Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way
PO Box 8366
Madison WI 53705-8366

Phone: 608-266-2112
Web: http://dsps.wi.gov
Email: dsps@wisconsin.gov

Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
MIDWIFE ADVISORY COMMITTEE
Virtual, 4822 Madison Yards Way, Madison
Contact: Tom Ryan (608) 266-2112
March 18, 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 January 21, 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. Legislative and Policy Matters – Discussion and Consideration

E. Midwifery Survey and Results - Discussion

F. Administrative Rule Matters – Discussion and Consideration (4-105)
1. Drafting Proposals: SPS 180 to 183, Relating to Licensed Midwives Comprehensive Review
2. Pending and Possible Rulemaking Projects

G. Licensed Midwives – Informed Consent Form – Discussion and Consideration (106-108)

H. 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

I. Public Comments

ADJOURNMENT

NEXT MEETING: MAY 13, 2025

****

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
JANUARY 21, 2025

PRESENT: Leslie Abitz, Korina Bauer, Kelsey Scherer

EXCUSED: Angela Guzzardo, Kayci Marie Stevenson

STAFF: Tom Ryan, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Dialah Azam, 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 three (3) members was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda

- **REMOVE** item C.4 Election of Officers

MOTION: Korina Bauer moved, seconded by Leslie Abitz, to adopt the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES FROM OCTOBER 17, 2024

MOTION: Korina Bauer moved, seconded by Leslie Abitz, to approve the minutes of October 17, 2024 as published. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 12:56 p.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**03/04/25** **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

3) Name of Board, Committee, Council, Sections:

Midwife Advisory Committee

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
03/18/25	☒ Yes ☐ No	**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**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

Attachments:

1. SPS 180 to 183 Redlined Code Text and Adjacent State Analysis
2. AMCB Information and Comparison Chart
3. International Conference of Midwives Statement on Tranexamic Acid
4. WHO Recommendation on Tranexamic Acid
5. Wis. Stat. Ch. 440 Subch. XIII
6. Wisc. Admin. Code Chapters SPS 180 to 183

Copies of current Department Rule Projects Can be Viewed Here:
https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization

Nilajah D. Hardin — 03/04/25

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 Bureau Assistant prior to the start of a meeting.

Chapter SPS 180

AUTHORITY AND 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 un- der 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 li- censed 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 auto- mated external defibrillator achieved through instruction pro- vided 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 per- son 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 12th Street SW, Suite 600, Washington, DC 20024-2188, (240) 485−1800, https://www.midwife.org/.

Chapter SPS 182

STANDARDS OF 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 in- formed, 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) Tranexamic acid for the 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)

negative women.

~~(f)~~(g) Intravenous fluids for maternal stabilization – 5% dextrose in 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 mid- wife may legally administer prescription drugs or devices only as an authorized agent of a practitioner with prescriptive authority. For physicians and advanced practice nurses, 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), tranexamic acid, 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:

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
Tranexamic acid 100mg/ml	Postpartum hemorrhage within 3 hours of birth only	1g (100mg/ml) fixed dose, IV at 1ml per minute	IV bolus infusion	First dose over 10 minutes, Second dose if bleeding continues after 30 minutes or restarts within 24 hours of first does
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
5% dextrose in lactated Ringer's solution (D5LR), unless unavailable or impractical in which case 0.9% sodium chloride may be administered	To achieve maternal stabilization during uncontrolled post-partum hemorrhage or anytime blood loss is accompanied by tachycardia, hypotension, de-creased level of consciousness, pallor or diaphoresis	First liter run in at a wide-open rate, the second liter titrated to client's condition	IV catheter 18 gauge or greater (2 if hemorrhage is severe)	Until maternal stabilization is achieved or transfer to a hospital is complete

(4) CONSULTATION AND REFERRAL. **(a)** A licensed midwife shall consult with a licensed physician 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.

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 licensed physician or certified 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. Hyperemisis 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 accept- able 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 pro- vide 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 intra- partum 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. Insulin requiring diabetes mellitus.
5. Known maternal congenital abnormalities 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 affecting normal vaginal births, including tumors and malformations.
11. Alcoholism or abuse.
12. Drug addiction or abuse.
13. Confirmed AIDS status.
14. Uncontrolled current serious psychiatric illness.
15. Social or familial conditions unsatisfactory for out-of- hospital maternity care services.
16. Fetus with suspected or diagnosed congenital abnormalities that may 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 im- pairs 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 ser- vice, 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

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 net- work 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

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of the practice of midwifery in Illinois, with input from the Illinois Midwifery Board. The Illinois Department is also responsible for the promulgation of rules to implement certain sections of the Illinois Licensed Certified Professional Midwife Practice Act. This Act contains requirements for applications, licensure, renewal, informed consent, consultation, referrals, and discipline for licensed certified professional midwives. As outlined in Section 45 of the Act, each applicant for a license must hold a valid professional midwife certification granted by the North American Registry of Midwives, a current cardiopulmonary resuscitation certification, and an active status as a neonatal resuscitation provider. Additionally, each applicant needs to submit proof of successful completion of a postsecondary midwifery education program accredited by the Midwife Education and Accreditation Council, successfully complete a licensure examination from the Illinois Department, and be at least 21 years old [225 Illinois Compiled Statutes ch. 64 s. 45]. In Illinois, a Licensed Certified Professional Midwife may administer oxygen, eye prophylactics, oxytocin, Pitocin, or misoprostol, methylergonovine or methergine, vitamin K, Rho (D) immune globulin, intravenous fluids, antibiotics, ibuprofen and lidocaine, among other drugs via the methods specified in the statute while performing the practice of midwifery. Additional medications, agents, or current evidence-based obstetric guidelines may be approved by the Illinois Department by rule [Illinois Compiled Statutes ch. 64 s. 70].
The Illinois Administrative Code further outlines requirements for licensed certified professional midwives. These rules include requirements for continuing education, midwife assistants, recordkeeping, adverse occurrences, and unprofessional conduct, among other topics. The additional medications specified by rule that can be administered by a Licensed Certified Professional Midwife include tranexamic acid, hemabate, penicillin, ampicillin, cefazolin, clindamycin, and acetaminophen [Illinois Administrative Code Title 68 Chapter VII Part 1345].

