force, violence, harassment, deprivation, neglect, or mental pressure which reasonably could cause physical pain or injury, or mental anguish or fear.
- (m) Engaging in inappropriate sexual contact, exposure, gratification, or other sexual behavior with or in the presence of a client. For the purposes of this paragraph, an adult shall continue to be a client for 2 years after the termination of professional services. If the person receiving services is a minor, the person shall continue to be a client for the purposes of this paragraph for 2 years after termination of services, or for one year after the client reaches age 18, whichever is later.
- (n) Obtaining or attempting to obtain anything of value from a client without the client's consent.
- (o) Obtaining or attempting to obtain any compensation by fraud, misrepresentation, deceit or undue influence in the course of practice.
- (p) Offering, giving or receiving commissions, rebates or any other forms of remuneration for a client referral.
- (q) Failing to provide the client or client's authorized representative a description of what may be expected in the way of tests, consultation, reports, fees, billing, therapeutic regimen, or schedule, or failing to inform a client of financial interests which might accrue to the midwife for referral to or for any use of service, product, or publication.
- (r) Failing to maintain adequate records relating to services provided a client in the course of a professional relationship.
- (s) Engaging in a single act of gross negligence or in a pattern of negligence as a midwife, or in other conduct that evidences an inability to apply the principles or skills of midwifery.
- (t) Failing to respond honestly and in a timely manner to a request for information from the department. Taking longer than 30 days to respond creates a rebuttable presumption that the response is not timely.
- (u) Failing to report to the department or to institutional supervisory personnel any violation of the rules of this chapter by a midwife.
- (v) Allowing another person to use a license granted under subch. XIII of ch. 440, Stats.

- (w) Failing to provide direct supervision over a temporary permit holder while the permit holder is engaging in the practice of midwifery.
- (2) Subject to the rules promulgated under s. 440.03 (1), Stats., the department shall revoke a license granted under subch. XIII of ch. 440, Stats., if the licensed midwife is convicted of any of the offenses specified in s. 440.982 (2), Stats.
- (3) Subject to s. 440.982, Stats., no person may engage in the practice of midwifery the person has been granted a license or a temporary permit to practice midwifery under subch. XIII of ch. 440, Stats., or granted a license to practice as a nurse-midwife under s. 441.15, Stats.
- (4) Subject to s. 440.981, Stats., no person may use the title “licensed midwife” unless the person has been granted a license to practice midwifery under subch. XIII of ch. 440, Stats., or granted a license to practice as a nurse-midwife under s. 441.15, Stats.

Chapter SPS 183

APPENDIX I

ESSENTIAL DOCUMENTS OF THE NATIONAL ASSOCIATION OF CERTIFIED  
PROFESSIONAL MIDWIVES

**Contents**

- I. Introduction
- II. Philosophy
- III. The NACPM Scope of Practice
- IV. Standards for NACPM Practice
- V. Endorsement Section

Gender references: To date, most NACPM members are women. For simplicity, this document uses female pronouns to refer to the NACPM member, with the understanding that men may also be NACPM members.

**I. Introduction**

The Essential Documents of the NACPM consist of the NACPM Philosophy, the NACPM Scope of Practice, and the Standards for NACPM Practice. They are written for Certified Professional Midwives (CPMs) who are members of the National Association of Certified Professional Midwives.

- They outline the understandings that NACPM members hold about midwifery.
- They identify the nature of responsible midwifery practice.

**II. Philosophy and Principles of Practice**

NACPM members respect the mystery, sanctity and potential for growth inherent in the experience of pregnancy and birth. NACPM members understand birth to be a pivotal life event for mother, baby, and family. It is the goal of midwifery care to support and empower the mother and to protect the natural process of birth. NACPM members respect the biological integrity of the processes of pregnancy and birth as aspects of a woman's sexuality.

NACPM members recognize the inseparable and interdependent nature of the mother-baby pair.

NACPM members believe that responsible and ethical midwifery care respects the life of the baby by nurturing and respecting the mother, and, when necessary, counseling and educating her in ways to improve fetal/infant well-being.

NACPM members work as autonomous practitioners, recognizing that this autonomy makes possible a true partnership with the women they serve, and enables them to bring a broad range of skills to the partnership.

NACPM members recognize that decision-making involves a synthesis of knowledge, skills, intuition and clinical judgment.

NACPM members know that the best research demonstrates that out-of-hospital birth is a safe and rational choice for healthy women, and that the out-of-hospital setting provides optimal opportunity for the empowerment of the mother and the support and protection of the normal process of birth.

NACPM members recognize that the mother or baby may on occasion require medical consultation or collaboration.

NACPM members recognize that optimal care of women and babies during pregnancy and birth takes place within a network of relationships with other care providers who can provide service outside the scope of midwifery practice when needed.

### **III. Scope of Practice for the National Association of Certified Professional Midwives**

The NACPM Scope of Practice is founded on the NACPM Philosophy. NACPM members offer expert care, education, counseling and support to women and their families throughout the caregiving partnership, including pregnancy, birth and the postpartum period. NACPM members work with women and families to identify their unique physical, social and emotional needs. They inform, educate and support women in making choices about their care through informed consent. NACPM members provide on-going care throughout pregnancy and continuous, hands-on care during labor, birth and the immediate postpartum period. NACPM members are trained to recognize abnormal or dangerous conditions needing expert help outside their scope. NACPM members each have a plan for consultation and referral when these conditions arise. When needed, they provide emergency care and support for mothers and babies until additional assistance is available. NACPM members may practice and serve women in all settings and have particular expertise in out-of-hospital settings.

### **IV. The Standards of Practice for NACPM Members**

The NACPM member is accountable to the women she serves, to herself, and to the midwifery profession. The NACPM Philosophy and the NACPM Scope of Practice are the foundation for the midwifery practice of the NACPM member. The NACPM Standards of Practice provide a tool for measuring actual practice and appropriate usage of the body of knowledge of midwifery.

Standard One: The NACPM member works in partnership with each woman she serves. The NACPM member:

- Offers her experience, care, respect, counsel and support to each woman she serves
- Freely shares her midwifery philosophy, professional standards, personal scope of practice and expertise, as well as any limitations imposed upon her practice by local regulatory agencies and state law
- Recognizes that each woman she cares for is responsible for her own health and well-being
- Accepts the right of each woman to make decisions about her general health care and her pregnancy and birthing experience
- Negotiates her role as caregiver with the woman and clearly identifies mutual and individual responsibilities, as well as fees for her services

- Communicates openly and interactively with each woman she serves
- Provides for the social, psychological, physical, emotional, spiritual and cultural needs of each woman
- Does not impose her value system on the woman
- Solicits and respects the woman's input regarding her own state of health
- Respects the importance of others in the woman's life.

Standard Two: Midwifery actions are prioritized to optimize well-being and minimize risk, with attention to the individual needs of each woman and baby.

The NACPM member:

- Supports the natural process of pregnancy and childbirth
- Provides continuous care, when possible, to protect the integrity of the woman's experience and the birth and to bring a broad range of skills and services into each woman's care
- Bases her choices of interventions on empirical and/or research evidence, verifying that the probable benefits outweigh the risks
- Strives to minimize technological interventions
- Demonstrates competency in emergencies and gives priority to potentially life-threatening situations
- Refers the woman or baby to appropriate professionals when either needs care outside her scope of practice or expertise
- Works collaboratively with other health professionals
- Continues to provide supportive care when care is transferred to another provider, if possible, unless the mother declines
- Maintains her own health and well-being to optimize her ability to provide care.

Standard Three: The midwife supports each woman's right to plan her care according to her needs and desires. The NACPM member:

- Shares all relevant information in language that is understandable to the woman
- Supports the woman in seeking information from a variety of sources to facilitate informed decision-making
- Reviews options with the woman and addresses her questions and concerns
- Respects the woman's right to decline treatments or procedures and properly documents her choices
- Develops and documents a plan for midwifery care together with the woman
- Clearly states and documents when her professional judgment is in conflict with the decision or plans of the woman
- Clearly states and documents when a woman's choices fall outside the NACPM member's legal scope of practice or expertise
- Helps the woman access the type of care she has chosen
- May refuse to provide or continue care and refers the woman to other professionals if she deems the situation or the care requested to be unsafe or unacceptable
- Has the right and responsibility to transfer care in critical situations that she deems to be unsafe. She refers the woman to other professionals and remains with the woman until the transfer is complete.

Standard Four: The midwife concludes the caregiving partnership with each woman responsibly. The NACPM member:

- Continues her partnership with the woman until that partnership is ended at the final postnatal visit or until she or the woman ends the partnership and the midwife documents same
- Ensures that the woman is educated to care for herself and her baby prior to discharge from midwifery care
- Ensures that the woman has had an opportunity to reflect on and discuss her childbirth experience
- Informs the woman and her family of available community support networks and refers appropriately.

Standard Five: The NACPM member collects and records the woman's and baby's health data, problems, decisions and plans comprehensively throughout the caregiving partnership. The NACPM member:

- Keeps legible records for each woman, beginning at the first formal contact and continuing throughout the caregiving relationship
- Does not share the woman's medical and midwifery records without her permission, except as legally required
- Reviews and updates records at each professional contact with the woman
- Includes the individual nature of each woman's pregnancy in her assessments and documentation
- Uses her assessments as the basis for on-going midwifery care
- Clearly documents her objective findings, decisions and professional actions
- Documents the woman's decisions regarding choices for care, including informed consent or refusal of care
- Makes records and other relevant information accessible and available at all times to the woman and other appropriate persons with the woman's knowledge and consent
- Files legal documents appropriately.

Standard Six: The midwife continuously evaluates and improves her knowledge, skills and practice in her endeavor to provide the best possible care. The NACPM member:

- Continuously involves the women for whom she provides care in the evaluation of her practice
- Uses feedback from the women she serves to improve her practice
- Collects her practice statistics and uses the data to improve her practice
- Informs each woman she serves of mechanisms for complaints and review, including the NARM peer review and grievance process
- Participates in continuing midwifery education and peer review
- May identify areas for research and may conduct and/or collaborate in research
- Shares research findings and incorporates these into midwifery practice as appropriate
- Knows and understands the history of midwifery in the United States
- Acknowledges that social policies can influence the health of mothers, babies and families; therefore, she acts to influence such policies, as appropriate.



## **V. Endorsement of Supportive Statements**

NACPM members endorse the Midwives Model of Care ({ 1996-2004 Midwifery Task Force), the Mother Friendly Childbirth Initiative ({ 1996 Coalition for Improving Maternity Services) and the Rights of Childbearing Women ({ 1999 Maternity Center Association, Revised 2004). For the full text of each of these statements, please refer to the following web pages.

Midwives Model of Care (MMOC)-<http://www.cfmidwifery.org/Citizens/mmoc/define.aspx>

Mother Friendly Childbirth Initiative (MFIC) -<http://www.motherfriendly.org/MFCI/>

Rights of Childbearing Women - <http://www.maternitywise.org/mw/rights.html>

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# Treatment of Post-Partum Haemorrhage with Misoprostol



FIGO GUIDELINE  
ANNOTATED VERSION

# Treatment of Post-Partum Haemorrhage with Misoprostol

## FIGO GUIDELINE

### Background Evidence

Post-partum haemorrhage (PPH) is a major cause of maternal death worldwide. When PPH occurs due to uterine atony, a number of medical and surgical interventions are used to control the bleeding [Mousa 2001, Ramanathan 2006]. A crucial aspect of PPH treatment is uterotonic therapy and the gold standard is oxytocin. However, it is often not available in low resource settings due to parenteral administration and cool storage requirements. Ergometrine is also commonly used for treatment of PPH, but needs to be given by injection and is unstable in heat and light. It is also contraindicated in women with hypertension and cardiac disease. It may not, therefore, be suitable for certain low resource settings.

Misoprostol, an E1 prostaglandin analogue, has been studied as an alternative to oxytocin due to its low cost, stability at room temperature, and ease of administration. Three randomised controlled trials (RCTs) have assessed the effectiveness of misoprostol for treatment of PPH [Winikoff 2010, Blum 2010, Lokugamage 2001]. Two compared 800 µg sublingual misoprostol with 40 IU intravenous oxytocin [Winikoff 2010, Blum 2010]. In the first tri-

al, involving 978 women diagnosed with PPH, oxytocin prophylaxis was not given [Winikoff 2010]. Results indicated IV oxytocin was more effective at controlling active bleeding within 20 minutes (96% vs. 90% of women) and preventing additional blood loss of 300 mL or more (17% vs. 30%). The second trial involved 809 women diagnosed with PPH, all of whom were given oxytocin prophylaxis (IV or IM) [Blum 2010]. Results indicated misoprostol was non-inferior to oxytocin at controlling active bleeding within 20 minutes (90% vs. 89%) and preventing additional blood loss of 300 mL or more (31% vs. 34%). The third RCT compared 800 µg rectal misoprostol with IM syntometrine plus IV syntocinon, also following receipt of oxytocin prophylaxis [Lokugamage 2001]. Results suggested that misoprostol may be more effective than syntometrine/syntocinon for treatment of PPH. However, this study was single blinded and the outcome was subjective assessment of response, and, therefore, prone to assessment bias.

Four RCTs have assessed the adjunct (simultaneous) use of misoprostol when given in conjunction with conventional uterotonics for treatment of PPH [Widmer 2010, Zuberi 2008, Walraven 2004, Hofmeyr 2004]. Two trials compared adjunct use of

600 µg sublingual misoprostol with placebo for treatment of PPH [Widmer 2010, Zuberi 2008]. Widmer et al. enrolled 1,422 women and found no differences between the misoprostol and placebo groups in terms of blood loss  $\geq 500$  mL, blood loss  $\geq 1000$  mL or post-partum haemoglobin changes. However, there was a higher incidence of side effects among those given misoprostol [Widmer 2010]. Zuberi et al. enrolled 61 women who had also received uterotonic prophylaxis for management of the third stage. Due to a lower than expected rate of PPH, the trial was unable to obtain statistical significance in any of the outcomes studied. There were non-significant trends, however, towards reduced post-partum blood loss, smaller drops in post-partum hemoglobin, and need for fewer additional interventions [Zuberi 2008]. A third trial by Walraven et al. compared adjunct use of 600 µg misoprostol (200 µg orally + 400 µg sublingually) with placebo among 160 women who had also received uterotonic prophylaxis. However, this pilot trial was not powered to detect significant differences between misoprostol and placebo [Walraven 2004]. Hofmeyr et al. compared adjunct use of a 1000 µg misoprostol regimen (200 µg oral + 400 µg sublingual + 400 µg rectal) with placebo in 238 women with uterotonic prophylaxis, and found no significant differences in blood loss  $\geq 500$  mL within one hour after treatment [Hofmeyr 2004].

No study has looked at the effectiveness of repeat doses of 800 µg sublingual misoprostol for treatment of PPH and as a result there is insufficient information about the risks and benefits of additional doses. Given documented side effects after a single dose of misoprostol for PPH treatment [Winikoff 2010, Blum 2010, Lokugamage 2001, Widmer 2010, Zuberi 2008, Walraven 2004, Hofmeyr 2004, Durocher 2010] and the absence of evidence of effect, repeat doses are not advised.

## Regimen

One dose of misoprostol **800 µg sublingually** is indicated for treatment of PPH when 40 IU IV oxytocin is not immediately available (irrespective of the prophylactic measures). The recommended dose does not change according to the woman's weight.

## Course of Treatment

Once PPH is diagnosed, the treatment should be given immediately.

## Repeat or Consecutive Doses

There is insufficient information about the effect of two or more consecutive doses of misoprostol for treatment of PPH. In absence of such information, repeat doses of misoprostol for PPH treatment are not recommended.

If oxytocin is already being provided for treatment of PPH, evidence suggests that adjunct (simultaneous) use of misoprostol has no added benefit.

Since the known side effects of misoprostol appear to be dose related, repeat or consecutive doses of misoprostol may increase the incidence of side effects.

## Contraindications

History of allergy to misoprostol or other prostaglandin.

## Precautions

1. Caution is advised in instances where the woman may have already received misoprostol as prophylaxis for PPH prevention, especially if an initial dose of misoprostol was associated with pyrexia or marked shivering.
2. After provision of uterotonics, the need for other steps to stop the bleeding should be explored, and causes of PPH other than uterine atony should be considered.

## Effects and Side Effects

Prolonged or serious effects and side effects are rare.

The most common known side effects associated with misoprostol are:

**Temperature changes:** Shivering, chills and/or fever are all commonly associated with use of misoprostol. Shivering has been reported in 37-47% of women following ad-

ministration of 800 µg sublingual misoprostol, fever in 22-44%, and hyperpyrexia (>40 degrees Celcius) in 1-14% [Blum 2010, Winikoff 2010, Durocher 2010]. The shivering is self-regulating and even if high temperatures occur, they are transient and settle with reassurance and symptomatic treatment.