Iowa: The Iowa Board of Nursing, with input from the Midwifery Advisory Council, is responsible for the licensure and regulation of the practice of midwifery in Iowa. Chapter 148I of the Iowa Code includes statutory requirements for licensure, adoptions of rules, and the composition of the Midwife Advisory Council. An applicant for licensure as a midwife needs to submit evidence of a high school diploma or equivalent, current certification as a Certified Professional Midwife from the North American Registry of Midwives, successful completion of an educational program accredited by the Midwifery Education Accreditation Council, and that they are at least 21 years of age. Additionally, the Iowa Board shall adopt rules to regulate midwifery that are based on the rules of the National Association of Certified Professional Midwives and the North American Registry of Midwives. In Iowa, a licensee may administer oxytocin, misoprostol, methylergonovine, intravenous fluids, vitamin K , antibiotic eye prophylaxis, oxygen, intravenous antibiotics for group B streptococcal prophylaxis, Rho (D) immune globulin, local anesthetic, epinephrine and other drugs consistent with the practice of Midwifery as approved by the Iowa Board [Iowa Code ch. 148I].
The Iowa Administrative Code includes the rules for regulation of midwifery, as well as further requirements for licensed midwives. The rules for midwife practice in Iowa require that each licensee shall comply with the practice standards of the National Association of Certified Professional Midwives. Other areas listed include requirements for delegation, testing and drugs,

discipline, and telehealth. The additional drugs specified by rule and approved by the Iowa Board that licensees may administer in Iowa include pyridoxine, terbutaline, and nifedipine [Iowa Administrative Code 655 Ch. 16].

Michigan: The Michigan Department of Licensing and Regulatory Affairs and the Michigan Board of Licensed Midwifery are responsible for the licensure and regulation of the practice of midwifery in Michigan. Act 368 Article 15 Part 171 of the Michigan Compiled Laws includes the regulations for midwifery in Michigan, among several other occupations. Some of the requirements in this part include those for licensure, renewal, transfer of care, informed consent, and duties of the Michigan Board. Each applicant for licensure as a midwife needs to have successfully completed an education program accredited by the Midwifery Education and Accreditation Council, have a current credential as a Certified Professional Midwife from the North American Registry of Midwives or an equivalent, and have successfully completed and examination provided by the Michigan Department. The Michigan Department and Board are also responsible for promulgation of rules for midwifery on licensure, continuing education, processes to obtain informed consent, protocols for transfer of care, among other areas [Michigan Compiled Laws ss. 333.17101-333.17123
The rules also outline requirements for pre-licensure education, consultation, referral, emergency transfer of care, administration of prescription medications, and prohibited conduct. In Michigan, a licensed midwife who has pharmacology training and a standing prescription order from a health professional with prescription authority may administer prophylactic vitamin K, antihemorrhagic agents (including tranexamic acid), local anesthetic, oxygen, prophylactic eye agents, prophylactic Rho (D) immunoglobulin, agents for group B streptococcus prophylaxis, intravenous fluids excluding blood products, antiemetics, and epinephrine via the methods outlined in the rules [Michigan Administrative Rules R 338.17101-338.17141].

Minnesota: The Minnesota Board of Medical Practice is responsible for the licensure and regulation of traditional midwifery in Minnesota with input from the Advisory Council of Traditional Midwifery. Chapter 147D of the Minnesota Statutes includes requirements for licensure, practice, informed consent, consultation, discipline, and make-up of the Advisory Council. To qualify for a license in traditional midwifery, each applicant needs to submit a diploma from an approved education program, a copy of a current credential from the North American Registry of Midwives as a Certified Professional Midwife, evidence of current certification in adult and infant cardiopulmonary resuscitation, a medical consultation plan, and documentation of practical experience through an apprenticeship or similar supervised practice setting. In Minnesota, a licensed traditional midwife may obtain and administer vitamin K, RhoGAM treatment, postpartum antihemorrhagic drugs, local anesthetic, oxygen, and prophylactic eye agents [Minnesota Statutes ch. 147D].

About American Midwifery Certification Board (AMCB)

The American Midwifery Certification Board (AMCB), formerly the ACNM Certification Council, Inc. (ACC) is the national certifying body for Certified Nurse-Midwives (CNMs*) and Certified Midwives (CMs*). The certification function is a critical aspect of professional quality assurance in midwifery. Nurse-midwives have been certified by examination since 1971. At that time, certification rested within the American College of Nurse-Midwives (ACNM), first within the Division of Examiners, and then within the Division of Competency Assessment. In 1991, in keeping with the professional standard that certification should be separated from the professional organization, the ACC was incorporated as a distinct organization charged with functions related to the midwifery certificate. These functions include initial certification, recertification (Certificate Maintenance Program) and discipline. In 1997, in addition to the CNM certificate, the ACC began to offer certification to professionally educated midwives who were not first educated as nurses. The CM certificate is offered to candidates from ACME accredited programs in midwifery. In 2005 the organization's name was changed to American Midwifery Certification Board but the goals of the organization have remained the same.

The AMCB consists of officers (President, Secretary and Treasurer), a Board of Directors, an office of full-time staff members and committees responsible for the creation of the national certification examination, certificate maintenance, and research and credentialing/reporting.

AMCB Bylaws 2020a
General Policies and Procedures- Updated July 2024

Mission Statement

The mission of AMCB is to protect and serve the public by leading the certification standards in midwifery.

Vision Statement

To advance the health and well-being of women and everyone for whom midwives provide care
by setting the standard for midwifery excellence.

Core Values

Integrity

Commitment to appropriate transparency, honesty, and fairness, as an ethical organization of excellence in midwifery.

Accountability

Ensure public safety by setting the standard for midwives and encouraging excellence by embracing the responsibility to delivery quality certification, recertification, and discipline processes.

Respect

Valuing and treating all employees, public, candidates, and certificants with dignity and worth, regardless of their background or perspective by creating an environment of inclusiveness, professionalism, and consistency for all.

Purpose

- To set the national certification standard for the profession of midwifery
- To develop and administer the certification examination for assessment of entry-level competencies for the practice of midwifery
- To award national certification as a Certified Nurse-Midwife (CNM) or Certified Midwife (CM) to candidates who have met the specified qualifications
- To provide a mechanism of certification and recertification for all CNMs/CMs
- To maintain professional discipline of all CNMs/CMs
- To adhere to national standards for certification bodies
- To liaison with other organizations to assure quality processes of midwifery certification and professional discipline

---

Accreditation

The National Commission for Certifying Agencies (NCCA) granted accreditation to the Certified Nurse-Midwife (CNM) and Certified Midwife (CM) certification programs administered by the American Midwifery Certification Board (AMCB) for demonstrating compliance with the NCCA Standards for the Accreditation of Certification Programs. NCCA is the accrediting body of the Institute of Credentialing Excellence (ICE), formerly National Organization for Competency Assurance (NOCA). The NCCA Standards were created in 1977, revised in 2003, and again in 2015 to ensure certification programs adhere to modern standards of practice in the certification industry. Both the Certified Nurse-Midwife (CNM) and Certified Midwife (CM) certification programs are accredited through 12/31/2026. Click here for more information on the NCCA or contact 202-367-1165.

* The titles CNM and CM are registered through the Federal Office of Patents and Trademarks.

Why AMCB Certification?

The chart below describes the different types of certified midwives in regards to educational requirements and licensure within the US. Please note, this comparison chart does not address individuals who are not certified and who may practice midwifery with or without legal recognition.

If viewing table on a mobile device, slide table for more content.

Certification	**Certified Nurse-Midwife (CNM®)**	**Certified Midwife (CM®)**	**Certified Professional Midwife (CPM) ®**
Certifying Organization	American Midwifery Certification Board (AMCB)		North American Registry of Midwives (NARM)
Certification Requirements (minimum degree and other requirements prior to taking national certifying exam)	Graduate Degree Required		High School Diploma or Equivalent
	1. Graduation from a nurse-midwifery education program accredited by ACNM Accreditation Commission for	1. Graduation from a midwifery education program accredited by ACNM Accreditation Commission for Midwifery Education	1. Completion of NARM's Portfolio Evaluation Process (PEP) pathway; **OR** 2. Graduate of a midwifery education program accredited by Midwifery

	Midwifery Education (ACME); **AND** 2. Verification by program director of completion of education program; **AND** 3. Active registered nurse (RN) license	(ACME); **AND** 2. Verification by program director of completion of education program	Education Accreditation Council (MEAC); **OR** 3. AMCB-certified CNM or CM; **OR** 4. Completion of state licensure program
Recertification Requirement	Every five years		Every three years

Education	**Certified Nurse-Midwife (CNM®)**	**Certified Midwife (CM®)**	**Certified Professional Midwife (CPM) ®**
Minimum Education Requirements for Admission to Midwifery Education Program	Graduate degree from accredited college/university 1. Some programs require RN license. If the applicant has a graduate degree, but not an RN license, some programs will require attainment of an RN license prior to entry into the midwifery program; others will allow the student to attain an RN license prior to graduate study; **OR** 2. If the applicant is an RN but does not have a graduate degree, some programs provide a bridge program to a graduate degree prior to the midwifery portion of the program; other programs require a graduate degree before entry into the midwifery program.	Graduate degree from accredited college/university and successful completion of specific science courses.	There are two primary pathways for CPM education, with differing admission requirements: 1. Portfolio Evaluation Process (PEP) pathway: an apprenticeship program; no degree or diploma required. Student must find a midwife preceptor who is nationally certified or state licensed, has practiced for at least 3 years, and attended at least 50 out-of-hospital births; **OR** 2. Accredited formal education pathway: for this pathway, a high school diploma from an accredited state or private school is required for admission.

	Note: Currently, the majority of AMCB- certified midwives enter midwifery through nursing.		*Note: Currently, half of CPMs have completed the Portfolio Evaluation Process(PEP) pathway to the CPM credential.*
Clinical Experience Requirement	Attainment of clinical skills must meet Core Competencies for Basic Midwifery Education (ACNM 2008). Clinical education must occur under the supervision of an AMCB-certified CNM/CM or Advanced Practice RN (APRN) who holds a graduate degree and has clinical expertise and didactic knowledge commensurate with content taught. Clinical skills include management of primary care for women throughout the lifespan, including reproductive health care, pregnancy, and birth; care of the normal newborn; and management of sexually transmitted infections in male partners.		Attainment of clinical skills must meet the Core Competencies developed by the Midwives Alliance of North America (MANA). Clinical education must occur under the supervision of a midwife who must be nationally certified, legally recognized, and who has practiced for at least 3 years, and attended at least 50 out-of-hospital births. Clinical skills include management of prenatal, birth and postpartum care for women and newborns.
Degree Granted	Master's or doctoral degree; a master's degree is the minimum requirement for the AMCB certification exam.	Master's degree; a master's degree is the minimum requirement for the AMCB certification exam.	No degree is granted through the PEP pathway. MEAC-accredited programs vary and my grant a certificate of an associate's, bachelor's, master's, or doctoral degree. Most graduates attain a certificate or associate degree; there is no minimum degree requirement for the CPM certification exam.

Licensure	**Certified Nurse-Midwife (CNM®)**	**Certified Midwife (CM®)**	**Certified Professional Midwife (CPM) ®**
Legal Status	Licensed in all 50 states plus the District of Columbia and US territories.	Licensed in Colorado, Delaware, District of Columbia, Hawaii, Maine, Maryland, New Jersey, New York, Oklahoma, Rhode Island, and Virginia.	Licenced or otherwise regulated in 31 states (4 states regulate by registration, certificate, or voluntary licensure).

		Authorized to practice in Missouri but not licensed.	
Licensure Agency	Boards of Nursing, Boards of Medicine, Boards of Midwifery/Nurse-Midwifery, or Departments of Health	Boards of Midwifery, Boards of Medicine, Complementary Health Care Providers, or Department of Health	Boards of Midwifery, Boards of Medicine, Boards of Nursing, Complementary Health Care Providers, Departments of Health, or Departments of Professional Licensure

If viewing table on a mobile device, slide table for more content.

Highlights

1. The American Midwifery Certification Board is the gold standard in midwifery and nurse-midwifery certification. Other certifying bodies do not ensure the same level of experience and educational standards and requirements.

2. While state licensure provides the legal basis for practice, most states require AMCB certification for licensure, and many institutions require AMCB certification to grant practice privileges.

3. The titles CNM and CM are registered through the Federal Office of Patents and Trademarks and can only be used by midwives certified through the AMCB. Suspected misuse of trademark should be reported to cbright@amcbmidwife.org. For more information, please see the below document:

AMCB Trademark Use Policy

4. AMCB CNM certification is accepted in all 50 states in the U.S., in addition to the District of Columbia and Puerto Rico. AMCB CMs are licensed in Delaware, District of Columbia, Hawaii, Maine, Maryland, New Jersey, New York, Oklahoma, Rhode Island, and Virginia. Authorized by permit to practice in Delaware. Authorized to practice in Missouri.

5. Midwives practicing in unregulated states have no legal, regulatory protection unless certified by the AMCB.

6. The AMCB provides you with the tools you need to maintain your certification through its comprehensive Certificate Maintenance Program.

7. Your certification by the AMCB assures your patients that you have met accepted national standards in midwifery care, and that you are committed to ongoing learning in your field.

8. The AMCB provides you with other valuable opportunities to become involved in midwifery certification through voluntary participation in a variety of committees: Certificate Maintenance Program (CMP) Committee; Credentials, Administration & Reporting (CAR) Committee; Examination Committee; Finance Committee; and Research Committee. You may also apply to become a member of the Board of Directors and play a role in the future of midwifery certification.