**Gastro-intestinal effects:** Nausea occurs in 10-15% of women given 800 µg sublingual misoprostol and vomiting in about 5% [Winikoff 2010, Blum 2010]. Both should resolve within two to six hours. An anti-emetic can be used if needed, but in general no action is required except to reassure the woman and her family. Diarrhoea may also occur in about 1% of women but should resolve within a day.

**Breast feeding:** Small amounts of misoprostol or its active metabolite may appear in breast milk. No adverse effects on nursing infants have been reported.

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Abbreviations	
FIGO	International Federation of Gynecology and Obstetrics
IM	intramuscular
IU	international unit
IV	intravenous
µg	microgramme
PPH	post-partum haemorrhage
RCT	randomised controlled trial



# ACOG COMMITTEE OPINION

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## Ethical Decision Making in Obstetrics and Gynecology\*

### Committee on Ethics

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**ABSTRACT:** Physicians vary widely in their familiarity with ethical theories and methods and their sensitivity toward ethical issues. It is important for physicians to improve their skills in addressing ethical questions. Obstetrician–gynecologists who are familiar with the concepts of medical ethics will be better able to approach complex ethical situations in a clear and structured way. By considering the ethical frameworks involving principles, virtues, care and feminist perspectives, concern for community, and case precedents, they can enhance their ability to make ethically justifiable clinical decisions. Guidelines, consisting of several logical steps, are offered to aid the practitioner in analyzing and resolving ethical problems.

The importance of ethics in the practice of medicine was manifested at least 2,500 years ago in the Hippocratic tradition, which emphasized the virtues that were expected to characterize and guide the behavior of physicians. Over the past 50 years, medical technology expanded exponentially, so that obstetrician–gynecologists have had to face complex ethical questions regarding assisted reproductive technologies, prenatal diagnosis and selective abortion, medical care at the beginning and end of life, the use of genetic information, and the like. Medical knowledge alone is not sufficient to solve these problems. Instead, responsible decisions in these areas depend on a thoughtful consideration of the values, interests, goals, rights, and obligations of those involved. All of these are the concern of medical ethics. The formal discipline of biomedical ethics and structured ethical analysis can help physicians resolve ethical dilemmas.

Physicians vary widely in their familiarity with ethical theories and methods and their sensitivity toward ethical issues. It is important for physicians to improve their skills in addressing ethical questions through formal undergraduate and graduate medical education, organized continuing education,

or personal experience and reading as well as discussion with others.

### Ethical Frameworks and Perspectives

#### Principle-Based Ethics

In recent decades, medical ethics has been dominated by principle-based ethics (1–3). In this approach, four principles offer a systematic and relatively objective way to identify, analyze, and address ethical issues, problems, and dilemmas: 1) respect for patient autonomy, 2) beneficence, 3) nonmaleficence, and 4) justice. (These four principles will be discussed in some detail in subsequent sections.) However, critics claim that a principle-based approach cannot adequately resolve or even helpfully evaluate many difficult clinical problems. As a result, several other perspectives and frameworks have emerged: virtue-based ethics, an ethic of care, feminist ethics, communitarian ethics, and case-based reasoning, all of which have merit as well as limitations (2–8). As this discussion will stress, these different perspectives and frameworks are not necessarily mutually exclusive. They often are complementary because each emphasizes some important features of moral reasoning, agents, situations, actions, or relationships. Perspectives such as an ethic of care or feminist ethics also may change the lens through which to view both principles



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and particular situations in which decisions have to be made.

### **Virtue Ethics**

A virtue-based approach relies on qualities of character that dispose health professionals to make choices and decisions that achieve the well-being of patients, respect their autonomous choices, and the like (8, 9). These qualities of character include trustworthiness, prudence, fairness, fortitude, temperance, integrity, self-effacement, and compassion. Virtues need not replace principles as a basis for ethical decision making or conduct. Indeed, some virtues correlate with principles and dispose people to act according to those principles—for instance, the virtue of benevolence disposes agents to act beneficently. Virtues also can complement and enhance the principles of medical ethics. Interpreting the principles, applying them in concrete situations, and setting priorities among them require the judgment of morally sensitive professionals with good moral character and the relevant virtues. Furthermore, in deliberating what to do, a physician may find helpful guidance by asking, “What would a good, that is, morally virtuous, physician do in these circumstances?” Ethical insight may come from imagining which actions would be compatible with, for instance, being a compassionate or honest or trustworthy physician.

### **Care-Based Ethics**

Care-based ethics, also called “the ethic of care,” directs attention to dimensions of moral experience often excluded from or neglected by traditional ethical theories (10). It is concerned primarily with responsibilities that arise from attachment to others rather than with impartial principles so emphasized in many ethical theories. The moral foundations of an ethic of care are located not in rights and duties, but rather in commitment, empathy, compassion, caring, and love (11). This perspective also pays closer attention to context and particularity than to abstract principles and rules. It suggests that good ethical decisions both result from personal caring in relationships, and should consider the impact of different possible actions on those relationships. An ethic of care overlaps with a virtue ethic, in emphasizing the caregiver’s orientation and qualities. In this ethical approach, care represents the fundamental orientation of obstetrics and gynecology as well as much of medicine and health care, and it indicates the direction and rationale of the relationship between professionals and those who seek their care. An ethic of care also joins case-based approaches in focusing on particular contexts of decision making.

### **Feminist Ethics**

Feminist ethics uses the tools of feminist theory to examine ethical issues in at least three distinctive ways (12). First, it indicates how conceptions of sex often distort people’s view of the world and, more specifically, how gendered conceptions constrain and restrict women. For

instance, feminist theory shows how human society tends to be androcentric, or male centered, so that man becomes the generic representative for what it means to be human, and woman is viewed as different or deviant. Thus, feminist ethics can expose forms of androcentric reasoning in ethics of clinical care and public policy, calling into question, for example, the rationale for excluding women from participation in clinical research. Second, feminist ethics indicates how gendered thinking has distorted the tools that philosophers and bioethicists use to examine ethical issues. Historically entrenched associations between man and reason, woman and emotion—dubious in and of themselves—have contributed to the tendency in moral theory to view emotion as irrelevant or, at worst, distorting. Some, including many feminist thinkers, however, have argued that appropriate emotion (eg, empathy) is indispensable to moral reasoning in the ethical conduct of medical care. This position, bolstered further by recent empirical research (13, 14), is consistent with the perspective represented by the ethic of care (see previous section). Third, in calling attention to and attempting to redress the ways that gendered concepts have produced constraints on women, feminism is concerned with oppression as a pervasive and insidious moral wrong (15, 16). The tools of feminist ethics can help to identify and challenge dominance and oppression not only of women, but also of other groups oppressed because of race, class, or other characteristics. These tools also can help to detect more subtle gender and other biases and assist in addressing significant health disparities. Rather than rejecting such principles as respect for autonomy and justice, feminist thinkers may interpret and apply these principles to highlight and redress various kinds of domination, oppression, and bias.

### **Communitarian Ethics**

Communitarian ethics challenges the primacy often attributed to personal autonomy in contemporary biomedical ethics (17). A communitarian ethic emphasizes a community’s other shared values, ideals, and goals and suggests that the needs of the larger community may take precedence, in some cases, over the rights and desires of individuals. If proponents of a communitarian ethic accept the four principles of Beauchamp and Childress (1), they will tend to interpret those principles through the lens of community, stressing, for example, benefits and harms to community and communities as well as the need to override autonomy in some cases. Major examples arise in the context of public health. However, in considering the proper framework for communitarian ethics, questions arise in a pluralistic society about which community is relevant. For instance, is the relevant community one embodied in particular traditions (eg, one religion) or is it the broader, pluralistic society? Even though there is a broad consensus that communal values and interests sometimes trump personal autonomy, disputes persist about exactly when it is justifiable to over-

ride personal autonomy. To take one example, apart from laws that specify which diseases are reportable, physicians may have to balance a patient's claims of privacy and confidentiality against risks to others. Different judgments about the appropriate balance often hinge on an assessment of risks: How probable and serious must the harm be to justify a breach of privacy and confidentiality?

### Case-Based Reasoning

In a final approach, case-based reasoning (sometimes called casuistry), ethical decision making builds on precedents set in specific cases (18, 19). This is analogous to the role of case law in jurisprudence in that an accumulated body of influential cases and their interpretation provide moral guidance. This approach analyzes current cases requiring decisions in light of relevantly similar cases that have already been settled or gained a rough consensus. Case-based reasoning asserts the priority of practice over both ethical theory and moral principles. It recognizes the principles that emerge by a process of generalization from the analysis of cases but views these principles as always open to future revision. In considering a particular case, someone taking this approach would seek to determine whether there are any relevantly similar cases, either positive or negative, that enjoy an ethical consensus. If, for example, a new research protocol is relevantly similar to an earlier and widely condemned one (eg, the Tuskegee Syphilis Study), that similarity is a reason for moral suspicion of the new protocol. A question for this approach is how to identify relevant similarities and differences among cases and whether ethical principles are sometimes useful in this process.

### Ethics as Toolbox

An example of how the different ethical frameworks and perspectives might address a particular case is shown in the box. From this analysis of different approaches, it is plausible to derive the following conclusion: enlightened ethical decision making in clinical medicine cannot rely exclusively on any single fundamental approach to biomedical ethics. The metaphor of toolbox or toolkit may provide a useful way to think about these different approaches to ethical decision making (20). Some ethical tools may fit some contexts, situations, and cases better than others, and more than one—or even all of them—usually are valuable.

It is helpful to have access to a variety of ethical tools because clinical problems often are too complex to be resolved by using simple rules or by rigidly applying ethical principles. Indeed, virtues such as prudence, fairness, and trustworthiness enable clinicians to apply ethical principles sensitively and wisely in situations of conflict. The specific virtues that are most important may vary from one circumstance to another, but in women's health care, there must be particular sensitivity to the needs of women. Furthermore, in many, perhaps most, difficult situations requiring ethical insight, tensions exist between

the well-being and interests of the individual patient and the interest of the "community," however that is defined. Finally, current ethical decisions can be improved by awareness of and guidance from existing precedents.

In short, even though a principle-based approach may provide a reasonable starting point for ethical decision making, it is not adequate by itself and needs the valuable contributions and insights of other approaches. Principles often serve as initial points of reference in ethical decision making in obstetrics and gynecology, however, and the next section examines several ethical principles in detail.

## Ethical Principles

Clinicians and others often make decisions without appealing to principles for guidance or justification. But when they experience unclear situations, uncertainties, or conflicts, principles often can be helpful. The major principles that are commonly invoked as guides to professional action and for resolving conflicting obligations in health care are respect for autonomy, beneficence and nonmaleficence, and justice (1). Other principles or rules, such as fidelity, honesty, privacy, and confidentiality, also are important, whether they are viewed as derived from the four broad principles or as independent.

### Respect for Autonomy

Autonomy, which derives from the Greek *autos* ("self") and *nomos* ("rule" or "governance"), literally means self-rule. In medical practice, the principle of respect for autonomy implies personal rule of the self that is free both from controlling interferences by others and from personal limitations that prevent meaningful choice, such as inadequate understanding (1). Respect for a patient's autonomy acknowledges an individual's right to hold views, to make choices, and to take actions based on her own personal values and beliefs. Respect for autonomy provides a strong moral foundation for informed consent, in which a patient, adequately informed about her medical condition and the available therapies, freely chooses specific treatments or nontreatment. Respect for patient autonomy, like all ethical principles, cannot be regarded as absolute. At times it may conflict with other principles or values and sometimes must yield to them.

### Beneficence and Nonmaleficence

The principle of beneficence, which literally means doing or producing good, expresses the obligation to promote the well-being of others. It requires a physician to act in a way that is likely to benefit the patient. Nonmaleficence is the obligation not to harm or cause injury, and it is best known in the maxim, *primum non nocere* ("First, do no harm."). Although there are some subtle distinctions between nonmaleficence and beneficence, they often are considered manifestations of a single principle. These two principles taken together are operative in almost every treatment decision because every medical or surgical pro-

## One Case Study: Five Approaches

Although the several approaches to ethical decision making may all produce the same answer in a situation that requires a decision, they focus on different, though related, aspects of the situation and decision. Consider, for instance, how they might address interventions for fetal well-being if a pregnant woman rejects medical recommendations or engages in actions that put the fetus at risk.\*

A *principle-based approach* would seek to identify the principles and rules pertinent to the case. These might include beneficence—nonmaleficence to both the pregnant woman and her fetus, justice to both parties, and respect for the pregnant woman's autonomous choices. These principles cannot be applied mechanically. After all, it may be unclear whether the pregnant woman is making an autonomous decision, and there may be debates about the balance of probable benefits and risks of interventions to all the stakeholders as well as about which principle should take priority in this conflict. Professional codes and commentaries may offer some guidance about how to resolve such conflicts.

A *virtue-based approach* would focus on the courses of action to which different virtues would and should dispose the obstetrician–gynecologist. For instance, which course of action would follow from compassion? From respectfulness? And so forth. In addition, the obstetrician–gynecologist may find it helpful to ask more broadly: Which course of action would best express the character of a good physician?

An *ethic of care* would concentrate on the implications of the virtue of caring in the obstetrician–gynecologist's special relationship with the pregnant woman and with the fetus. In the process of deliberation, individuals using this approach generally would resist viewing the relationship between the pregnant woman and her fetus as adversarial, acknowledging that most of the time women are paradigmatically invested in their fetus' well-being and that maternal and fetal interests usually are aligned.\* If, however, a real conflict does exist, the obstetrician–gynecologist should resist feeling the need to take one side or the other. Instead, he or she should seek a solution in identifying and balancing his or her duties in these special relationships, situating these duties in the context of a pregnant woman's

values and concerns, instead of specifying and balancing abstract principles or rights.

To take one example, in considering a case of a pregnant woman in preterm labor who refuses admission to the hospital for bed rest or tocolytics, Harris combines a care or relational perspective with a feminist perspective to provide a "much wider gaze" than a principle-based approach might\*:

The clinician would focus attention on important social and family relationships, contexts or constraints that might come to bear on [a] pregnant [woman's] decision making, such as her need to care for other children at home or to continue working to support other family members, or whatever life project occupied her, and attempt to provide relief in those areas....[Often] fetal well-being is achieved when maternal well-being is achieved.

As this example suggests, a *feminist ethics* approach would attend to the social structures and factors that limit and control the pregnant woman's options and decisions in this situation and would seek to alter any that can be changed.\* It also would consider the implications any intervention might have for further control of women's choices and actions—for instance, by reducing a pregnant woman, in extreme cases, to the status of "fetal container" or "incubator."

Finally, a *case-based approach* would consider whether there are any relevantly similar cases that constitute precedents for the current one. For instance, an obstetrician–gynecologist may wonder whether to seek a court order for a cesarean delivery that he or she believes would increase the chances of survival for the child-to-be but that the pregnant woman continues to reject. In considering what to do, the physician may ask, as some courts have asked, whether there is a helpful precedent in the settled consensus of not subjecting a nonconsenting person to a surgical procedure to benefit a third party, for instance, by removing an organ for transplantation.<sup>†</sup>

\*Harris LH. Rethinking maternal-fetal conflict: gender and equality in perinatal ethics. *Obstet Gynecol* 2000;96:786–91.

<sup>†</sup>In re A.C., 572 A.2d 1235 (D.C. Ct. App. 1990).

cedure has both benefits and risks, which must be balanced knowledgeably and wisely. Beneficence, the obligation to promote the patient's well-being, may sometimes conflict with the obligation to respect the patient's autonomy. For example, a patient may desire to deliver a fatally malformed fetus by cesarean because she believes that this procedure will increase the newborn's chance of surviving, if only for a few hours. However, in the physician's best judgment, the theoretical benefit to a "nonviable" infant may not justify the risks of the surgical delivery to the woman. In such a situation, the physician's task is further complicated by the need to consider the patient's psychological, physical, and spiritual well-being.

## Justice

Justice is the principle of rendering to others what is due to them. It is the most complex of the ethical principles to be considered because it deals not only with the physician's obligation to render to a patient what is owed but also with the physician's role in the allocation of limited medical resources in the broader community. In addition, various criteria such as need, effort, contribution, and merit are important in determining what is owed and to whom it is owed. Justice is the obligation to treat equally those who are alike or similar according to whatever criteria are selected. Individuals should receive equal treatment unless scientific and clinical evidence establishes

that they differ from others in ways that are relevant to the treatments in question. Determination of the criteria on which these judgments are based is a highly complex moral process, as exemplified by the ethical controversies about providing or withholding renal dialysis and organ transplantation.

The principle of justice applies at many levels. At the societal level, it addresses the criteria for allocating scarce resources, such as organs for transplantation. At a more local level, it is relevant to questions such as which patients (and physicians) receive priority for operating room times. Even at the level of the physician–patient relationship, the principle of justice applies to matters such as the timing of patient discharge. The principle also governs relationships between physicians and third parties, such as payers and regulators. In the context of the physician–patient relationship, the physician should be the patient’s advocate when institutional decisions about allocation of resources must be made.

### **Balancing the Principles**

In order to guide actions, each of these broad principles needs to be made more concrete. Sometimes the principles can be addressed in more definite rules—for instance, rules of voluntary, informed consent express requirements of the principle of respect for personal autonomy, and rules of confidentiality rest on several principles (see “Common Ethical Issues and Problems in Obstetrics and Gynecology”). Nevertheless, conflicts may arise among these various principles and rules. In cases of conflict, physicians have to determine which principle(s) should have priority. Some ethical theories view all of these principles as *prima facie* binding, resist any effort to prioritize them apart from particular situations, and call for balancing in particular situations (1). Some other theories attempt to rank principles in advance of actual conflicts (21).

Obstetrician–gynecologists, like other physicians, often face a conflict between principles of beneficence–nonmaleficence in relation to a patient and respect for that patient’s personal autonomy. In such cases, the physician’s judgment about what is in the patient’s best interests conflicts with the patient’s preferences. The physician then has to decide whether to respect the patient’s choices or to refuse to act on the patient’s preferences in order to achieve what the physician believes to be a better outcome for the patient. Paternalistic models of physician–patient relationships have been sharply challenged and often supplanted by other models. At the other end of the spectrum, however, the model of following patients’ choices, whatever they are, as long as they are informed choices, also has been criticized for reducing the physician to a mere technician (22). Other models have been proposed, such as negotiation (23), shared decision making (24), or a deliberative model, in which the physician integrates information about the patient’s condition with the patient’s values to make a cogent recommendation (22). Whatever model is selected, a physician may still, in a par-

ticular situation, have to decide whether to act on the patient’s request that does not appear to accord with the patient’s best interests. These dilemmas are considered in greater detail elsewhere (25).

## **Common Ethical Issues and Problems in Obstetrics and Gynecology**

Almost everything obstetrician–gynecologists do in their professional lives involves one or more of the ethical principles and personal virtues to a greater or lesser degree. Nevertheless, several specific areas deserve special attention: the role of the obstetrician–gynecologist in the society at large; the process of voluntary, informed consent; confidentiality; and conflict of interest.

### **The Obstetrician–Gynecologist’s Role in Society at Large**

In addition to their ethical responsibilities in direct patient care, obstetrician–gynecologists have ethical responsibilities related to their involvement in the organization, administration, and evaluation of health care. They exercise these broader responsibilities through membership in professional organizations; consultation with and advice to community leaders, government officials, and members of the judiciary; expert witness testimony; and education of the public. Justice is both the operative principle and the defining virtue in decisions about the distribution of scarce health care resources and the provision of health care for the medically indigent and uninsured. Obstetricians and gynecologists should offer their support for institutions, policies, and practices that ensure quality of and more equitable access to health care, particularly, but not exclusively, for women and children. The virtues of truthfulness, fidelity, trustworthiness, and integrity must guide physicians in their roles as expert witnesses, as consultants to public officials, as educators of the lay public, and as health advocates (26).

### **Informed Consent Process**

Often, informed consent is confused with the consent form. In fact, informed consent is “the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention with its risks and benefits and of the alternatives with their risks and benefits” (27). The consent form only documents the process and the patient decision. The primary purpose of the consent process is to protect patient autonomy. By encouraging an ongoing and open communication of relevant information (adequate disclosure), the physician enables the patient to exercise personal choice. This sort of communication is central to a satisfactory physician–patient relationship. Unfortunately, discussions for the purpose of educating and informing patients about their health care options are never completely free of the informant’s bias. Practitioners should seek to uncover their own biases and endeavor to maintain objectivity in the face of those biases, while disclosing to the

patient any personal biases that could influence the practitioner's recommendations (28, 29). A patient's right to make her own decisions about medical issues extends to the right to refuse recommended medical treatment. The freedom to accept or refuse recommended medical treatment has legal as well as ethical foundations.

As previously noted, one of the most important elements of informed consent is the patient's capacity to understand the nature of her condition and the benefits and risks of the treatment that is recommended as well as those of the alternative treatments (30). A patient's capacity to understand depends on her maturity, state of consciousness, mental acuity, education, cultural background, native language, the opportunity and willingness to ask questions, and the way in which the information is presented. Diminished capacity to understand is not necessarily the same as legal incompetence. Psychiatric consultation may be helpful in establishing a patient's capacity, or ability to comprehend relevant information. Critical to the process of informing the patient is the physician's integrity in choosing the information that is given to the patient and respectfulness in presenting it in a comprehensible way. The point is not merely to disclose information but to ensure patient comprehension of relevant information. Voluntariness—the patient's freedom to choose among alternatives—is also an important element of informed consent, which should be free from coercion, pressure, or undue influence (31).

### **Confidentiality**

Confidentiality applies when an individual to whom information is disclosed is obligated not to divulge this information to a third party. Rules of confidentiality are among the most ancient and widespread components of codes of medical ethics. Confidentiality is based on the principle of respect for patient autonomy, which includes a patient's right to privacy, and on the physician's fidelity-based responsibility to respect a patient's privacy. Rules of confidentiality also are justified by their good effects: Assurance of confidentiality encourages patients to disclose information that may be essential in making an accurate diagnosis and planning appropriate treatment. However, rules of confidentiality are not absolute, either legally or ethically. Legal exceptions to confidentiality include the requirements to report certain sexually transmitted diseases or suspected child abuse. Ethically, breaches of confidentiality also may be justified in rare cases to protect others from serious harm.

The need for storing and transmitting medical information about patients is a serious threat to confidentiality and privacy, a problem made more complex by the use of electronic storage and transmission of patient data. The recent increase in the use of genetic testing and screening also highlights the need for strong protections of confidentiality and patient privacy because genetic information has lifelong implications for patients and their families.

Obstetrician-gynecologists also are confronted with issues of confidentiality in dealing with adolescents, especially regarding the diagnosis and treatment of sexually transmitted diseases, contraceptive counseling, and pregnancy (32). The physician's willingness and ability to protect confidentiality should be discussed with all adolescent patients early in their care. Many state laws protect adolescent confidentiality in certain types of situations, and obstetrician-gynecologists should be aware of the laws in their own states.

### **Conflict of Interest**

It is necessary to distinguish conflicts of interest from conflicts of obligation. A conflict of obligation exists when a physician has two or more obligations that sometimes conflict—for example, an obligation to patients and an obligation to a managed care organization. By contrast, a conflict of interest exists when a primary interest (usually the patient's well-being) is in conflict with a physician's secondary interest (such as his or her financial interest). A conflict of interest is not necessarily wrong, but it creates the occasion and temptation for the physician to breach a primary obligation to the patient.

Many kinds of conflicts of interest arise in obstetrics and gynecology; some are obvious, others more subtle. Following are a few examples: a managed care guideline limits coverage for diagnostic tests that physicians consider necessary for patients and penalizes physicians who order such tests (or rewards physicians who do not order such tests); a physician recommends products to patients that are sold for a profit in his or her office (33); a physician refers patients for tests or procedures at an entity in which the physician has a financial interest; a physician accepts gifts from a pharmaceutical or medical device company (34). It is important for physicians to be attentive to the wide range of actual and perceived conflicts of interest. Even perceived conflicts of interest can threaten patient and societal trust.

There is ever-increasing intrusion into the patient-physician relationship by government and by the marketplace. Care plans, practice guidelines, and treatment protocols may substantially limit physicians' ability to provide what they consider proper care for patients. If the conflict is too great, the physician should withdraw from the organization. In addition to such conflicts of obligation, a conflict of interest exists if the organization's incentive plans create inducements to limit care in the interest of increasing physicians' incomes. At one time, the tension between physicians' financial self-interest and patients' interests often encouraged unnecessary testing and excessive treatment, but the current tension may provide incentives for too little care. Conflicts of interest should be avoided whenever possible, and when they are unavoidable and material to patients' decisions, it is the physician's responsibility to disclose them to patients. Serious ethical problems arise if organizational rules (so-called "gag rules") preclude such disclosures.

## Guidelines for Ethical Decision Making

Often, more than one course of action may be morally justifiable. At times, however, no course of action may seem acceptable because each may result in significant harms or compromise important principles or values. Nevertheless, the clinician must select one of the available options, justify that decision by ethical reasons, and apply the same critical thinking faculties that would be applied to issues of medical evidence. An analysis of the various factors involved in ethical decisions can aid attempts to resolve difficult cases. In addition, the involvement of individuals with a variety of backgrounds and perspectives can be useful in addressing ethical questions. Informal or formal consultation with those from related services or with a hospital ethics committee can help ensure that all stakeholders, viewpoints, and options are considered as a decision is made.

It is important for the individual physician to find or develop guidelines for decision making that can be applied consistently in facing ethical dilemmas. Guidelines consisting of several logical steps can aid the practitioner analyzing and resolving an ethical problem. The approach that follows incorporates elements of several proposed schemes (27, 35–38).

1. *Identify the decision makers.* The first step in addressing any problem is to answer the question, “Whose decision is it?” Generally, the patient is presumed to have the authority and capacity to choose among medically acceptable alternatives or to refuse treatment.
  - a. Assess the patient’s ability to make a decision. At times, this is not clear. An individual’s capacity to make a decision depends on that individual’s ability to understand information and appreciate the implications of that information when making a personal decision (30). In contrast, competence and incompetence are legal determinations that may or may not truly reflect functional capacity. Assessment of a patient’s capacity to make decisions must at times be made by professionals with expertise in making such determinations. Decisions about competence can be made only in a court of law.
  - b. Identify a surrogate decision maker for incompetent patients. If a patient is thought to be incapable of making a decision or has been found legally incompetent, a surrogate decision maker must be identified. In the absence of a durable power of attorney, family members have been called on to render proxy decisions. In some situations, the court may be called on to appoint a guardian. A surrogate decision maker should make the decision that the patient would have wanted or, if the patient’s wishes are not known, that will promote the best interests of the patient.
- The physician has an obligation to assist the patient’s representatives in examining the issues and reaching a resolution.
- c. In the obstetric setting, recognize that a competent pregnant woman is the appropriate decision maker for the fetus that she is carrying.
2. *Collect data, establish facts.*
  - a. Be aware that perceptions about what may or may not be relevant or important to a case reflect values—whether personal, professional, institutional, or societal. Hence, one should strive to be as objective as possible when collecting the information on which to base a decision.
  - b. Use consultants as needed to ensure that all available information about the diagnosis, treatment, and prognosis has been obtained.
3. *Identify all medically appropriate options.*
  - a. Use consultation as necessary.
  - b. Identify other options raised by the patient or other concerned parties.
4. *Evaluate options according to the values and principles involved.*
  - a. Start by gathering information about the values of the involved parties, the primary stakeholders, and try to get a sense of the perspective each is bringing to the discussion. The values of the patient generally will be the most important consideration as decision making proceeds.
  - b. Determine whether any of the options violates ethical principles that all agree are important. Eliminate those options that, after analysis, are found to be morally unacceptable by all parties.
  - c. Reexamine the remaining options according to the interests and values of each party. Some alternatives may be combined successfully.
5. *Identify ethical conflicts and set priorities.*
  - a. Try to define the problem in terms of the ethical principles involved (eg, beneficence versus respect for autonomy).
  - b. Weigh the principles underlying each of the arguments made. Does one of the principles appear more important than others in this conflict? Does one proposed course of action seem to have more merit than the others?
  - c. Consider respected opinions about similar cases and decide to what extent they can be useful in addressing the current problem. Look for morally relevant differences and similarities between this and other cases. Usually, physicians find that the basic dilemma at hand is not a new one and that points considered by others in resolving past dilemmas can be useful.
6. *Select the option that can be best justified.* Try to arrive at a rational resolution to the problem, one that can

be justified to others in terms of widely recognized ethical principles.

7. *Reevaluate the decision after it is acted on.* Repeat the evaluation of the major options in light of information gained during the implementation of the decision. Was the best possible decision made? What lessons can be learned from the discussion and resolution of the problem?

## Summary

Obstetrician–gynecologists who are familiar with the concepts of medical ethics will be better able to approach complex ethical situations in a clear and structured way. By considering the ethical frameworks involving principles, virtues, care and feminist perspectives, concern for community, and case precedents, they can enhance their ability to make ethically justifiable clinical decisions. They also need to attend to the kinds of ethical issues and problems that arise particularly or with special features in obstetrics and gynecology. Finally, obstetricians and gynecologists can enhance their decision-making process by considering when it would be useful to seek a formal or informal ethics consult as well as which guidelines would be most helpful to them as they move from case to case and decision to decision.

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# ACOG COMMITTEE OPINION

Number 819 (Replaces Committee Opinion Number 363, April 2007, and Committee Opinion Number 439, August 2009)

## Committee on Ethics

*This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Ethics in collaboration with committee members Ginny L. Ryan, MD, MA; and Kristyn Brandi, MD, MPH.*

## Informed Consent and Shared Decision Making in Obstetrics and Gynecology

**ABSTRACT:** Meeting the ethical obligations of informed consent requires that an obstetrician–gynecologist gives the patient adequate, accurate, and understandable information and requires that the patient has the ability to understand and reason through this information and is free to ask questions and to make an intentional and voluntary choice, which may include refusal of care or treatment. Shared decision making is a patient-centered, individualized approach to the informed consent process that involves discussion of the benefits and risks of available treatment options in the context of a patient's values and priorities. Some informed consent challenges are universal to medicine, whereas other challenges arise more commonly in the practice of obstetrics and gynecology than in other specialty areas. This Committee Opinion focuses on informed consent for adult patients in clinical practice and provides new guidance on the practical application of informed consent through shared decision making. The principles outlined in this Committee Opinion will help support the obstetrician–gynecologist in the patient-centered informed consent process.

### Recommendations and Conclusions

On the basis of the principles outlined in this Committee Opinion, the American College of Obstetricians and Gynecologists offers the following recommendations and conclusions:

- The goal of the informed consent process is to provide patients with information that is necessary and relevant to their decision making (including the risks and benefits of accepting or declining recommended treatment) and to assist patients in identifying the best course of action for their medical care.
- Shared decision making is a patient-centered, individualized approach to the informed consent process that involves discussion of the benefits and risks of available treatment options in the context of a patient's values and priorities.
- The informed consent conversation, including the required elements of consent and any challenges to the requirements, should be documented in the medical record.
- A signed consent document, however, does not guarantee that the patient's values and priorities have been taken into consideration in a meaningful way and that the ethical requirements of informed consent have been met.
- Meeting the ethical obligations of informed consent requires that an obstetrician–gynecologist gives the patient adequate, accurate, and understandable information and requires that the patient has the ability to understand and reason through this information and is free to ask questions and to make an intentional and voluntary choice, which may include refusal of care or treatment.
- Adult patients are presumed to have decision-making capacity unless formally determined otherwise, and physicians generally can determine a patient's capacity to make informed decisions through typical patient–physician interactions. An adult patient with decision-making capacity has the right to refuse treatment, including during pregnancy, labor, and delivery and when treatment is necessary for the patient's health or survival, that of the patient's fetus, or both.

- The highest ethical standard for adequacy of clinical information requires that the amount and complexity of information be tailored to the desires of the individual patient and to the patient's ability to understand this information. The legal standard for adequacy of the amount of clinical information or content given to the patient during an informed consent process may vary from state to state; obstetrician–gynecologists should be familiar with their state and institutional requirements for informed consent.
- Using decision aids may increase patient knowledge and understanding of risk, reduce decisional uncertainty, and lead to care that more closely represents patient values. However, decision aids are intended to complement the discussion and do not replace the deliberative and supportive responsibilities of the obstetrician–gynecologist throughout the process.

## Introduction

This Committee Opinion focuses on informed consent for adult patients in clinical practice and provides new guidance on the practical application of informed consent through shared decision making. Ethical issues related to informed consent for research, clinical situations that involve adolescent and pediatric patients, medical treatment during pregnancy, and pelvic examinations under anesthesia in medical education are addressed elsewhere (1–5).

## Background

### Informed Consent

Informed consent is a practical application of the bioethics principle of respect for patient autonomy and self-determination as well as the legal right of a patient to bodily integrity. Although informed consent has legal implications, this Committee Opinion focuses on obstetrician–gynecologists' ethical obligations surrounding informed consent. Respect for patient autonomy is one of the four pillars of principle-based medical ethics (autonomy, beneficence, nonmaleficence, and justice) and is considered by some to be the “first among equals” of these four principles because of the value placed in modern Western society on individualism and liberty (6). The essential components of the informed consent process are listed in Box 1 (7). The goal of the informed consent process is to provide patients with information that is necessary and relevant to their decision making (including the risks and benefits of accepting or declining recommended treatment) and to assist patients in identifying the best course of action for their medical care.

Meeting the ethical obligations of informed consent requires that an obstetrician–gynecologist gives the patient adequate, accurate, and understandable information and requires that the patient has the ability to understand and reason through this information and is free to ask questions and to make an intentional and

### Box 1. Essential Elements of the Informed Consent Process

In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision making capacity or declines to participate in making decisions), physicians should do the following:

- Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
- Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about the following:
  - The diagnosis (when known)
  - The nature and purpose of recommended interventions
  - Treatment alternatives, including options for non-operative care in the setting of a consent process for surgery
  - The burdens, risks, and expected benefits of all options, including forgoing treatment
- Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the medical record.