9. The AMCB offers computer-based testing for the certification examination in collaboration with Applied Measurement Professionals, Inc. There are more than 120 testing sites nationally—at least one in each state plus Puerto Rico and the District of Columbia. In addition, you receive immediate, official results at the testing site.

Joint statement of recommendation for the use of tranexamic acid for the treatment of postpartum haemorrhage

June 2021

Postpartum haemorrhage (PPH) is a devastating but preventable condition that affects mothers and their children around the world. PPH occurs when a mother has serious bleeding after giving birth. When not treated quickly, it can be fatal. Most deaths from PPH could be avoided through active management of the third stage of labour, and prompt and effective application of the first response bundle (use of uterotonics, uterine massage, fluid replacement and tranexamic acid [TXA]).

Preventing and treating PPH

As leading organisations representing specialists in midwifery, obstetrics and gynaecology, the International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM) draw attention to a range of aspects of care that are essential to the prevention and treatment of PPH. These include:

- organisation of care
- pre-service and in-service training of care providers
- identification and treatment of anaemia in women of childbearing age
- increased availability of contraception and family planning
- improved referral pathways
- development of clinical protocols for prevention and treatment of PPH.[1]

FIGO and ICM recommendations

FIGO and ICM recommend the early use of TXA within three hours of birth, in addition to standard care for women with clinically diagnosed PPH following vaginal birth or caesarean section.

Standard care in the context of this recommendation covers routine care for PPH, including fluid replacement, administration of uterotonics, monitoring of vital signs, non-surgical (e.g. bimanual compression, intrauterine balloon tamponade, nonpneumatic antishock garment, aortic compression) and surgical interventions (e.g. brace sutures, arterial ligation, or hysterectomy) in accordance with WHO guidelines, FIGO recommendations or adapted local PPH treatment protocols.

TXA is a competitive inhibitor of plasminogen activation. It can reduce bleeding by inhibiting the enzymatic breakdown of fibrinogen and fibrin clots. TXA is in routine clinical use for reduction of blood loss in surgery and trauma and is listed on the WHO Essential Medicines List for management of postpartum haemorrhage.

Use of tranexamic acid for the treatment of PPH

FIGO and ICM strongly recommend the use of TXA for the treatment of PPH as a component of the first response bundle when the bleeding is thought to be due or partly due to trauma. Our recommendations (below) align with those made in the WHO 2017 recommendation on tranexamic acid for the treatment of postpartum haemorrhage, in response to moderate supporting evidence from the WOMAN Trial.[1,2,3]

- Initial dose of TXA should be administered within 3 hours of birth, at a fixed dose of 1g (100mg/ml), IV at 1ml per minute (i.e. administered over 10–20 minutes). Infusion rate of more than 1ml/minute can cause hypotension.
- Initial administration of TXA beyond 3 hours does not confer any clinical benefit.
- If needed after initial dose, a second dose of TXA of 1g (100mg/ml), IV at 1ml per minute should be administered if bleeding continues after 30 minutes, or if bleeding restarts within 24 hours of completing the first dose.
- TXA should be used in all cases of PPH regardless of whether the bleeding is due to genital tract trauma or other causes.
- Use of TXA should be avoided in women with a contraindication to antifibrinolytic therapy or thromboembolic disorder during pregnancy.
- Standard IV infusion equipment is required, as well as health care providers with sufficient training to safely administer IV bolus infusions.
- TXA should be recognised as a life-saving intervention and be made readily available for the management of PPH in settings where emergency obstetric care is provided.

Actions for midwives' associations and OBGYN societies

FIGO and ICM recommend that national professional midwives' associations and obstetrics and gynaecology societies have an important and collaborative role to play in:

- the dissemination and implementation of recommendations for the use of tranexamic acid for the treatment of PPH
- advocacy to increase women's access to quality maternal health care at all levels
- strengthening capacity at all levels of health care facilities to ensure the provision of high-quality services to all women giving birth
- translating recommendations into care packages and programmes at country and facility level, where appropriate to the context.

References

[1] World Health Organization. *WHO recommendation for the prevention and treatment of postpartum haemorrhage*. 2012. www.who.int/maternal_child_adolescent/documents/postpartum_haemorrge/en/
[2] WOMAN Trial Collaborators. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage: an international, randomised, double-blind, placebo-controlled trial. *The Lancet*. 389(10084):2105-2116. https://doi.org/10.1016/S0140-6736(17)30638-4
[3] World Health Organization. *WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage*. 2017. http://apps.who.int/iris/bitstream/handle/10665/259374/9789241550154-eng.pdf;jsessionid=6531461E34BFCD79B66F059354589757?sequence=1

About our organisations

ICM and FIGO work together and with their extensive and globally diverse network of professional members to support women to achieve the highest standards of health and wellbeing, to keep birth normal and to promote equity for all women's sexual, reproductive health and rights. ICM and FIGO promote the use of respectful, dignified and evidence-based care to reduce the global burden of maternal morbidity and mortality, of which the most significant contribution is postpartum haemorrhage (PPH), occurring during or within 24 hours of childbirth.

Quality care provided by midwives, obstetricians and gynaecologists contributes to the achievement of the Sustainable Development Goals (SDG) and the attainment of universal health coverage (UHC). FIGO and ICM develop standards and guidance for their respective professions that are aligned with World Health Organization (WHO) recommendations.

FIGO

FIGO is a professional organisation that brings together more than 130 obstetrical and gynaecological associations from all over the world. FIGO's vision is that women of the world achieve the highest possible standards of physical, mental, reproductive and sexual health and wellbeing throughout their lives. We lead on global programme activities, with a particular focus on sub-Saharan Africa and South East Asia.

FIGO advocates on a global stage, especially in relation to the Sustainable Development Goals (SDGs) pertaining to reproductive, maternal, newborn, child and adolescent health and non-communicable diseases (SDG3). We also work to raise the status of women and enable their active participation to achieve their reproductive and sexual rights, including addressing female-genital mutilation (FGM) and gender-based violence (SDG5).

communications@figo.org / +44 (0) 20 7928 1166

ICM

The International Confederation of Midwives (ICM) supports, represents and works to strengthen professional associations of midwives throughout the world. The ICM has 143 members associations, representing 124 countries across every continent. ICM envisions a world where every childbearing woman has access to a midwife's care for herself and her newborn. ICM's mission is to strengthen midwives' associations and advance the profession of midwifery.

ICM is an accredited non-governmental organisation representing midwives and midwifery to organisations worldwide to achieve common goals in the care of mothers and newborns. ICM works closely with the WHO, UNFPA and other UN Agencies; global professional health care organisations including FIGO, the International Pediatric Association (IPA), the International Council of Nurses (ICN), non-governmental organisations, and bilateral and civil society groups.

info@internationalmidwives.org / +31 (0) 70 306 0520

Referencing this statement

International Federation of Gynecology and Obstetrics, International Confederation of Midwives. *Joint statement of recommendation for the use of tranexamic acid for the treatment of postpartum haemorrhage*. 2021. Available from: www.figo.org/joint-statement-recommendation-tranexamic-acid-treatment-pph

WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage

World Health Organization

WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage

World Health Organization

WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage

ISBN 978-92-4-155015-4

Suggested citation. WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Printed in Switzerland

Contents

Acknowledgements

The Department of Reproductive Health and Research of the World Health Organization gratefully acknowledges the contributions of many individuals and organizations to the updating of this recommendation. Work on this update was coordinated by Olufemi Oladapo, Joshua Vogel and A. Metin Gülmezoglu of the WHO Department of Reproductive Health and Research.

WHO extends sincere thanks to Edgardo Abalos, Yap-Seng Chong, Catherine Deneux-Tharaux, Bukola Fawole, Justus Hofmeyr, Caroline Homer, Pisake Lumbiganon, Suellen Miller, Ashraf Nabhan, Hiromi Obara, Zahida Qureshi, Rahat Qureshi and Helen West who served as members of the Guideline Development Group (GDG), and to James Neilson for chairing the technical consultation. We also thank Richard Adanu, Fernando Althabe, Sue Fawcus, Jamilu Tukur and Dilys Walker who were members of the External Review Group. WHO also gratefully acknowledges the contribution of the members of the Executive Guideline Steering Group.

Therese Dowswell and Anna Cuthbert reviewed the scientific evidence, prepared the GRADE tables and drafted the narrative summary of evidence. Joshua Vogel and Olufemi Oladapo revised the narrative summaries and double-checked the corresponding GRADE tables. Joshua Vogel, Olufemi Oladapo, A. Metin Gülmezoglu and Mercedes Bonet commented on the draft document before it was reviewed by participants at the WHO technical consultation. The External Review Group peer-reviewed the final document.

We acknowledge the various organizations that were represented by observers at the final technical consultation, including Deborah Armbruster (United States Agency for International Development), Kusum Thapa (Maternal and Child Survival Program/Jhpiego), Janna Patterson (Bill & Melinda Gates Foundation), Sally Tracy (International Confederation of Midwives), Gerard Visser (International Federation of Gynecology and Obstetrics) and Beverly Winikoff (Gynuity Health Projects). Haleema Shakur-Still (London School of Hygiene and Tropical Medicine) provided an overview of the conduct and findings of the WOMAN trial but did not participate in the GDG deliberations. We appreciate the contributions of WHO Regional Office staff to this update – Mavjuda Babamuradova, Ramez Khairi Mahaini, Anoma Jayathilaka, Bremen De Mucio, Claudio Sosa, Mari Nagai and Léopold Ouedraogo.

The United States Agency for International Development and the Department of Reproductive Health and Research provided financial support for this work. The views of the funding body have not influenced the content of this recommendation.

Acronyms and abbreviations

CI	confidence interval
CRASH-2	Clinical Randomization of an Antifibrinolytic in Significant Haemorrhage trial
DOI	Declaration of Interest
FIGO	International Federation of Gynecology and Obstetrics
FWC	Family, Women's and Children's Health (a WHO cluster)
GDG	Guideline Development Group
GRC	Guideline Review Committee
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
GSG	Executive Guideline Steering Group
ICM	International Confederation of Midwives
IPD	individual participant data meta-analysis
LMIC	low- and middle-income country
LY	life-year
MCA	WHO Department of Maternal, Newborn, Child and Adolescent Health
MPA	Maternal and Perinatal Health & Preventing Unsafe Abortion (a team in WHO's Department of Reproductive Health and Research)
MPH	maternal and perinatal health
NNT	number needed to treat
PICO	population (P), intervention (I), comparison (C), outcome (O)
PPH	postpartum haemorrhage
RHR	[WHO Department of] Reproductive Health and Research
RR	relative risk
SDG	Sustainable Development Goals
TXA	tranexamic acid
UN	United Nations
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WOMAN	World Maternal Antifibrinolytics trial

Executive Summary

Introduction

Postpartum haemorrhage (PPH) is commonly defined as a blood loss of 500 ml or more within 24 hours after birth, and it affects about 5% of all women giving birth around the world. Globally, nearly one quarter of all maternal deaths are associated with PPH, and in most low-income countries it is the main cause of maternal mortality.

Improving care for women around the time of childbirth to prevent and treat PPH is a necessary step towards achievement of the health targets of the Sustainable Development Goals (SDGs). Efforts to prevent and reduce PPH-associated morbidity and mortality can reduce the profound inequities in maternal health globally. To achieve this, healthcare providers, health managers, policy makers and other stakeholders need up-to-date and evidence-based recommendations to inform clinical policies and practices.

In 2017, the Executive Guideline Steering Group (GSG) on WHO maternal and perinatal health recommendations prioritized the updating of the existing WHO recommendation on the use of tranexamic acid (TXA) for PPH treatment in response to important new evidence on this intervention. This updated recommendation thus supersedes the previous recommendation on TXA for PPH treatment, which was issued in the 2012 WHO recommendations on prevention and treatment of PPH.

Target audience

The primary audience includes health professionals who are responsible for developing national and local health protocols (particularly those related to PPH) and those directly providing care to pregnant women and their newborns, including midwives, nurses, general medical practitioners, obstetricians, managers of maternal and child health programmes, and relevant staff in ministries of health, in all settings.

Guideline development methods

The updating of this recommendation was guided by standardized operating procedures in accordance with the process described in the *WHO handbook for guideline development.* The recommendation was initially developed using this process, namely (i) identification of the priority question and critical outcomes, (ii) retrieval of the evidence, (iii) assessment and synthesis of evidence, (iv) formulation of the recommendation, and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendation.

The scientific evidence supporting the recommendation was synthesized using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach. The systematic review was used to prepare evidence profiles for the prioritized question. WHO convened an online technical consultation on 29 August 2017 where an international group of experts – the Guideline Development Group (GDG) – formulated and approved the recommendation.

Recommendation

The WHO technical consultation adopted one recommendation related to the use of TXA for the treatment of PPH. In formulating the recommendation, the GDG reviewed the balance between desirable and undesirable effects of TXA and overall quality of supporting evidence, values and preferences of stakeholders, resource requirements and cost-effectiveness, acceptability, feasibility and equity. To ensure that the recommendation is correctly understood and applied in practice, the contributing experts provided additional remarks. Guideline users should refer to these remarks, as well as to the evidence summary, if there is any doubt as to the basis for the recommendation and how best to implement it. The WHO recommendation on TXA for treatment of PPH is summarized in Table 1 below.