Adapted from Opinion 2.1.1, Informed Consent of the American Medical Association Code of Medical Ethics. Full original text is available at <https://www.ama-assn.org/delivering-care/ethics/informed-consent>. Retrieved July 27, 2020.

voluntary choice, which may include refusal of care or treatment. The information provided to the patient does not need to include an exhaustive list of all possible courses of action and outcomes but rather those that are relevant to the patient's situation. The highest ethical standard for adequacy of clinical information requires that the amount and complexity of information be tailored to the desires of the individual patient and to the patient's ability to understand this information (8). The legal standard for adequacy of the amount of clinical information or content given to the patient during an informed consent process may vary from state to state; obstetrician–gynecologists should be familiar with their state and institutional requirements for informed consent.

To meet the requirement of disclosure of accurate and comprehensible information, the counseling obstetrician–gynecologist should engage in effective patient-centered and culturally responsive communication (9), and patients should have adequate understanding of the language used by their obstetrician–gynecologist during this informed consent process.

Ambiguities in communication of medical information because of cultural or language differences between physicians and patients present a challenge to the informed consent process that disproportionately affects people of color, immigrants, and other marginalized groups, adding to health disparities (10). To help avoid miscommunication related to language differences, a professional medical interpreter should be made available in person, by phone, or through video remote technology to assist with the informed consent process (9, 11). More information on racial and ethnic disparities in obstetrics and gynecology and the importance of social determinants of health and cultural awareness is available in other ACOG documents (10, 11).

The informed consent conversation, including the required elements of consent and any challenges to the requirements, should be documented in the medical record. Any refusal of recommended testing or treatment should be included in this documentation. If written consent has been part of this process, a copy of this document should be included in the records (Box 1) (7). A signed consent document, however, does not guarantee that the patient's values and priorities have been taken into consideration in a meaningful way and that the ethical requirements of informed consent have been met.

A physician's freedom to decline to provide a patient with standard or potentially beneficial care to which the physician ethically objects is sometimes called a right to "conscientious refusal," although this right is limited (12). Even in the context of conscientious refusal, physicians must provide the patient with accurate and unbiased information about the patient's medical options and make appropriate referrals. More information on conscientious refusal in obstetrics and gynecology is available in a separate ACOG publication (12).

### Shared Decision Making

It is important for obstetrician-gynecologists to acknowledge that the information and options that a physician shares with patients during the informed consent process are often a reflection of the physician's own values, priorities, and culture, and that these do not always align with the values, priorities, and culture of their patient population. Shared decision making is a patient-centered, individualized approach to the informed consent process that involves discussion of the benefits and risks of available treatment options in the context of a patient's values and priorities. During the shared decision-making process, patients are encouraged to share information, express value-based preferences, and provide input on a treatment plan. A shared decision-making approach facilitates meeting the highest ethical standard for the informed consent process.

A shared decision-making model of informed consent encourages physicians to reframe autonomy as "relational," that is, informed by a patient's interpersonal relationships and broader social environment (13). Thus, shared decision

making allows patients to obtain personalized information about their treatment options with the goal of improving their ability to make an autonomous decision. This practice has been shown to improve patient knowledge around their care, allow for better understanding of risk, and improve patient outcomes and satisfaction (14, 15).

From the standpoint of the obstetrician-gynecologist, the process of shared decision making involves a complex interplay of ethical obligations: respect for patient autonomy, beneficence and non-maleficence, professional responsibility and integrity, stewardship, and the fiduciary responsibility to refer or consult with other physicians when in the best interest of the patient (13). An example of the shared decision-making model, the SHARE approach, is illustrated in Figure 1 (16). The implementation of informed consent through a shared decision-making framework should be taught and modeled early and often for medical trainees.

Decision aids are multimedia tools, such as printed information or educational videos, that may be used to facilitate physician counseling and shared decision making. Using decision aids may increase patient knowledge and understanding of risk, reduce decisional uncertainty, and lead to care that more closely represents patient values (14, 17). However, decision aids are intended to complement the discussion and do not replace the deliberative and supportive responsibilities of the obstetrician-gynecologist throughout the process.

## Ethical Issues and Considerations

### Decision-Making Capacity

Individuals demonstrate decision-making capacity when they are able to understand their clinical condition as well as the benefits, risks, and alternatives to their treatment options; to appreciate the potential consequences of their decision on their own health and welfare; to reason logically through the options and possible outcomes; and to communicate a choice clearly and consistently (18). Adult patients are presumed to have decision-making capacity unless formally determined otherwise, and physicians generally can determine a patient's capacity to make informed decisions through typical patient-physician interactions. An adult patient with decision-making capacity has the right to refuse treatment, including during pregnancy, labor, and delivery and when treatment is necessary for the patient's health or survival, that of the patient's fetus, or both (4).

If there is doubt about a patient's decision-making capacity, consultation with ethics, legal, and psychiatric experts is recommended. Such efforts should always be made in the interest of respecting patient autonomy and never with the goal of coercing a patient to accept medically recommended treatment that the patient has declined (4).

For patients who have either temporarily or permanently lost the capacity to make an informed decision, respect for autonomy is best demonstrated by adhering

**Figure 1.** Reprinted with permission from The SHARE Approach: A Model for Shared Decisionmaking - Fact Sheet. Agency for Healthcare Research and Quality, Rockville, MD. Available at: <https://www.ahrq.gov/health-literacy/professional-training/shared-decision/tools/factsheet.html>



to advance directives, when available. Advance directives are valid regardless of pregnancy status and throughout labor and delivery. State laws that suggest otherwise are problematic because they conflict with obstetrician-gynecologists' ethical obligation to respect patient autonomy. When clinically relevant advance directives do not exist, appropriate surrogate decision makers should take part in the informed consent process and endeavor to make decisions in line with the patient's values and in light of the patient's particular context. In other words, a surrogate decision maker should be identified to provide a "substituted judgment" (a decision based on what the patient would have wanted, assuming some knowledge of what the patient's wishes would be). If the patient's wishes are unknown, the surrogate should make a decision according to the "best interests" of the patient. A surrogate decision maker who is legally designated as such by the patient (eg, an individual with a durable power of attorney for health care) is the first-line surrogate (19). In the absence of such a person, next of kin are often asked to fulfill this duty, and there may be a hierarchy of next-of-kin and nonrelatives (specified in many states' statutes) who have this responsibility (19, 20). If there is any doubt in a particular situation, consultation with local ethics and legal experts is encouraged.

Adult patients who have never had the intellectual capacity to make informed decisions related to their

health care should have a legal or court-appointed guardian to represent their best interest when making health care decisions (19–21). It is important to note that a guardian may not have the legal standing to make certain health care decisions for the patient depending on the patient's age and the details of the guardianship agreement; examples include sterilization (permanent contraception) and withdrawal of life-prolonging treatments (22–24). In these cases, an independent guardian ad litem may be assigned by the courts with the goal of providing further unbiased representation of the patient's interests. Obstetrician-gynecologists should be aware of the legal environment that surrounds guardianship and the limits of decision making for dependents in their home state and institution.

The ethical considerations regarding informed consent and confidentiality in the setting of adolescent health care, including counseling regarding contraceptive options, are complex and beyond the scope of this document. For more information, please see ACOG's other publications on these topics (2, 25).

### Emergency Situations

In life-threatening emergency situations in which the patient is unable to give consent and an appropriate advance directive or surrogate is not available, it is ethically acceptable for physicians to provide life-saving treatment to the patient using presumed consent (26,

27). Even in these situations, efforts to contact a surrogate should continue, and the treating physician must update the patient (if capacity is restored) or surrogate as soon as possible (26). However, if the patient has an appropriate advance directive that specifically directs against active life-saving efforts in the setting of chronic life-limiting illness, the directive must be respected even in emergency situations.

### **Therapeutic Privilege**

Therapeutic privilege refers to a physician's withholding of medical information from a patient because of concern that it may cause psychological or emotional harm to the patient. The concept of therapeutic privilege has been misinterpreted in the past to be an exception to the ethical requirement of providing adequate, accurate, and comprehensible information to a patient with decision-making capacity. Invoking therapeutic privilege is ethically unacceptable because it suggests that physicians always know what is best for their patients, requires a physician to predict the future, and opens the door for coercive misuse under the guise of the patient's best interest (28). The American College of Obstetricians and Gynecologists and the American Medical Association assert that although it is never ethically acceptable to withhold information without the patient's knowledge and consent, it is acceptable to communicate information over time based on the patient's stated preferences and ability to understand the information (26).

### **Patient Testing**

Just as in the case of medical treatment, informed consent for any patient testing (eg, laboratory testing of serum or salivary samples, imaging, or pathology evaluations) requires explanation of risks and benefits, including those associated with declining the test. Counseling about more complex testing options can be particularly challenging as technology rapidly advances, and in these situations the informed consent process is optimized by using a shared decision-making model. Referral for comprehensive counseling may be needed in complex situations such as those that involve the multigenerational and variable effects of genetic abnormalities. Additional information about patient counseling regarding genetic testing is available in other ACOG publications (29, 30). For more routine testing, such as HIV testing during prenatal care, patient counseling should include the fact that certain tests are standard and that patients may refuse, or "opt out" of, such tests. Additional information on HIV testing is available in other ACOG publications (31, 32).

Physicians must be aware of relevant laws and regulations related to mandatory reporting of test results to local or state agencies, and patients must be informed about this necessity when applicable. Testing at the request of third parties such as family members, social contacts, or health care professionals

or institutions that are concerned about exposure to infectious agents, should be done only when the patient understands the risks and benefits and gives consent for such testing.

### **Innovative Practice**

Innovative practice involves providing medicines, procedures, or tests that show therapeutic promise but have not yet become standard practice and have a limited evidence base (33). Although innovative procedures, tests, and treatment strategies may benefit individual patients and lead to advancement in medical care more broadly, obstetrician-gynecologists must consider the unique ethical obligations that arise when they offer clinical techniques that have yet to be adequately tested or validated and are not part of a formal research protocol. In keeping with the obligation to inform patients of all information relevant to their decision about a treatment option, the informed consent process in this scenario must include the innovative nature of the practice, the experience of the individual obstetrician-gynecologist and cumulative experience with this practice, and potential risks yet to be quantified (33). Physicians have a particular obligation to protect the patient from potential harms that are not proportionate to expected benefits, a role that an institutional review board assumes with respect to formal research protocols (33). Obstetrician-gynecologists also must recognize their own motivations for offering this innovation and ensure that the patient's best interest is a priority. If there are any economic motivations or potential conflicts of interest involved, these also must be disclosed to the patient as part of the informed consent process (34).

### **Legislative Interference**

Examples of legislative interference in the informed consent process include state-mandated consent forms; laws that require physicians to give, or withhold, specific information when counseling patients before undergoing an abortion; and laws that prohibit physicians from speaking to their patients about firearms and gun safety (35–38). Laws should not interfere with the ability of physicians to have open, honest, and confidential communications with their patients. Nor should laws interfere with the patient's right to be counseled by a physician according to the best currently available medical evidence and the physician's professional medical judgment (35). Absent a substantial public health justification, government should not interfere with individual patient-physician encounters (35). Despite differing legal requirements, in all cases, physicians continue to have an ethical obligation to provide each patient with information that is evidence-based, tailored to that patient, and comprehensive enough to allow that patient to make an informed decision about care and treatment.

## Situations Unique to Obstetrics and Gynecology

The informed consent process may become more complicated during pregnancy because of the presence of the fetus and the obstetrician–gynecologist’s dual concern for maternal and fetal well-being. However, the ethical obligation to obtain informed consent using shared decision making does not change based on pregnancy or parenting status (4, 39). A patient who is pregnant is fully capable of making medical care decisions during pregnancy and during labor and delivery, even if those decisions are in disagreement with obstetrician–gynecologists or family members, involve withdrawal of life-sustaining treatment, or may adversely affect the health of the fetus (4). It is commonplace for clinical decisions to be made quickly during labor and delivery, such as when obstetricians must respond to fetal distress with a change in delivery plans, thus challenging an optimal shared decision-making process. Whenever feasible, it is particularly important to initiate anticipatory conversations about delivery possibilities during prenatal care and to continue these conversations early in admission. Regardless of anticipatory conversations, physicians are expected to initiate as full an informed consent process as possible in time-limited scenarios.

The informed consent process for other unique clinical scenarios in obstetrics and gynecology, such as sterilization (permanent contraception) and fertility-restricting treatments, can be negatively influenced by practitioner-level factors, including racism and biases about culture, religion, gender, reproduction, sexuality, family, and parenting (40, 41). A patient-centered, shared decision-making approach that focuses on the reproductive desires of individual patients within the context of their beliefs, values, and culture can help to mitigate some of the potentially negative effects of conscious or unconscious biases and of the larger social climate of race and class inequality in which health care is carried out (40). For more information on the ethical complexities of informed consent for sterilization and fertility-restricting treatments, as well as the importance of cultural and racial awareness in the delivery of reproductive health care, please see separate publications on these topics from ACOG and others (10, 11, 40, 41).

## Conclusion

Informed consent is the practical application of the foundational bioethics principle of respect for autonomy. It is not an end in itself, but rather a means to responsible participation by patients in their own medical care and to a stronger therapeutic relationship with their obstetrician–gynecologist. In practice, a shared decision-making framework can operationalize the informed consent process in a way that is relational and patient-centered and does not nullify the contributions of the obstetrician–gynecologist to medical decision making. Some informed consent challenges are universal to medicine, whereas other chal-

lenges arise more commonly in the practice of obstetrics and gynecology than in other specialty areas. In each case, the principles outlined in this Committee Opinion will help support the obstetrician–gynecologist in the patient-centered informed consent process.

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Informed consent and shared decision making in obstetrics and gynecology. ACOG Committee Opinion No. 819. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2021;137:e34–41.

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

# COMMITTEE OPINION

Number 664 • June 2016

(Replaces Committee Opinion Number 321, November 2005)

(Reaffirmed 2019)

## Committee on Ethics

*This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Ethics in collaboration with committee members Mary Faith Marshall, PhD, and Brownsyne M. Tucker Edmonds, MD, MPH, MS. The Committee on Ethics wishes to acknowledge the assistance of Ashley R. Filo, MD, in the development of this document.*

*While this document reflects the current viewpoint of the College, it is not intended to dictate an exclusive course of action in all cases. This Committee Opinion was approved by the Committee on Ethics and the Executive Board of the American College of Obstetricians and Gynecologists.*

## Refusal of Medically Recommended Treatment During Pregnancy

**ABSTRACT:** One of the most challenging scenarios in obstetric care occurs when a pregnant patient refuses recommended medical treatment that aims to support her well-being, her fetus's well-being, or both. In such circumstances, the obstetrician–gynecologist's ethical obligation to safeguard the pregnant woman's autonomy may conflict with the ethical desire to optimize the health of the fetus. Forced compliance—the alternative to respecting a patient's refusal of treatment—raises profoundly important issues about patient rights, respect for autonomy, violations of bodily integrity, power differentials, and gender equality. The purpose of this document is to provide obstetrician–gynecologists with an ethical approach to addressing a pregnant woman's decision to refuse recommended medical treatment that recognizes the centrality of the pregnant woman's decisional authority and the interconnection between the pregnant woman and the fetus.

When a pregnant woman refuses medically recommended treatment, her decision may not result in optimal fetal well-being, which creates an ethical dilemma for her obstetrician–gynecologist. In such circumstances, the obstetrician–gynecologist's ethical obligation to safeguard the pregnant woman's autonomy may conflict with the ethical desire to optimize the health of the fetus. The obstetrician–gynecologist's professional obligation to respect a pregnant patient's refusal of treatment may conflict with his or her personal values. Forced compliance—the alternative to respecting a patient's refusal of treatment—raises profoundly important issues about patient rights, respect for autonomy, violations of bodily integrity, power differentials, and gender equality. Coercive interventions often are discriminatory and act as barriers to needed care.

The purpose of this document is to provide obstetrician–gynecologists with an ethical approach to addressing a pregnant woman's decision to refuse recommended medical treatment that recognizes the centrality of the pregnant woman's decisional authority and the

interconnection between the pregnant woman and the fetus. This document is not intended to address professional liability or legal issues that may arise in association with decision making when a pregnant woman refuses medically recommended treatment. Information regarding professional and legal issues is available elsewhere (see [www.acog.org/About-ACOG/ACOG-Departments/Professional-Liability](http://www.acog.org/About-ACOG/ACOG-Departments/Professional-Liability) and the American Congress of Obstetricians and Gynecologists' *Professional Liability and Risk Management: An Essential Guide for Obstetrician–Gynecologists*, 3rd edition). Fellows are encouraged to seek legal advice when concerns arise regarding professional liability or the legal implications of their actions.

## Recommendations

On the basis of the principles outlined in this Committee Opinion, the American College of Obstetricians and Gynecologists (the College) makes the following recommendations:

- Pregnancy is not an exception to the principle that a decisionally capable patient has the right to refuse

treatment, even treatment needed to maintain life. Therefore, a decisionally capable pregnant woman's decision to refuse recommended medical or surgical interventions should be respected.

- The use of coercion is not only ethically impermissible but also medically inadvisable because of the realities of prognostic uncertainty and the limitations of medical knowledge. As such, it is never acceptable for obstetrician–gynecologists to attempt to influence patients toward a clinical decision using coercion. Obstetrician–gynecologists are discouraged in the strongest possible terms from the use of duress, manipulation, coercion, physical force, or threats, including threats to involve the courts or child protective services, to motivate women toward a specific clinical decision.
- Eliciting the patient's reasoning, lived experience, and values is critically important when engaging with a pregnant woman who refuses an intervention that the obstetrician–gynecologist judges to be medically indicated for her well-being, her fetus's well-being, or both. Medical expertise is best applied when the physician strives to understand the context within which the patient is making her decision.
- When working to reach a resolution with a patient who has refused medically recommended treatment, consideration should be given to the following factors: the reliability and validity of the evidence base, the severity of the prospective outcome, the degree of burden or risk placed on the patient, the extent to which the pregnant woman understands the potential gravity of the situation or the risk involved, and the degree of urgency that the case presents. Ultimately, however, the patient should be reassured that her wishes will be respected when treatment recommendations are refused.
- Obstetrician–gynecologists are encouraged to resolve differences by using a team approach that recognizes the patient in the context of her life and beliefs and to consider seeking advice from ethics consultants when the clinician or the patient feels that this would help in conflict resolution.
- The College opposes the use of coerced medical interventions for pregnant women, including the use of the courts to mandate medical interventions for unwilling patients. Principles of medical ethics support obstetrician–gynecologists' refusal to participate in court-ordered interventions that violate their professional norms or their consciences. However, obstetrician–gynecologists should consider the potential legal or employment-related consequences of their refusal. Although in most cases such court orders give legal permission for but do not require obstetrician–gynecologists' participation in forced medical interventions, obstetrician–gynecologists who find themselves in this situation should famil-

iarize themselves with the specific circumstances of the case.

- It is not ethically defensible to evoke conscience as a justification to attempt to coerce a patient into accepting care that she does not desire.
- The College strongly discourages medical institutions from pursuing court-ordered interventions or taking action against obstetrician–gynecologists who refuse to perform them.
- Resources and counseling should be made available to patients who experience an adverse outcome after refusing recommended treatment. Resources also should be established to support debriefing and counseling for health care professionals when adverse outcomes occur after a pregnant patient's refusal of treatment.

## Refusal of Treatment

When a pregnant woman refuses recommended medical treatments or chooses not to follow medical recommendations, there can be a range of minor to major risks to the patient or the fetus. In certain situations, a pregnant woman might refuse therapies that the medical professional believes are necessary for her health or survival, that of her fetus, or both. Examples of these situations include a pregnant woman refusing to treat a fetal condition or infection in utero or to undergo cesarean delivery when it is thought to be medically necessary to avoid an adverse fetal or maternal outcome.

Such cases can be distressing for the health care team. Obstetrician–gynecologists may feel deep concern for the pregnant woman and fetus entrusted to their care, worry about the pregnant woman's reaction if a potentially avoidable adverse outcome occurs, or be apprehensive regarding liability issues resulting from an adverse outcome. Members of the health care team may disagree about case management and feel uneasy about their roles or even experience moral distress (1).

In these circumstances, as in all clinical encounters, the obstetrician–gynecologist's actions should be guided by the ethical principle that adult patients who are capable decision makers have the right to refuse recommended medical treatment. This doctrine has evolved through legal cases, regulations, and statutes that have established the requirement of informed consent to medical treatment in order to effect patient self-determination and preclude violations of bodily integrity. Informed refusal is the corollary of the doctrine of informed consent; it is an ongoing process of mutual communication between the patient and the physician and enables a patient to make an informed and voluntary decision about accepting or declining medical care. The informed consent process ideally begins before decision making so that the patient is able to make an informed choice (ie, informed consent or informed refusal) based on clinical information, the

patient's values, and other considerations of importance to her.

Voluntariness is a background condition of informed consent. As noted in Committee Opinion No. 439, *Informed Consent*, "Consenting freely is incompatible with being coerced or unwillingly pressured by forces beyond oneself. It involves the ability to choose among options and select a course other than what may be recommended" (2). Pregnancy is not an exception to the principle that a decisionally capable patient has the right to refuse treatment, even treatment needed to maintain life. Therefore, a decisionally capable pregnant woman's decision to refuse recommended medical or surgical interventions should be respected.

### **Complexities of Refusal of Medically Recommended Treatment During Pregnancy**

In obstetrics, pregnant women typically make clinical decisions that are in the best interest of their fetuses. In most desired pregnancies, the interests of the pregnant woman and the fetus converge. However, a pregnant woman and her obstetrician–gynecologist may disagree about which clinical decisions and treatments are in her best interest and that of her fetus. As with a nonpregnant patient, a pregnant woman may evaluate the risks and benefits of recommended medical treatment differently than her obstetrician–gynecologist and, therefore, may refuse recommended therapies or treatments. Such refusals are based not only on clinical considerations but also on the patient's roles and relationships; they reflect her assessment of multiple converging interests: her own, those of her developing fetus, and those of her family or community.

Special complexities are inherent in a woman's decision to refuse recommended medical treatment during pregnancy because of the presence of the fetus. The maternal–fetal relationship is unique in medicine because of the physiologic dependence of the fetus on the pregnant woman. Moreover, therapeutic access to the fetus occurs through the body of the pregnant woman. A joint guidance document from the College and the American Academy of Pediatrics states that "any fetal intervention has implications for the pregnant woman's health and necessarily her bodily integrity, and therefore cannot be performed without her explicit informed consent" (2, 3).

The emergence over the past four decades of enhanced techniques for imaging, testing, and treating fetuses has led some to endorse the notion that fetuses are independent patients with treatment options and decisions separate from those of pregnant women (4–6). Although the care model that fetuses are independent patients was meant to clarify complex issues that arise in obstetrics, many writers have noted that it instead distorts ethical and policy debates (7–11). When the pregnant woman and fetus are conceptualized as separate patients, the pregnant woman and her medical interests, health

needs, and rights can become secondary to those of the fetus. At the extreme, construing the fetus as a patient sometimes can lead to the pregnant woman being seen as a "fetal container" rather than as an autonomous agent (12). In one example, researchers performing fetal surgery (interventions to correct anatomic abnormalities in utero) have been criticized for their failure to assess the effect of surgery on the pregnant women, who also undertake the risks of the surgical procedures (13).

The most suitable ethical approach for medical decision making in obstetrics is one that recognizes the pregnant woman's freedom to make decisions within caring relationships, incorporates a commitment to informed consent and refusal within a commitment to provide medical benefit to patients, and respects patients as whole and embodied individuals (14). This ethical approach recognizes that the obstetrician–gynecologist's primary duty is to the pregnant woman. This duty most often also benefits the fetus. However, circumstances may arise during pregnancy in which the interests of the pregnant woman and those of the fetus diverge. These circumstances demonstrate the primacy of the obstetrician–gynecologist's duties to the pregnant woman. For example, if a woman with severe cardiopulmonary disease becomes pregnant, and her condition becomes life threatening as a result, her obstetrician–gynecologist may recommend terminating the pregnancy. This medical recommendation would not make sense if the obstetrician–gynecologist was primarily obligated to care for the fetus (10).

Instead, it is more helpful to speak of the obstetrician–gynecologist as having beneficence-based *motivations* toward the fetus of a woman who presents for obstetric care and a beneficence-based *obligation* to the pregnant woman who is the patient. Intervention on behalf of the fetus must be undertaken through the pregnant woman's body. Thus, questions of how to care for the fetus cannot be viewed as a simple ratio of maternal and fetal risks but should account for the need to respect fundamental values, such as the pregnant woman's autonomy and control over her body (15).

### **Directive Counseling Versus Coercion**

When a physician is faced with a situation in which a patient refuses a medical recommendation, it is useful to distinguish the use of directive counseling from efforts aimed at coercion. *Directive counseling* is defined as patient counseling in which the obstetrician–gynecologist plays an active role in the patient's decision making by offering advice, guidance, recommendations, or some combination thereof. *Coercion* is defined as the practice of compelling someone to do something by using force or threats. Directive counseling often is appropriate and typically is welcomed in the medical encounter because medical recommendations—when they are not coercive—do not violate but rather enhance the requirements of informed consent (2). However, if a patient refuses the recommended course of care, it is vitally

important that physicians recognize when they cross the line that separates directive counseling from coercion. Good intentions can lead to inappropriate behavior. The use of coercion is not only ethically impermissible but also medically inadvisable because of the realities of prognostic uncertainty and the limitations of medical knowledge. As such, it is never acceptable for obstetrician-gynecologists to attempt to influence patients toward a clinical decision using coercion. Obstetrician-gynecologists are discouraged in the strongest possible terms from the use of duress, manipulation, coercion, physical force, or threats, including threats to involve the courts or child protective services, to motivate women toward a specific clinical decision.

Although the physician aims to provide recommendations that are based on the best available medical evidence (16), data and technology are imperfect, and responses to treatment are not always predictable for a given patient. As such, it is difficult to determine the outcome of treatment—or lack of treatment—with absolute certainty. It requires a measure of humility for the obstetrician-gynecologist to acknowledge this to the patient and to herself or himself.

Because of the potential inability to determine with certainty when a situation will cause harm to the fetus, as well as the potential inability to guarantee that the pregnant woman will not be harmed by the medical intervention itself, a balance of potential outcomes that addresses the pregnant woman and her fetus should be presented. The obstetrician-gynecologist should affirm the importance of the pregnant woman's assessment of her relational interests (personal, familial, social, or community) and acknowledge prognostic uncertainty. In addition, the following should be acknowledged: the limitations of the patient's understanding of her clinical situation; cultural, social, and value differences; power differentials; and language barriers. When working to reach a resolution with a patient who has refused medically recommended treatment, consideration should be given to the following factors: the reliability and validity of the evidence base, the severity of the prospective outcome, the degree of burden or risk placed on the patient, the extent to which the pregnant woman understands the potential gravity of the situation or the risk involved, and the degree of urgency that the case presents. Ultimately, however, the patient should be reassured that her wishes will be respected when treatment recommendations are refused. When a pregnant patient refuses a recommended medical treatment, the physician should carefully document the refusal in the medical record. Examples of important information to document are as follows (17):

- The need for the treatment has been explained to the patient—including discussion of the risks and benefits of treatment, alternatives to treatment, and the risks and possible consequences of refusing the recommended treatment (including the possible risk to her health or life, the fetus's health or life, or both)

- The patient's refusal to consent to a medical treatment
- The reasons (if any) stated by the patient for such refusal

## Arguments Against Court-Ordered Interventions

When the obstetrician-gynecologist and the patient are unable to agree on a plan of care and a pregnant woman continues to refuse recommended treatment, some obstetrician-gynecologists, hospital staff, or legal teams have attempted to force compliance through the courts, most notably for cesarean delivery or blood transfusion (18–20). Court-ordered interventions against decisionally capable pregnant women are extremely controversial. They exploit power differentials; involve incursions against individual rights and autonomy; and manifest as violations of bodily integrity and, often, gender and socioeconomic equality (14).

The College opposes the use of coerced medical interventions for pregnant women, including the use of the courts to mandate medical interventions for unwilling patients. Principles of medical ethics support obstetrician-gynecologists' refusal to participate in court-ordered interventions that violate their professional norms or their consciences. However, obstetrician-gynecologists should consider the potential legal or employment-related consequences of their refusal. Although in most cases such court orders give legal permission for but do not require obstetrician-gynecologists' participation in forced medical interventions, obstetrician-gynecologists who find themselves in this situation should familiarize themselves with the specific circumstances of the case. The College strongly discourages medical institutions from pursuing court-ordered interventions or taking action against obstetrician-gynecologists who refuse to perform them. It is not ethically defensible to evoke conscience as a justification to attempt to coerce a patient into accepting care that she does not desire.

## Prognostic Uncertainty

Prognostic uncertainty is present to various degrees in all medical encounters across all specialties and is common enough in obstetric decision making to warrant serious concern about legal coercion and the tremendous effect on the lives and civil liberties of pregnant women that court-ordered intervention entails (15, 21). A study of court-ordered obstetric interventions suggested that in almost one third of cases in which court orders were sought, the medical judgment, in retrospect, was incorrect (22).

## Barriers to Needed Care

Coercive and punitive policies are potentially counterproductive because they are likely to discourage prenatal care and successful treatment while undermining the patient-physician relationship. Attempts to criminalize



pregnant women's behavior may discourage women from seeking prenatal care (23). Likewise, court-ordered interventions and other coercive measures may result in fear on the patient's part about whether her wishes in the delivery room will be respected, which could discourage the pregnant patient from seeking care. Therefore, when obstetrician–gynecologists participate in forced treatment of their pregnant patients, outcomes for the patients and the fetuses may worsen rather than improve.

### Discriminatory Effects

Coercive policies directed toward pregnant women may be disproportionately applied to disadvantaged populations. In cases of court-ordered cesarean deliveries, for instance, most court orders have been obtained against women of color or of low socioeconomic status. In a review of 21 court-ordered interventions, 81% involved women of color and 24% involved women who did not speak English as a first language (22). Likewise, a systematic review of more than 400 cases of coerced interventions found that most cases included allegations against low-income women (23). The inclusion of an ethics committee or a patient advocate could help mitigate the disproportionate application of coercive policies to certain subpopulations of women and should be made available whenever possible.

### Process for Addressing Refusal of Medically Recommended Treatment During Pregnancy

Although there is no universal approach to communicating with and caring for a pregnant patient who refuses medically recommended treatment, steps can be taken to mediate conflict, diffuse intense emotions, and encourage consideration of the patient's perspective. These steps may create space, even under time constraints, to ensure that patients are fully heard and considered.

#### Seek to Understand the Patient's Perspective

Eliciting the patient's reasoning, lived experience, and values is critically important when engaging with a pregnant woman who refuses an intervention that the obstetrician–gynecologist judges to be medically indicated for her well-being, her fetus's well-being, or both. Medical expertise is best applied when the physician strives to understand the context within which the patient is making her decision. The obstetrician–gynecologist should acknowledge the importance of the pregnant woman's knowledge and values when making medical recommendations. A pregnant woman's decision to refuse treatment may be based on religious or cultural grounds; her assessment of the converging interests of herself, her fetus, her family, or her community; a misunderstanding of the clinical situation; or the experience of a family member or friend. Determining the basis for a pregnant woman's decision to refuse medically recommended treatment enables the physician to address her concern or understand its

importance to her and then take steps toward resolution (24). To that end, effective communication skills and strategies are critically important. Use of empathic statements, listening without interrupting, and taking a short break before revisiting the case can help defuse tensions, foster a calmer atmosphere, and establish trust (25, 26). The RESPECT model (Box 1) is an example of one tool that can be used to help optimize patient-centered

### Box 1. The RESPECT Communication Model

#### Rapport

- Connect on a social level.
- See the patient's point of view. Consciously suspend judgment. Recognize and avoid making assumptions.

#### Empathy

- Remember that the patient has come to you for help.
- Seek out and understand the patient's rationale for her behaviors or illness. Verbally acknowledge and legitimize the patient's feelings.

#### Support

- Ask about and understand the barriers to care and adherence. Help the patient overcome barriers.
- Involve family members, if appropriate.
- Reassure the patient that you are and will be able to help.

#### Partnership

- Be flexible with regard to control issues. Negotiate roles, when necessary.
- Stress that you are working together to address health problems.

#### Explanations

- Check often for understanding. Use verbal clarification techniques.

#### Cultural Competence

- Respect the patient's cultural beliefs.
- Understand that the patient's view of you may be defined by ethnic or cultural stereotypes.
- Be aware of your own cultural biases and preconceptions.
- Know your limitations in addressing medical issues across cultures.
- Understand your personal style and recognize when it may not be working with a given patient.

#### Trust

- Recognize that self-disclosure may be difficult for some patients.
- Consciously work to establish trust.

Modified with permission from Mutha S, Allen C, Welch M. Toward culturally competent care: a toolbox for teaching communication strategies. San Francisco (CA): Center for the Health Professions, University of California; 2002.

communication. Physicians also are referred to additional College resources that relate to effective communication, cultural sensitivity, empathy, and health literacy (2, 26–30).