Table 1: Updated WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage

Early use of intravenous tranexamic acid (within 3 hours of birth) in addition to standard care is recommended for women with clinically diagnosed postpartum haemorrhage following vaginal birth or caesarean section. *(Strong recommendation, moderate quality of evidence)*
Remarks
• Based on the dosing regimen used in the WOMAN trial, the GDG supports the administration of tranexamic acid (TXA) at a fixed dose of 1 g (100 mg/ml) intravenously (IV) at 1 ml per minute (i.e. administered over 10 minutes), with a second dose of 1 g IV if bleeding continues after 30 minutes, or if bleeding restarts within 24 hours of completing the first dose.
• The WOMAN trial defined "clinically diagnosed postpartum haemorrhage" as clinically estimated blood loss of more than 500 ml after a vaginal birth or 1000 ml after caesarean section, or any blood loss sufficient to compromise haemodynamic stability.
• Based on evidence from the WOMAN trial, the reference point for the start of the 3-hour window for starting TXA administration is time of birth. If time of birth is unknown, the best estimate of time of birth should be used as the reference point. As most deaths due to postpartum haemorrhage (PPH) occur within the first 2 to 3 hours after birth, it is critical that TXA is given as soon as possible to achieve clinical benefits.
• Analysis of the effects of timing of administration in the WOMAN trial, as well as an individual participant data (IPD) meta-analysis of 40 138 bleeding patients (including WOMAN trial participants), indicates that TXA administration beyond 3 hours does not confer any clinical benefit. Furthermore, the point estimates of effect of TXA use beyond 3 hours on death for trauma or after PPH were both in the direction of harm, albeit not statistically significant for women with PPH. In view of this evidence, the GDG does not support the use of TXA more than 3 hours after birth.
• Administration of TXA should be considered as part of the standard PPH treatment package. Standard care in the context of this recommendation includes routine care for PPH treatment, including fluid replacement, medical (uterotonics), monitoring of vital signs, nonsurgical (e.g. bimanual compression, intrauterine balloon tamponade, nonpneumatic antishock garment, aortic compression) and surgical interventions (e.g. brace sutures, arterial ligation, or hysterectomy) in accordance with WHO guidelines or adapted local PPH treatment protocols.
• TXA should be used in all cases of PPH, regardless of whether the bleeding is due to genital tract trauma or other causes.
• The use of TXA should be avoided in women with a clear contraindication to antifibrinolytic therapy (including TXA) (e.g. a known thromboembolic event during pregnancy).
• This recommendation applies only to IV use. The evaluation of benefits and potential harms of other routes of TXA administration is a research priority.
• Regardless of the level of health system resources, TXA should be recognized as a life-saving intervention and be made readily available for the management of PPH in settings where emergency obstetric care is provided.

1. Background

PPH is commonly defined as a blood loss of 500 ml or more within 24 hours after birth, and affects about 5% of all women giving birth around the world.[1,2] Globally, nearly one quarter of all maternal deaths are associated with PPH, and in most low-income countries it is the main cause of maternal mortality.[3]

Severe PPH is generally defined as a blood loss of 1000 ml or more after birth. Severe maternal health conditions, such as organ dysfunction or death, generally occur following substantial blood loss that compromises maternal haemodynamic stability. Uterine atony is the most common cause of PPH and a leading cause of maternal mortality worldwide.[3] Genital tract trauma (that is, vaginal or cervical lacerations), uterine rupture, retained placental tissue, or maternal bleeding disorders are frequently associated with PPH. Although the majority of women presenting with PPH have no identifiable risk factor, grandmultiparity, prolonged labour and multiple gestation are obstetric conditions that are associated with an increased risk of bleeding after birth.[4] In addition, anaemia is a common aggravating factor.

The majority of PPH-associated deaths could be avoided by the use of prophylactic uterotonics during the third stage of labour and appropriate treatment. Thus, improving health care for women during childbirth to prevent and treat PPH is a necessary step towards achievement of the health targets of the Sustainable Development Goals (SDGs). Furthermore, 99% of all maternal deaths occur in low- and middle-income countries (LMICs). Efforts to prevent and reduce PPH-associated morbidity and mortality can thus reduce the profound inequities in maternal health globally. In support of this, health workers at all levels of care (particularly in LMICs) need to have access to appropriate medications and training in relevant procedures. Healthcare providers, health managers, policy-makers and other stakeholders also need up-to-date, evidence-based recommendations to inform clinical policies and practices, in order to enable improved healthcare outcomes.

In 2012, WHO published 32 recommendations for the prevention and treatment of PPH, including a recommendation on the use of TXA for treatment of PPH.[5] These recommendations were developed according to WHO guideline development standards, including synthesis of available research evidence, use of the GRADE methodology, and formulation of recommendations by a guideline panel of international experts.

In 2017, the Executive GSG on WHO maternal and perinatal health recommendations prioritized the updating of the existing WHO recommendation on the use of TXA for PPH treatment in response to important new evidence on this question. This updated recommendation thus supersedes the previous recommendation on TXA for PPH treatment, issued in the 2012 WHO recommendations on prevention and treatment of PPH.

Rationale and objectives

TXA is a competitive inhibitor of plasminogen activation, and it can reduce bleeding by inhibiting the enzymatic breakdown of fibrinogen and fibrin clots.[6] It is in routine clinical use for reduction of blood loss in surgery and trauma, and it is listed on the WHO Essential Medicines List for management of anticoagulation.[7] At the time of

the GDG meeting on prevention and treatment of PPH in March 2012, there was no direct evidence on the effectiveness and safety of TXA when used for treatment of PPH. The GDG conditionally recommended the use of TXA for the treatment of PPH only when uterotonics fail to control the bleeding or when the bleeding is thought to be partly due to trauma. The GDG noted that a large, randomized controlled trial – the World Maternal Antifibrinolytic (WOMAN) trial examining the effect of early administration of TXA on mortality, hysterectomy, and other morbidities in women with clinically diagnosed PPH – was ongoing.[8] The WOMAN trial has now concluded, and the primary findings were published in April 2017.[9] In light of this new evidence, the Executive GSG prioritized the updating of the recommendation on TXA use for PPH treatment.

As part of WHO's normative work on supporting evidence-informed policies and practices, the Department of Reproductive Health and Research (RHR) has now updated the recommendation on the use of TXA for treatment of PPH. This recommendation provides a foundation for the sustainable implementation of the intervention globally.