### **Enhance the Patient’s Understanding**

Just as the patient must be free of external constraints on her freedom of choice, so must she be free of misinformation regarding the clinical factors on which the physician’s medical recommendations are formulated (2, 30). Adequate disclosure of relevant information may include that which is common to the practice of the profession, the reasonable needs and expectations of an ordinary patient, and, ideally, the needs and expectations of the patient making the decision. It also is important to inform the patient that other aspects of her care are not conditioned on making a choice that her obstetrician–gynecologist might prefer. Forthright and transparent communication of clinical information should encompass the range of clinical options available to the patient, including the potential risks, benefits, and consequences of each option and the likelihood of achieving goals of care. The discussion should include the treatment option that the patient prefers, as well as the benefits, risks, and consequences of no treatment or alternative treatments. Acknowledging that the patient is free at any time to refuse or withdraw her consent is an important part of the discussion. However, the physician should attempt to give the patient as much information as possible so that she has a basic understanding of her clinical situation and the implications of not receiving the treatment. Ideally, after the patient and the physician have discussed the clinical situation and the benefits and risks of the recommended treatment or intervention, the patient should decide whether or not to proceed with the recommended treatment (informed consent) or to forgo the recommended treatment (informed refusal).

Efforts to enhance patient understanding of relevant clinical information include the use of lay language rather than technical jargon, discourse in or translation to the patient’s primary language if the patient’s proficiency in English is limited, use of education materials such as those developed by the College, and efforts to mitigate patient stress (27, 30, 31). Most important is the acknowledgment that informed consent is an ongoing process, not an event or a signature on a document, and involves a willingness on the part of the obstetrician–gynecologist to engage in open, nonjudgmental, and continued dialogue.

### **Determine the Patient’s Decisional Capacity**

A pregnant woman’s decision to refuse medically necessary treatment may occasion questions regarding her decisional capacity. Patients are, by law, presumed to be decisionally capable unless formally determined otherwise. The obstetrician–gynecologist should not infer from a patient’s decision to refuse treatment that the patient’s capacity to make medical decisions about pro-

posed care is diminished. Disagreement with a physician’s recommendation is not, per se, evidence of decisional incapacity. Although psychiatric consultation may justifiably be sought when a pregnant woman’s decision-making capacity (ie, her capacity to understand her options and appreciate the potential consequences of her choice) is in question, in no circumstance should a psychiatric consultation be used as a punitive measure or viewed as a means to coerce a patient into making a specific decision. Genuine differences in how obstetrician–gynecologists and patients assess and balance risk; the pregnant woman’s assessment of the collective interests of herself, her fetus, her family, or her community; and religious beliefs and cultural meanings of interventions may all lead decisionally capable patients to choose options other than those strongly recommended by their obstetrician–gynecologists (25). When a patient has been determined to lack decisional capacity, the decisions of her legally authorized surrogate generally should be honored. Such decisions should reflect the patient’s previously expressed values and preferences when these are known.

### **Emergency Cases**

Decision making can be particularly difficult and emotionally charged in emergency scenarios (32). Emergency cases may raise two distinct problems. First, fully informing the patient may not be possible. Nevertheless, a patient retains the right to make an uninformed refusal. Even if the patient has not been fully informed, a decisionally capable adult patient’s refusal of emergent care should be respected. Second, the patient may be incapacitated and, therefore, unable to consent for herself. “Presumptive consent” for critically needed care for a patient can sometimes be used, but only if it is critically necessary to proceed with care immediately (33) and a patient’s preference is not known. Use of presumptive consent is limited to emergency clinical situations in which the patient is completely decisionally incapable and no surrogate decision maker is reasonably available. Presumptive consent applies to cases in which an unconscious patient has not indicated a preference for treatment. Circumstances should support a reasonable presumption that the patient would retrospectively endorse the intervention. Expressions of disagreement or unwillingness preclude presumptive consent (33). A previously documented or expressed refusal should be respected.

### **Evaluate Maternal and Fetal Risk**

Risk assessment during pregnancy poses unique challenges to patients and physicians. Interventions recommended during pregnancy and childbirth may reflect distortions of risk based on concerns about failure to intervene rather than robust considerations of risks associated with those interventions (34). Risk assessment in the context of a pregnant woman’s refusal of recommended treatment should address concerns regarding

the respective benefits of the procedure to the pregnant woman and the fetus, the probability of harm to the pregnant woman and the fetus from either performing or withholding the procedure, and the risks and benefits of less intrusive treatments, when available.

### Interdisciplinary Team Approach

Obstetrician–gynecologists are encouraged to resolve differences by using a team approach that recognizes the patient in the context of her life and beliefs and to consider seeking advice from ethics consultants when the clinician or the patient feels that this would help in conflict resolution. The team may include colleagues from other disciplines, such as nursing, social work, chaplains, or ethics consultation. With the patient's consent, it also may be helpful to include in the discussion members of the pregnant woman's personal support network. However, these individuals cannot make the decision for the decisionally capable patient. Obstetrician–gynecologists are encouraged to consider seeking an ethics consultation and to discuss the clinical situation with their colleagues. A team approach can help increase the likelihood of realliance with the patient by underscoring that the patient's concerns are shared among the health care team and her personal support system, particularly when the patient is included in the decision to use this collaborative approach.

### Supporting the Patient and the Health Care Team When Adverse Outcomes Occur

When adverse outcomes occur after a pregnant patient's decision to refuse recommended treatment, she may feel guilty about her decision, and members of the health care team may experience frustration and moral distress about whether they took all possible preventive measures. As with any adverse outcome, it is important that the patient and health care team members engage in honest communication and receive compassionate support.

Resources and counseling should be made available to patients who experience an adverse outcome after refusing recommended treatment. Patients can be reminded that medical decision making is complex and that well-intentioned people can make decisions they regret. The fact that the adverse outcome was not a certainty should be reinforced. Most critically, the clinical team's efforts should be directed toward helping the woman with any grief that she may experience. Judgmental or punishing behaviors regarding the patient's decision can be harmful.

Resources also should be established to support debriefing and counseling for health care professionals when adverse outcomes occur after a pregnant patient's refusal of treatment. Medical practitioners can be reminded that respecting and supporting patients' autonomy is a core ethical principle, even when it involves risk of adverse outcomes. Clinician grief and

anger are understandable, but these feelings need to be processed outside of interactions with the patient. As with any adverse outcome, debriefing in a supportive context should be undertaken to identify any measures that would help in future cases.

### Conclusion

One of the most challenging scenarios in obstetric care occurs when a pregnant patient refuses recommended medical treatment that aims to support her well-being, her fetus's well-being, or both. Such cases call for an interdisciplinary approach, strong efforts at effective medical communication, and resources for the patient and the health care team. The most suitable ethical framework for addressing a pregnant woman's refusal of recommended care is one that recognizes the interconnectedness of the pregnant woman and her fetus but maintains as a central component respect for the pregnant woman's autonomous decision making. This approach does not restrict the obstetrician–gynecologist from providing medical advice based on fetal well-being, but it preserves the woman's autonomy and decision-making capacity surrounding her pregnancy. Pregnancy does not lessen or limit the requirement to obtain informed consent or to honor a pregnant woman's refusal of recommended treatment.

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

Refusal of medically recommended treatment during pregnancy. Committee Opinion No. 664. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2016;127:e175–82.



## MATERNITY CARE DESERT

Maternity care deserts are counties across the U.S. in which access to maternity care services is limited or absent, either through lack of services or barriers to a woman's ability to access that care within counties. Specifically, a maternity care desert is any county without a hospital or birth center offering obstetric care and without any obstetric clinicians. Obstetric clinicians include obstetricians, family physicians who reported delivering babies, certified nurse midwives and nurse midwives. The three other classifications of maternity care levels include low access, moderate access and full access. Low access to care is defined as counties with one or fewer hospitals or birth centers that provide obstetric care, few obstetric clinicians (fewer than 60 per 10,000 births) or a high proportion of women without health insurance (greater than or equal to 10 percent of reproductive aged women). Moderate access to care is defined as living in a county with access to one or fewer hospitals/birth centers and few obstetric clinicians or adequate health insurance coverage (less than 10 percent of women of reproductive age uninsured). Full access to maternity care can be defined by the availability of two or more hospitals or birth centers providing obstetric care in a given county or availability of at least 60 clinicians offering obstetric care.

- More than 2.3 million women of childbearing age live in maternity care deserts (1,104 counties) that have no hospital offering obstetric care, no birth center and no obstetric clinician.
- More than 150,000 babies were born to birthing people living in maternity care deserts.
- An additional 3.3 million women of childbearing age live in counties with limited access to maternity care.

Access to quality maternity care is a critical component of maternal health and positive birth outcomes, especially in light of the high rates of maternal mortality and severe maternal morbidity in the U.S. Find the most recent full report here:

<https://www.marchofdimes.org/research/maternity-care-deserts-report.aspx>

Find the most recent state-level reports here: <https://www.marchofdimes.org/peristats/reports/alabama/maternity-care-deserts>

Explore the data on this page to better understand maternity care access in your state.

*Last updated: April 2025*

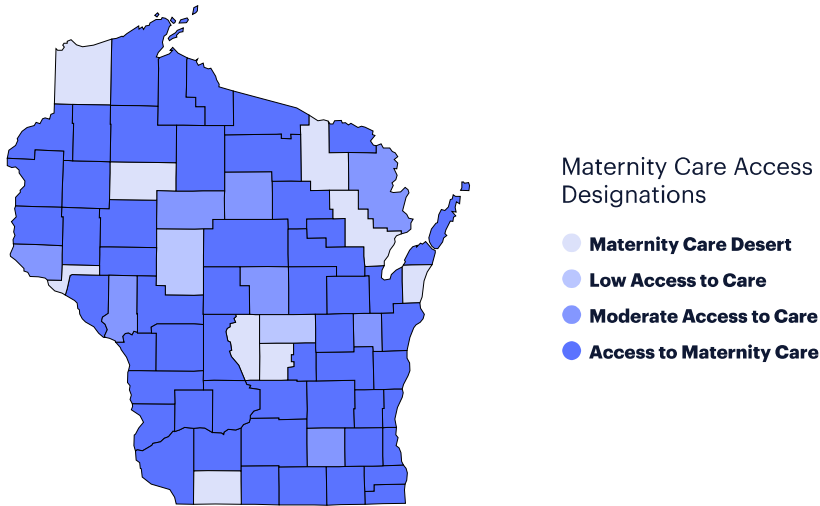
[FIND MORE DATA](#)

## DATA FOR WISCONSIN



### Maternity Care Desert:

# Wisconsin, 2024 Report



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**Notes:** March of Dimes defines a maternity care desert as any county without a hospital or birth center offering obstetric care and without any obstetric clinician. Obstetric clinician are defined as obstetricians, family physicians who reported delivering babies, certified nurse midwives and nurse midwives. Women may have low access to appropriate preventive, prenatal and postpartum care if they live in counties with few hospitals or birth centers (one or fewer) providing obstetric care, few obstetric clinician (fewer than 60 per 10,000 births) or a high proportion of reproductive-aged women without health insurance (10 percent or more). Moderate access to care is defined as living in a county with access to one or fewer hospitals/birth centers and obstetric clinician or adequate health insurance coverage (less than 10 percent of women of reproductive age uninsured). Full access to maternity care is defined by the availability of two or more hospitals or birth centers providing obstetric care in a county or the availability of at least 60 clinicians per 10,000 births offering obstetric care.

**Sources:** US Health Resources and Services Administration (HRSA), Area Health Resources Files, 2022-2023 file; American Board of Family Medicine, 2019-2022; American Association of Birth Centers, 2023; Centers for Medicare and Medicaid Services, National Plan and Provider Enumeration System (NPPES), November 2023 file; National Center for Health Statistics, 2022 final natality data; US Census Bureau, 2022 American Community Survey 5-Year Estimates; American Hospital Association, 2022. Retrieved July 2, 2025, from [www.marchofdimes.org/peristats](http://www.marchofdimes.org/peristats).

- In Wisconsin, 12.5% of counties are maternity care deserts.
- In Wisconsin, 13.9% of counties have low or moderate, not full, access.

## ADDITIONAL DATA

### DISTRIBUTION OF OBSTETRIC CLINICIANS

Wisconsin, 2021

[VIEW](#)

### WOMEN WITHOUT HEALTH INSURANCE

Wisconsin, 2022

[VIEW](#)

### ACCESS TO HOSPITALS OR BIRTH CENTERS

Wisconsin, 2022

[VIEW](#)

The goal of the Perinatal Data Center is to clearly present perinatal data, so that professionals focused on issues related to maternal and infant health can make more informed decisions to ultimately improve mom and baby health.

## **STATE SUMMARIES**

## **REPORTS**

## **DATA**

## **ABOUT US**

## **CONTACT**

**DONATE**

## **SIGN UP FOR DATA UPDATES**

We are constantly updating our data points throughout the year as soon as the new data is released.

**SIGN UP**

## **CONNECT WITH US**

© 2025 March of Dimes, a not-for-profit, section 501c(3).

The preterm birth rate in Wisconsin was **9.9%** in 2023, lower than the rate in 2022

## PRETERM BIRTH GRADE



US RATE



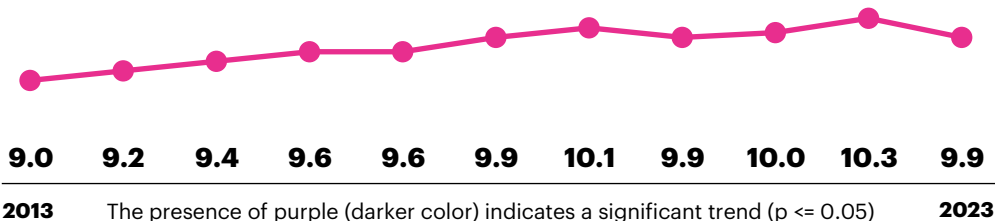
WI RATE



WI RANK

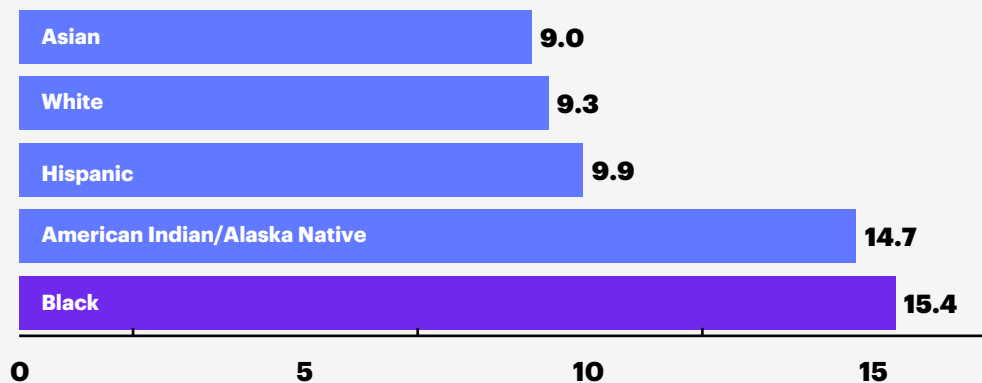


Percentage of live births born preterm



The preterm birth rate among babies born to Black birthing people is **1.4x higher** than the rate among all other babies

Preterm birth rate by race/ethnicity, 2021-2023



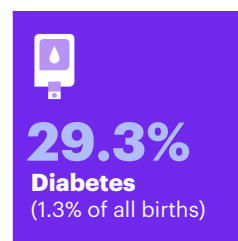
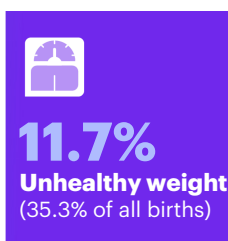
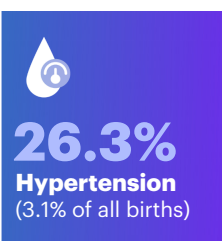
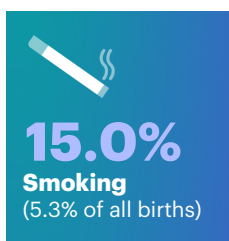
DISPARITY RATIO **1.37**

This data is intended to highlight disparities in outcomes related to race/ethnicity and should serve as a starting point for discussions about addressing systemic racism and inequality.

**Note:** The disparity ratio is a summary measure of the gap between the racial/ethnic group with the lowest rate of preterm birth compared to all others. A value closer to 1 is most desirable, with 1 indicating no disparity. The United States preterm birth disparity ratio is 1.29.

## Chronic health conditions make people more likely to have a preterm birth

The tiles display the 2023 preterm birth rate for babies born to birthing people with each chronic condition (in blue) and percentage of all births exposed to each condition (in parentheses).



**Note:** More than one condition can occur at the same time. All conditions occur prior to pregnancy. US preterm birth rates for birthing people with each condition are as follows: smoking: 15.5%; hypertension: 23.3%; unhealthy weight: 12.3%; and diabetes: 28.8%.

**Source:** National Center for Health Statistics, Natality data, 2013-2023.

The infant mortality rate increased in the last decade; In 2022, 348 babies died before their first birthday

INFANT MORTALITY RATE

5.8

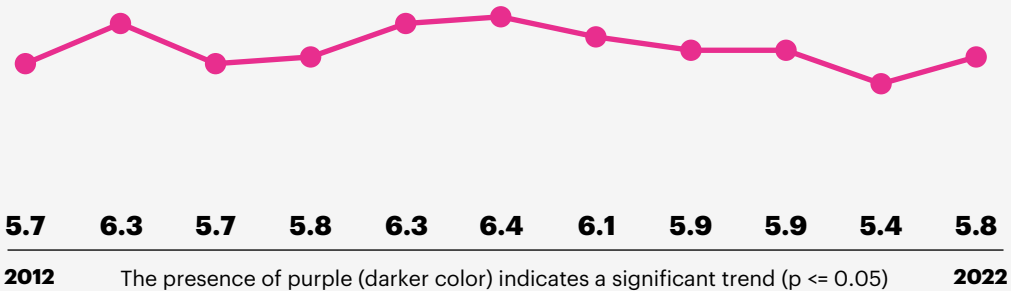
US RATE



WI RANK



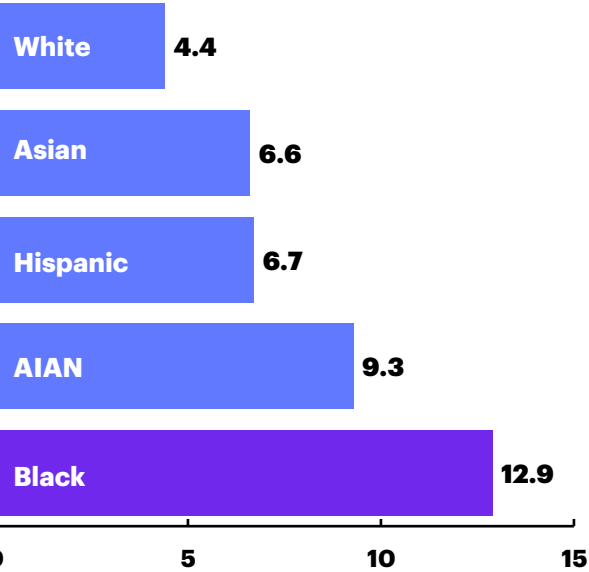
Rate per 1,000 live births



The infant mortality rate among babies born to Black birthing people is 2.2x the state rate

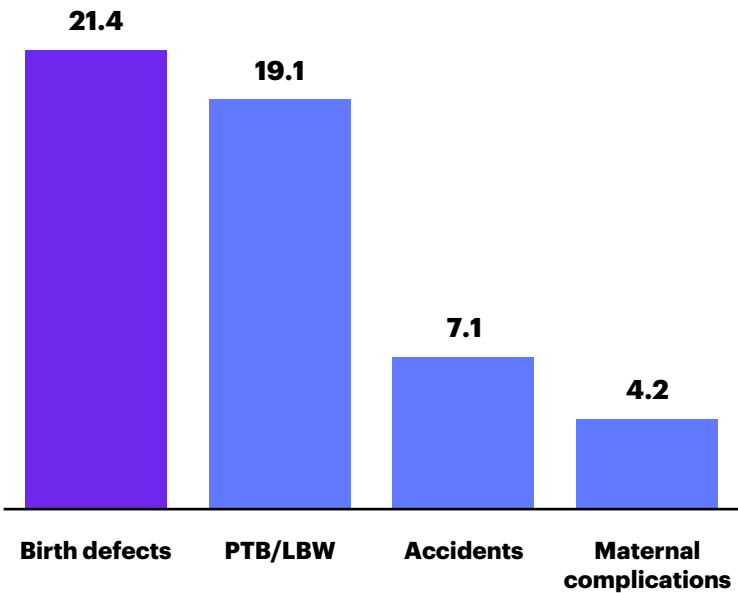
Infant mortality rate

Rate per 1,000 live births by maternal race/ethnicity, 2020-2022



Leading causes of infant death

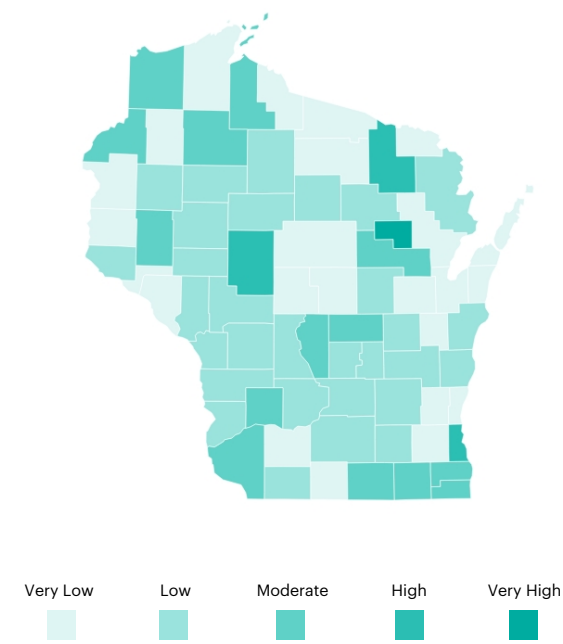
Percent of total deaths by underlying cause, 2020-2022



**Notes:** PI = Pacific Islander; AIAN = American Indian/Alaska Native; PTB/LBW = preterm birth and low birth weight; SIDS = sudden infant death syndrome. Other causes account for 48.2% of infant deaths.  
**Source:** National Center for Health Statistics, Period Linked Birth/Infant Death data, 2012-2022.

# WISCONSIN

## Maternal Vulnerability Index by county



The Maternal Vulnerability Index is used to understand **where and why** birthing people may be more likely to have poor health outcomes

Birthing people in Wisconsin are most vulnerable to poor outcomes due to the following factors:



Source: Surgo Health, Maternal Vulnerability Index (MVI), 2024.  
<https://mvi.surgoventures.org/>

## Exposure to **extreme heat or air pollution** can increase the risk of poor maternal and infant health outcomes, including preterm birth

Community and individual risk mitigation efforts can help reduce the risk of exposure to extreme heat and poor air quality.

Birthing people can check their local heat risk and air quality at:  
<http://www.cdc.gov/heatrisk>

**23**  
DAYS

### EXTREME HEAT

This shows the average number of days in the year that birthing people were at risk for exposure to extreme heat.

**18**  
DAYS

### POOR AIR QUALITY

This shows the average number of days in the year that birthing people were at risk for exposure to poor air quality.

Source: Centers for Disease Control and Prevention National Environmental Public Health Tracking Network, Historical Temperature and Heat Index, 2023; Environmental Protection Agency, Air Quality Statistics by County, 2023. See technical notes for more details.

## The measures below are important indicators for how Wisconsin is supporting the health of birthing people

**13.2**

PER 100,000 BIRTHS

### MATERNAL MORTALITY

The maternal mortality rate cannot be shown due to unreliable estimates and concerns with confidentiality.



23.2

**22.6**

PERCENT

### LOW-RISK CESAREAN BIRTH

This shows Cesarean births for first-time moms, carrying a single baby, positioned head-first, and at least 37 weeks pregnant.



26.6

**10.9**

PERCENT

### INADEQUATE PRENATAL CARE

Percentage of birthing people who initiated care in the fifth month or later or less than 50% of the appropriate number of visits for the infant's gestational age.



15.7

Source: National Center for Health Statistics, Mortality data, 2018-2022. National Center for Health Statistics, Natality data, 2023.

Adoption of the following policies and sufficient funding in Wisconsin is critical to improve and sustain maternal and infant healthcare



MIDWIFE POLICY

State has adopted 1 of 4 supportive midwifery policies.

State has adopted policies that support the growth and sustainability of the midwifery workforce.



INDEPENDENT PRACTICE



PAY PARITY



PRESCRIPTIVE AUTHORITY



LICENSURE FOR CERTIFIED MIDWIVES



MEDICAID EXTENSION

State has extended coverage for women to one year postpartum.



MEDICAID EXPANSION

State has adopted this policy, which allows greater access to preventative care.



MENTAL HEALTH

State Medicaid program requires and reimburses for postpartum mental health screening at well-child visits.



DOULA REIMBURSEMENT

State Medicaid agency is actively reimbursing doula care.



PAID FAMILY LEAVE

State has required employers to provide a paid option while out on parental leave.



COMMITMENT TO PREVENTION

State has a CDC funded maternal mortality review committee and reviews fetal and infant deaths.

Legend State has the indicated funding/policy State reimburses up to \$1,500 State does not have the indicated policy/funding

This table is a summary of report card measures. Refer to each individual section for more info on each measure.

	Preterm birth	Preterm disparity ratio	Infant mortality	Maternal mortality	Low-risk Cesarean	Adequate PNC
Measure	9.9%	1.37	5.8 deaths per 1K births	13.2 deaths per 100K births	22.6%	82.2%
Rank	20th of 52	43rd of 47	26th of 52	3rd of 40	7th of 52	10th of 52
Direction from prior year	Improved	Improved	Worsened	Worsened	Improved	Improved
HP2030 Target	9.4%	1.00	5.0 deaths per 1k births	15.7 deaths per 100K births	23.6%	80.5%

Note: All policies were assessed on October 15, 2024. Adequate PNC measure differs from inadequate PNC. Adequate is presented here to align with Healthy People 2030 target. Ranks are determined for all states with available data with 1 being the best.

**State of Wisconsin  
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:  Whitney DeVoe, Board Counsel		2) Date When Request Submitted: 05/01/25	
		Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> <li>▪ 10 work days before the meeting for Medical Board</li> <li>▪ 14 work days before the meeting for all others</li> </ul>	
3) Name of Board, Committee, Council, Sections: <b>Midwife Advisory Committee</b>			
4) Meeting Date:	5) Attachments: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	6) How should the item be titled on the agenda page?  Licensed Midwives – Informed Consent Form – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both		8) Is an appearance before the Board being scheduled?  <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed:  <b>Discussion and consideration of updates to DSPS form #2795 related to informed consent.</b>			
11) Authorization			
<b>Whitney DeVoe</b>		<b>05/01/25</b>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)     Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Board Admin Specialist prior to the start of a meeting.			



# Wisconsin Department of Safety and Professional Services

Office Location: 4822 Madison Yards Way  
Madison, WI 53705  
Phone number: (608) 266-2112

LicensE Portal: <https://license.wi.gov/>  
Email: [dsps@wisconsin.gov](mailto:dsps@wisconsin.gov)  
Website: <http://dsps.wi.gov>

## DIVISION OF PROFESSIONAL CREDENTIAL PROCESSING

### LICENSED MIDWIVES – INFORMED CONSENT FORM

<b>Last Name</b>	<b>First Name</b>	<b>MI</b>	<b>Former / Maiden Name(s)</b>
<b>Address</b> (number street, city, state, zip code)			<b>Daytime Telephone Number</b>
			_____ - _____ - _____

<b>TRAINING:</b> List location, type of training (self-study, apprenticeship, direct-entry school, nurse midwifery school) and dates of attendance.			
Facility Name, City, State	Type of Training	Dates	
		From (month/year)	To (month/year)
		____ / ____	____ / ____
		____ / ____	____ / ____
		____ / ____	____ / ____
		____ / ____	____ / ____
		____ / ____	____ / ____
		____ / ____	____ / ____
		____ / ____	____ / ____

<b>CERTIFICATION:</b> List name and address of certifying body, date of certification and type of certification.		
Name and City/State of Certifying Body	Type of Certification	Date of Certification
		____ / ____ / ____
		____ / ____ / ____
		____ / ____ / ____
		____ / ____ / ____
		____ / ____ / ____

<b>MIDWIFE EXPERIENCE:</b>		
1.	Total number of births attended:	
2.	Number of home births as primary/managing midwife:	
3.	Number of home births as primary assistant to the midwife:	
3.	Number of years in practice as primary midwife:	
4.	Number of births as doula/hospital support:	
5.	Number of clients transferred to a hospital since commencement of practice of midwifery:	

<b>MALPRACTICE LIABILITY INSURANCE:</b>	
Do you have malpractice liability insurance coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No List policy limits of coverage (if applicable):	

# Wisconsin Department of Safety and Professional Services

**MEDICAL EMERGENCIES:**

The following is my protocol for handling medical emergencies, including transportation to a hospital. Attach additional sheets if necessary.

**VAGINAL BIRTH AFTER CESAREAN SECTION (VAC):**

The following is my protocol for disclosure of risks associated with vaginal birth after a cesarean section. Attach additional sheets if necessary.

**DISCLOSURE RELATING TO NEONATAL RESUSCITATIONS:**

Licensed midwives do not have the equipment, drugs or personnel available to perform neonatal resuscitations that would normally be available in a hospital setting.

**COPY OF DEPARTMENT RULES PROVIDED TO CLIENT:** As required under Wis. Admin. Code § [SPS 182.02\(1\)](#), I certify that on this date I provided a copy of the Department's rules pertaining to the practice of midwifery to the client. (**List client name below.**)

<b>Printed Name of Midwife</b>	<b>WI License Number</b>
<b>Signature of Midwife</b> (If unable to provide a digital signature print and sign form.)	<b>Date</b>
	____/____/____

**ACKNOWLEDGEMENT BY CLIENT:** I acknowledge that I have received the oral and written disclosures required under Wis. Admin. Code § [SPS 182.02](#).

<b>Printed Name of Client</b>	
<b>Signature of Client</b> (If unable to provide a digital signature print and sign form.)	<b>Date</b>
	____/____/____

# Information

## regarding

### VAGINAL BIRTH AFTER CESAREAN SECTION

#### ***What is VBAC?***

VBAC stands for Vaginal Birth After Cesarean, which is exactly what it sounds like - pushing a baby out through the birth canal (vagina) after having given birth by cesarean section. Some folks think that the VBAC term applies only to the first vaginal birth following a cesarean. In actuality, the VBAC label applies to every intended vaginal birth following the cesarean. In other words, if someone's first baby was born by cesarean, and their second baby was a successful VBAC, their third vaginal birth (and any after that) will similarly be VBACs.

Some important abbreviations that you'll run into in this article and as you further research this topic via other resources:

- VBAC (Vaginal birth after cesarean)
- HBAC (Home birth after cesarean)
- TOLAC (Trial of labor after cesarean)
- VBA2C (Vaginal birth after 2 cesareans)
- C/S (Cesarean section)
- PRCS (Planned repeat cesarean section)

Please understand that this handout is simply a jumping-off point for the research that we implore each family to do as they investigate their birthing options.

#### ***What's the big deal about VBAC?***

Let's start by understanding that when a baby is born surgically (by cesarean section), the doctor needs to make an incision first through the skin and fat layers of the lower abdomen, at which point the layers of abdominal muscles are essentially stretched apart.

Through that newly-created opening, another incision is made into the uterus, which is the large, balloon-like muscle in which the baby grows and develops. The baby is then pulled out through this incision, followed by the placenta soon after. Afterward, the incisions to the uterus and then to the skin are sutured (sewn) back together and allowed to heal.

The medical world has learned a lot over the years about how to do cesarean sections in a way that encourages the strongest healing - considerations like where and how to make

the incision into the uterus, as well as how to repair it after the birth. However, the fact still remains that there will forever be scar tissue there, making that spot weaker than the rest of the muscle of the uterus - this is where the extra risks and considerations come into play for pregnancies and births following a cesarean section.

That scarred portion of the uterus increases the possibility of some complications with the placenta, as well as a severe complication called uterine rupture, both of which we'll discuss in more detail. It's due to these elevated risks that pursuing a VBAC should be a very thoughtful decision for every family - one that they make on a basis of individual risk-assessment and with evidence-based information that's current and thorough.

It used to be the case that once a mother had a cesarean section, it was considered too dangerous to attempt a VBAC. She would have planned repeat cesarean sections (PRCS) for the rest of her childbearing years. However, we now understand more about how to improve the likelihood of a successful VBAC, and we also understand that each C/S a woman undergoes brings more risk to her future childbearing years. Even the conservative American College of Obstetricians and Gynecologists (ACOG) now recommends encouraging a "trial of labor after cesarean" (TOLAC) for most women, though they assert the birth should take place in a hospital.

### ***What are the major benefits of VBAC?***

Many of the benefits of pursuing a VBAC boil down to avoiding the risks and the challenges that come along with major abdominal surgery. Of course, none of the following are guaranteed, but are statistically likely:

- ***Shorter recovery after birth.*** Pushing a baby out vaginally is hard work - especially if it's someone's first time! However, the recovery afterward tends to be much easier than recovery from a surgical birth. A C/S is major abdominal surgery and the recovery is no joke.
- ***Microbiome benefits for baby.*** A baby who is born vaginally is exposed to all sorts of helpful bacteria on their trip through the birth canal. Those bacteria colonize the infant's gut, which leads to improved immune function and reduces the risk of various autoimmune disorders and other long-term health consequences for the child. Babies born by cesarean miss out on this beneficial bacterial exposure and we're only now beginning to understand the long-term impacts.
- ***Reducing the increased risks of repeat cesareans.*** It's important to understand that some of the risk factors associated with a cesarean section actually accumulate, or build up, with each additional C/S. In other words, with each additional cesarean section that a woman undergoes, she carries more risk into future pregnancies and births. For couples desiring a large family, this can be a significant problem, especially if the cesarean is early in her childbearing years.