Target audience

The primary audience includes health professionals who are responsible for developing national and local health guidelines and protocols (particularly those related to PPH) and those directly providing care to women during labour and childbirth, including midwives, nurses, general medical practitioners, obstetricians, managers of maternal and child health programmes and relevant staff in ministries of health, in all settings.

This recommendation will also be of interest to professional societies involved in the care of pregnant women, nongovernmental organizations concerned with promotion of people-centred maternal care, and implementers of maternal and child health programmes.

Scope of the recommendation

The question for this recommendation was: in women with PPH (P), does administration of TXA for PPH treatment (I) compared to placebo, no treatment or other treatments (C), improve outcomes (O)? If so, what is the most appropriate period to administer TXA to improve outcomes? The population affected by this recommendation includes women who experience PPH in low-, middle- or high-income settings.

2. Methods

This recommendation is an update of the existing recommendation relating to TXA use for PPH treatment, published in the *WHO recommendations for prevention and treatment of postpartum haemorrhage* (2012).[5]

The recommendation was first developed using standardized operating procedures in accordance with the process described in the *WHO handbook for guideline development*.[10] In summary, the process included: (i) identification of the priority question and critical outcomes, (ii) retrieval of the evidence, (iii) assessment and

synthesis of evidence, (iv) formulation of the recommendation, and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendation. The WHO recommendation on TXA use for treatment of PPH was identified by the Executive GSG as a high priority for updating in response to new, important evidence on this question.

The updating of this recommendation involved five main groups to guide the process, with their specific roles as described in the following sections.

Contributors to the guideline

Executive Guideline Steering Group (Executive GSG)

The Executive GSG is an independent panel of external experts and relevant stakeholders from the six WHO regions. This group advises WHO on the prioritization of new and existing questions in maternal and perinatal health for recommendation development or updating.

WHO Steering Group

The WHO Steering Group, comprising WHO staff members from the Departments of Reproductive Health and Research (RHR) and Maternal, Newborn, Child and Adolescent Health (MCA), managed the updating process. The Group drafted the key recommendation question in PICO format, identified the systematic review team and guideline methodologist, as well as the guideline development and external review groups. In addition, the WHO Steering Group supervised the retrieval and syntheses of evidence, organized the Guideline Development Group meeting, drafted and finalized the guideline document, and managed the guideline dissemination, implementation and impact assessment. The members of the Steering Group are presented in Annex 1.

Guideline Development Group

The WHO Steering Group identified a pool of approximately 50 experts and relevant stakeholders from the six WHO regions to constitute the WHO Maternal and Perinatal Health Guideline Development Group (MPH-GDG). This is a diverse group of experts who are skilled in critical appraisal of research evidence; implementation of evidence-based recommendations; guideline development methods; and clinical practice, policy and programmes relating to maternal and perinatal health. Members of the MPH-GDG are identified in a way that ensures geographic representation and gender balance, and there were no significant conflicts of interest. Members' expertise cuts across thematic areas within maternal and perinatal health.

From the MPH-GDG pool, 14 external experts and relevant stakeholders were invited to constitute the Guideline Development Group (GDG) for updating this recommendation. This wasis a diverse group of individuals with expertise in PPH research, guideline development methods, and clinical policy and programmes relating to PPH prevention and treatment.

The GDG members convened for this recommendation were selected in a way that ensured geographic representation and gender balance, and there were no important conflicts of interest. The Group appraised the evidence that was used to inform the recommendation, advised on the interpretation of this evidence,

formulated the final recommendation based on the draft prepared by the Steering Group, and reviewed and approved the final document. The members of this Group are presented in Annex 1.

External Review Group

This Group included five technical experts with sufficient interest in the provision of evidence-based obstetric care. None of its members declared a conflict of interest. The Group reviewed the final document to identify any errors of fact and commented on clarity of the language, contextual issues and implications for implementation. The Group ensured that the decision-making processes have considered and incorporated contextual values and preferences of potential users of the recommendations, healthcare professionals and policy makers. They did not change the recommendation that was formulated by the GDG. The members of the External Review Group are presented in Annex 1.

Systematic review team and guideline methodologists

A Cochrane systematic review on this question was initiated, supported by the Cochrane Pregnancy and Childbirth Group. The WHO Steering Group reviewed and provided input into the protocol, and it worked closely with the Cochrane Pregnancy and Childbirth Group to appraise the evidence using the GRADE methodology. A representative of the Cochrane Pregnancy and Childbirth Group attended the GDG meeting to provide an overview of the available evidence and GRADE tables and to respond to technical queries from the GDG.

External partners and observers

Representatives of the United States Agency for International Development (USAID), the Maternal and Child Survival Programme (MCSP)/Jhpiego, the Bill & Melinda Gates Foundation (BMGF), the International Confederation of Midwives (ICM), the International Federation of Gynecology and Obstetrics (FIGO) and Gynuity Health Projects participated in the GDG meeting as observers. These organizations, with a long history of collaboration with the RHR Department in guideline dissemination and implementation, are implementers of the updated recommendation. In addition, one of the WOMAN trial co-ordinators from the London School of Hygiene and Tropical Medicine (LSHTM) provided an overview of the conduct and findings of the WOMAN trial and responded to questions from the GDG, but did not participate in GDG deliberations nor revision of the recommendation. The list of observers who participated in the final technical consultation is presented in Annex 1.

Identification of critical outcomes

The critical and important outcomes were aligned with the prioritized outcomes from the WHO recommendations on prevention and treatment of PPH (2012).[5] These outcomes were initially identified through a search of key sources of relevant, published, systematic reviews and a prioritization of outcomes by the 2012 GDG panel. During the updating of this recommendation, a further two outcomes were identified by the WHO Steering Group and the GDG as critical outcomes for this question: namely, maternal death (all causes) and maternal death due to bleeding. Thus, a total of 13 outcomes were rated as 'critical' and nine outcomes were rated as 'important' for this question. All outcomes were included in the scope of

this document for evidence searching, retrieval, grading and formulation of the recommendation. The list of critical and important outcomes is provided in Annex 2.

Evidence identification and retrieval

A Cochrane systematic review on the efficacy of TXA for PPH treatment was initiated by the Cochrane Pregnancy and Childbirth Group, as an offshoot of the existing Cochrane review of treatment for PPH.[11] This systematic review[12] was the primary source of evidence for this recommendation.

Randomized, controlled trials relevant to the key question were screened by the review authors, and data on relevant outcomes and comparisons were extracted into Review Manager (RevMan) software. The RevMan file was retrieved from the Cochrane Pregnancy and Childbirth Group and customized to reflect the key comparisons and outcomes (those that were not relevant to the recommendation were excluded). Then the RevMan file was exported to GRADE profiler software (GRADEpro) and GRADE criteria were used to critically appraise the retrieved scientific evidence. Finally, evidence profiles (in the form of GRADE tables) were prepared for comparisons of interest, including the assessment and judgements for each outcome, and the estimated risks.