- **Avoiding the immediate risks of surgery.** As with any surgery, there are risk factors to consider. A C/S puts someone at higher risk of:
  - Elevated blood loss
  - Infection of uterus, bladder, or incision (*20x greater risk than following vaginal birth*)
  - Hematoma, which is a burst blood vessel inside your body
  - Blood clots (*Doubles the risk compared to natural birth*)
  - Accidental injury to internal organs (*Most likely after multiple cesareans or during an emergency C/S*)
  - Accidental injury to the baby (*Most likely during an emergency C/S*)
  - Anesthesia complications (*More likely during an emergency C/S*)
  - Allergic reaction to medications
  - Delayed/impaired bowel function
  - Extended hospital stay
- **Decreased cost.** This is deliberately last on the list of benefits because it should not be the first consideration, safety should always be our primary concern. However, we can't ignore the fact that it's usually MUCH cheaper to have a vaginal birth than to undergo a cesarean. A recent three-year study showed that American families pay, on average, approximately \$19,000 more per birth for an uncomplicated cesarean section than for an uncomplicated vaginal birth.

### ***What are the major risks of VBAC?***

**Uterine rupture** - As discussed earlier, with every cesarean birth in a woman's history, there remains a scar on the uterus. The vast majority of times, that scar heals well and remains strong, but it's true that the scarred portion remains weaker than the rest of the muscle of the uterus. The stresses of full-term pregnancy, and then of labor and birth, can be a real test of that scar tissue.

Once a cesarean is in a person's history, the most feared complication of a subsequent pregnancy and birth is uterine rupture. Uterine rupture is when the uterus tears open, usually at the site of the scar. In the event of a rupture, doctors must work quickly to first deliver the baby so they do not suffer from oxygen deprivation which can cause brain damage or death. Doctors must then try to repair the uterus in order to stop the mother's blood loss.

Most times, uterine repair is possible, though sometimes the damage is extensive enough that the uterus can not be saved and must be removed altogether (called a hysterectomy). Transfusion(s) of blood products may be necessary to overcome the mother's blood loss. These are time-sensitive emergencies and the closer that mother and baby are to an operating room, the better the outcome will likely be.

Uterine rupture can happen to anyone, but is EXTREMELY rare for someone who has never had a uterine surgery. Reported rates of uterine rupture vary a bit from one study to the next, but are approximately:

- **0.006%** for someone with an unscarred uterus (*no history of C/S*)
- **0.3%** for someone who's having a planned repeat cesarean section (PRCS)
- **0.5%** for someone who's having a trial of labor after cesarean section (TOLAC) that is allowed to progress naturally (*without medications to start labor or speed it up*)
- **1%** for someone who's having a TOLAC and is given pitocin (*a medication given through one's IV to start or speed up labor*)
- **1.4%** for someone who's having a TOLA2C (trial of labor after 2 cesareans) that is allowed to progress naturally (*without medications to start labor or speed it up*)
- **2%** for someone who's having a TOLAC and is given prostaglandins (*a medication sometimes used to soften the cervix in preparation for labor*)
- **6%** for someone who's having a TOLAC and is given misoprostol (*a medication sometimes used to to start or speed up labor*)

I know these numbers seem low - it's true that uterine rupture is rare. However, when it does occur, it can be a life-threatening emergency for mother and baby and every family deserves to know and understand the risks.

**Placenta complications** - The placenta is a flat, disc-shaped organ that develops during pregnancy and is attached to the inside of the mother's uterus. Its job is to pass oxygen and nutrients from the mother's blood stream, through the umbilical cord, and to the baby. In order to sustain the baby, the placenta has to remain attached to the uterus throughout the entirety of pregnancy, labor, and birth. However, after the baby is born, the placenta is *designed to detach from where it's stuck on the inside of the uterus* and pass out of the birth canal.

The more C/Ss that a person has had, the more likelihood there is to be troubles with the placenta, specifically with its ability to detach and be born after the birth. It might attach too deeply to the uterus, a condition called **placenta accreta**. This is an exceedingly rare complication for women who have never had a uterine surgery, but one that will be experienced by approximately 1 out of 1,229 who have previously had a cesarean (based on a 2023 nation-wide study). The rate of placenta accreta increases with every C/S as follows:

- 0.31% chance after 2 C/Ss
- 0.57% after 3 C/Ss
- 2.13% after 4 C/Ss
- 2.33% after 5 C/Ss
- 6.74% after 6 C/Ss

Another possible complication is the placenta attaching over the cervix, which is the part of the uterus that must open up to let a baby be born through the birth canal. This condition is called placenta previa and can quickly threaten the lives of both mother and baby due to blood loss, which in many cases can be severe. Sometimes placenta previa and accreta happen at the same time and that can be a particularly dangerous situation!

Both of these placenta complications, while uncommon, can cause significant blood loss - the type that can quickly become a life-threatening emergency. Medications can be necessary to slow the bleeding, but the mother may require an emergency operation to remove the placenta in order to fix the problem. In dire circumstances, surgeons may even need to remove the uterus altogether. Depending on the situation, mother and/or baby may need a transfusion(s) of blood products if the blood loss was severe.

### ***After reading about those possible complications, why do folks want a VBAC?***

It's important to understand that the post-cesarean risks are NOT contained to just VBACs - there are potentially severe risks associated with repeat C/S as well. In other words, a repeat surgical birth is not an "easy-out". As mentioned before, the risks of repeat C/S accumulate with each additional surgery, so with every birth, *more risk* is actually being borne by the mother. The main risks that tend to increase with each additional cesarean are:

- **Placenta accreta** (the placenta attaching too deeply to the uterine wall)
- **Placenta previa** (the placenta attaching over the cervix)
- **Uterine rupture** (the uterus rupturing)
- **Hernia** (a weakening of the abdominal muscles possibly allowing abdominal tissues and organs to protrude through)
- **Adhesions** (bands of abnormal, fibrous tissue developing between abdominal organs. Their presence can contribute to future complications including infertility, ectopic pregnancy, abdominal and pelvic pain, and difficulty with future abdominal surgeries.)

### ***Considering a VBAC?***

***Discuss your childbearing history with your provider, including:***

1. Number of prior cesareans or other uterine surgeries (example: fibroid removal, D&C, biopsy, etc.)
2. Reason for the prior C/S
3. Amount of time that will have passed between the C/S and the next birth
4. Location and type of uterine scar
5. Any post-cesarean complications that occurred

**Evaluate the birthing location and emergency response time.** If you're considering birthing out-of-hospital (home birth or birth center), what is the emergency transport plan? How long will it take to access higher-level medical care if needed? The severe complications of VBAC are, admittedly, rare. However, when they do occur, minutes matter. If you're birthing in a hospital, check into their resources; for example, do they have 24/7 anesthesia in case a quick cesarean is needed? Everyone's birthing situation is different and you need to make sure that you're familiar with and comfortable with the option that you're selecting.

**Ask about the VBAC success rate of the provider/institution that you're considering.** Some institutions and providers have better VBAC success rates than others. Inquire about the experience, outcomes, and rates of complications for that specific practice.

### ***Risk factors preventing VBAC***

Things that would make a VBAC too risky include:

**A history of vertical C/S incision** - The safest uterine incision for a C/S is normally just above the pubic bone - a low, transverse line between 6 and 9 inches long. In cases of challenging or emergency cesareans, a vertical incision - up and down, right on the mother's midline - may have been necessary (other possibilities are an inverted-J or -T shape incision). These incisions leave someone at much higher risk of uterine rupture and VBAC should not be attempted.

**A short interval between a person's cesarean birth and their desired VBAC** - 18 months is minimum (24 months is preferred) in order to ensure good healing of the prior uterine incision.

**A history of prior rupture** - If someone has had a uterine rupture that was repaired, they are at a much higher risk of rupture for future pregnancies, even after it is healed.

**A history of other uterine surgeries** - There are other uterine procedures aside from cesarean section that may cause weakness similar to a cesarean. This is not an automatic risk-out, however, it's important to discuss any surgery (examples: fibroid removal, D&C, biopsies, etc.) with your care provider so that you can get a proper and accurate evaluation of your risk.

**The presence of any other factor that makes natural birth unsafe** - There are other conditions, for example, some malformations of the growing baby, or a maternal problem like an untreated herpes (viral) infection that would make any natural birth (not just a VBAC) too high-risk.



## ***Tips for a successful VBAC:***

- ***Strive for at least 24 months between the C/S and the next birth.*** As stated earlier, this gives the uterine scar time to heal and strengthen. A short interval between the cesarean and a next pregnancy causes a higher risk of uterine rupture.
- ***Allow labor to start up and progress naturally.*** Inducing labor or using medications to keep labor progressing puts an unusual amount of stress on the uterus and increases the risk of uterine rupture. In most VBAC situations, allowing things to progress naturally is safest!
- ***Having already had a successful vaginal birth or VBAC*** increases the success rate. It doesn't matter if your vaginal birth was before or after your cesarean - the fact that your body has pushed out a baby at least once before means the odds of doing so again are high! Again, the following statistics will vary from one institution to the next, but: having never had a prior natural birth, a woman has a 63% VBAC success rate. If a woman has already had one baby naturally, the VBAC success rate jumps up to about 87%.
- ***Select a care provider and birth setting that you feel comfortable with.*** When a mother is comfortable with her care team and her environment, the odds of a successful VBAC go up because the body responds to the labor process more effectively. As a result, less medications and interventions are needed and it's easier to stay in a safe zone.
- ***Understand that your labor will be monitored more closely.*** Both of the major possible complications of VBAC can occur without much in the way of symptoms, so it will be more important that your care providers monitor maternal vitals and baby's heart rate more closely than they likely would for a "normal" labor and birth.
- ***Be willing to change your birthing plans.*** If risk factors over the course of pregnancy or labor/birth would change, the setting and/or method of birth may have to change as well. Early warning signs should be acted upon in a conservative way so that mother and baby both have a safety net underneath them in the event it's needed.

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# Informed Consent

## for

### VAGINAL BIRTH AFTER CESAREAN SECTION

I, \_\_\_\_\_ understand and appreciate that a major tenet of  
(Print full name)  
midwifery care is the ability to retain my own decision making. I also understand that it means I bear an increased  
burden to inform myself and take responsibility for my care decisions. By initialing next to each of the statements  
that follow, I affirm that:

- I have read and given careful consideration to the information and options given to me by  
Windy Hill Midwifery, LLC (WHM)
- I have had time to research the topic from different sources and ask questions
- I am making a fully-informed decision

#### Regarding my VBAC:

In the event of a non-emergent transport or transfer of care, my preferred provider and location are:

\_\_\_\_\_  
(Provider Name)

\_\_\_\_\_  
(Provider Location)

(Initials)

I realize that in a time-sensitive situation, transport will be to the closest location that provides birthing  
services, which in my situation, is:

\_\_\_\_\_  
(Hospital)

(Initials)

I understand that my care team will monitor my labor more frequently and I agree to give prompt and  
serious consideration to any concern that develops over the course of labor, as well as to subsequent  
recommendations from my care team.

(Initials)

I understand the risks and benefits of Vaginal Birth after Cesarean. Furthermore, I understand the risks and  
benefits of VBAC in an out-of-hospital setting. I realize that the provision of emergency interventions such  
as cesarean section, transfusions of blood products, etc, will be delayed compared to birthing in a hospital.

Client

Signature: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

# Primary VBAC/TOLAC

## M I D W I F E R Y C O N S E N T F O R M

### **We support a client's right to self-determination.**

Therefore, we support clients who would like to attempt to have a VBAC (vaginal birth after cesarean) or what is referred to as 'trial of labor after cesarean' (TOLAC). We believe that in most cases, TOLAC is a safe option for families. Because TOLAC does carry some increased risk, we want to make sure that you fully understand the risks and benefits and are choosing this option knowing how a TOLAC is different from other births.

### **To reduce unnecessary risk, we only take the lowest risk clients desiring a TOLAC at home with the following criteria:**

- No more than one previous cesarean birth.
- Surgical records demonstrating a low, transverse surgical scar from your cesarean birth.
- An ultrasound record from this current pregnancy showing that your placenta is not lying across your cesarean scar.
- Minimum 18 months between your cesarean birth and your current due date.
- You must be willing to allow extra monitoring of you and the baby during your labor and birth.
- You must be willing to transport to the hospital at the request of the midwife if she feels anything about your labor or birth is straying from a normal course.

### **Current ACOG Standards for VBAC/TOLAC**

"In keeping with past recommendations, most women with one previous cesarean delivery with a low- transverse incision are candidates for and should be counseled about VBAC and offered a TOLAC [trial of labor after cesarean]." [1]

### **TOLAC Counseling on Benefits and Risks**

Both a repeat cesarean and a trial of labor after cesarean (TOLAC) carry risks including: maternal hemorrhage, infection, operative injury, blood clots, hysterectomy, and death.

### **Risks of a TOLAC:**

**The need for a repeat/emergency cesarean.** Most maternal injury that occurs during a TOLAC happens when a repeat cesarean becomes necessary after the TOLAC does not proceed to a normal birth. A successful VBAC has fewer complications than an elective repeat cesarean while a TOLAC that ends in cesarean has more complications than an elective repeat cesarean.

### **Uterine rupture.**

The risk of uterine rupture during a TOLAC is low-between 0.5% and 0.9%.[2] If a uterine rupture occurs, it is an emergency. A uterine rupture can lead to emergency surgery, blood transfusions, hysterectomy, and in extreme cases even death to a client and/or baby. However, the extreme of a neonatal demise happens in only 3-6% of cases where there is a uterine rupture. This makes the overall risk of a serious adverse outcome in a primary TOLAC very low.

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[1] (Humphry, Laura. New VBAC Guidelines. ACOG Today, August 2010.)

[2](Guise Jm, Eden K, Emeis C, Denman MA, Marshall B, Fu Rr, et al. 2010. "Vaginal birth after cesarean:new insights. ." Evid Rep Technol Assess ( Full Rep) 1-397.)

### Benefits of VBAC:

- Approximately 60-80% of appropriate candidates who attempt TOLAC will be successful with a VBAC.
- A VBAC avoids major abdominal surgery, lowers the risk of hemorrhage and infection, and shortens postpartum recovery. It may also help folks avoid the possible future risks of having multiple cesareans such as hysterectomy, bowel and bladder injury, transfusion, infection, and abnormal placenta conditions (such as placenta previa and placenta accreta). [3]
- Easier bonding and breastfeeding initiation postpartum.

### Risks Associated with Elective Repeat Cesarean Section

#### Risks to the baby:

- Increased risk of neonatal respiratory distress syndrome (RDS)
- Increase in persistent pulmonary hypertension
- Increased risk of physician caused prematurity
- 0.5 %-1.5% chance of laceration by the surgeon's scalpel [4]

#### Risks to the pregnant person:

- Increased risk of postpartum infection
- Increased risk of hemorrhage, transfusions, ureter or bowel injury, incisional endometriosis
- Increased risk of re-hospitalization due to infection, gallbladder disease, surgical wound complications, cardiopulmonary conditions, thromboembolic conditions, and appendicitis
- Longer hospital stay
- Increased risk of hysterectomy in both the current and future pregnancies
- Increased maternal death rate
- Higher rates in subsequent pregnancies of placental abnormalities such as placenta previa or accreta
- Higher rates of secondary infertility, miscarriage, and ectopic pregnancy [5]

### Benefits of Elective Repeat Cesarean:

- Convenience of scheduling the birth
- Avoidance of a labor that may result in a repeat cesarean
- Decreased risk of uterine rupture [6]

### Further Reading:

VBAC Facts: <http://vbacfacts.com/>

ICAN <http://www.ican-online.org/vbac-education-project>

ACOG <https://www.acog.org/Womens-Health/Vaginal-Birth-After-Cesarean-VBAC>

ACOG Practice Bulletin on VBAC: <https://www.ncbi.nlm.nih.gov/pubmed/20664418>

[3] (Bennet S, Bourret K, Meuser A. "Vaginal Birth after Previous Low-Segment Caesarean Section" Clinical Practice Guidelines.Vol 14. (2010): 13-18)

[4] (IBID: 12)

[5] (IBID: 12)

[6] (Guise Jm, Eden K, Emeis C, Denman MA, Marshall B, Fu Rr, et al. 2010. "Vaginal birth after cesarean:new insights. ." Evid Rep Technol Assess ( Full Rep) 1-397.)

# Primary VBAC/TOLAC

## MIDWIFERY CONSENT FORMS

Please use this space below to declare, in your own words, your choice to pursue a TOLAC in the community setting and your understanding of the risks and benefits of your choice:

### Your Choice:

I have had all my questions regarding the risks and benefits of a TOLAC clearly explained to me. I am pursuing a TOLAC as a matter of personal preference. I know that a repeat elective Cesarean Section is an option available to me, but I am choosing to attempt a VBAC instead.

---

Client Name

Client Signature

Date

---

Witness Name

Witness Signature

Date

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Midwife Name

Midwife Signature

Date