Quality assessment and grading of the evidence

The quality assessment of the body of evidence for each outcome was performed using the GRADE approach.[13] Using this approach, the quality of evidence for each outcome was rated as 'high', 'moderate', 'low' or 'very low' based on a set of established criteria. The final rating of quality of evidence was dependent on the factors briefly described below.

Study design limitations The risk of bias was first examined at the level of individual study and then across studies contributing to the outcome. For randomized trials, quality was first rated as 'high' and then downgraded by one ('moderate') or two ('low') levels, depending on the minimum quality criteria met by the majority of the studies contributing to the outcome.

Inconsistency of the results The similarity in the results for a given outcome was assessed by exploring the magnitude of differences in the direction and size of effects observed from different studies. The quality of evidence was not downgraded when the directions of the findings were similar and confidence limits overlapped, whereas quality was downgraded when the results were in different directions, and confidence limits showed minimal or no overlap.

Indirectness The quality of evidence was downgraded when there were serious or very serious concerns regarding the directness of the evidence, that is, whether there were important differences between the research reported and the context for which the recommendation was being prepared. Such differences were related, for instance, to populations, interventions, comparisons or outcomes of interest.

Imprecision This assessed the degree of uncertainty around the estimate of effect. As this is often a function of sample size and number of events, studies with relatively few participants or events, and thus wide confidence intervals around effect estimates, were downgraded for imprecision.

Publication bias Quality rating could also be affected by perceived or statistical evidence of bias to underestimate or overestimate the effect of an intervention as a result of selective publication based on study results. We considered downgrading evidence by one level for strong suspicion of publication bias.

Formulation of recommendations

The WHO Steering Group used the evidence profiles to summarise evidence on effects of TXA on the prespecified outcomes. The evidence summary and corresponding GRADE tables, other related documents for assessment of values and preferences, resource requirements and cost-effectiveness, acceptability, feasibility and equity were provided in advance to members of the GDG. The GDG members and other participants were then invited to attend an online technical consultation (see Annex 1 for the list of participants) organized by the Steering Group in Geneva, Switzerland, on 29 August 2017. During the technical consultation, the GDG members reviewed and discussed the balance between desirable and undesirable effects of TXA and the overall quality of supporting evidence, values and preferences of stakeholders, resource requirements and cost-effectiveness, acceptability, feasibility and equity, before finalizing the recommendation and remarks.

Declaration of interests by external contributors

According to WHO regulations, all experts must declare their relevant interests prior to participation in WHO guideline development processes and meetings. All GDG members were therefore required to complete a standard WHO Declaration of Interest (DOI) form before engaging in the guideline development process and before participating in the guideline-related meeting. The WHO Steering Group reviewed all declarations before finalizing the experts' invitations to participate. Where any conflict of interest was declared, the Steering Group determined whether such conflicts were serious enough to affect objective judgement of the expert on the guideline development process and recommendation. To ensure consistency, the Steering Group applied the criteria for assessing the severity of conflict of interests in the *WHO Handbook for Guideline Development* for all experts. All findings from the received DOI statements were managed in accordance with the WHO DOI guidelines on a case-by-case basis and communicated to the experts. Where a conflict of interest was not considered significant enough to pose any risk to the guideline development process or reduce its credibility, the experts were only required to openly declare such conflict at the beginning of the GDG meeting, and no further actions were taken.

Annex 3 shows a summary of the DOI statements, and how declared conflicts of interest were managed by the Steering Group.

Decision-making during the technical consultation

During the technical consultation, the GDG reviewed and discussed the evidence summary and sought clarifications. In addition to evaluating the balance between desirable and undesirable effects of TXA and the overall quality of the evidence, the GDG applied additional criteria based on the GRADE evidence-to-decision framework to determine the direction and strength of the recommendation. These criteria

included values of stakeholders, resource implications, acceptability, feasibility and equity. Considerations were based on the experience and opinions of members of the GDG and supported by evidence from a literature search where available. However, specific systematic reviews of evidence (for example, qualitative evidence synthesis or detailed economic evaluation) were not performed to inform discussions on these criteria. Evidence-to-decision tables were used to describe and synthesize these considerations.

The decision was based on consensus defined as the agreement by three quarters or more of the participants. None of the GDG members expressed opposition to the recommendation.

Document preparation

Prior to the online technical consultation, the WHO Steering Group prepared a draft version of the GRADE evidence profiles, evidence summary and other documents relevant to the deliberation of the GDG. The draft documents were made available to the participants of the technical consultation two weeks before the meeting for their comments. During the meeting, these documents were modified in line with the participants' deliberations and remarks. Following the meeting, members of the WHO Steering Group drafted a full guideline document to accurately reflect the deliberations and decisions of the participants. The draft document was sent electronically to GDG members and the External Review Group for final review and approval.

Peer review

The final document was sent to five external independent experts who were not involved in the guideline panel for peer review. The WHO Steering Group evaluated the inputs of the peer reviewers for inclusion in this document. After the technical consultation and peer review, the modifications made by the WHO Steering Group to the document were limited to correction of factual errors and improvement in language to address any lack of clarity.

3. Evidence and recommendation

The following section outlines the recommendation and the corresponding narrative summary of evidence for the prioritized question. The GRADE table is presented in Annex 5. The evidence-to-decision table, summarizing the balance between desirable and undesirable effects and the overall quality of the supporting evidence, values and preferences of stakeholders, resource requirements, cost-effectiveness, acceptability, feasibility and equity that were considered in determining the strength and direction of the recommendation, is presented in Annex 4.

The following recommendation was adopted by the GDG. Evidence on the effectiveness of the intervention was derived from one systematic review and was summarized in GRADE tables (Annex 5). The quality of the supporting evidence was rated as 'moderate' for most critical outcomes. To ensure that the recommendation is correctly understood and appropriately implemented in practice, additional 'remarks' reflecting the summary of the discussion by GDG are included under the recommendation.

Early use of intravenous tranexamic acid (within 3 hours of birth) in addition to standard care is recommended for women with clinically diagnosed postpartum haemorrhage following vaginal birth or caesarean section. *(Strong recommendation, moderate quality of evidence)*

Remarks

- Based on the dosing regimen used in the WOMAN trial, the GDG supports the administration of tranexamic acid (TXA) at a fixed dose of 1 g (100 mg/ml) intravenously (IV) at 1 ml per minute (i.e. administered over 10 minutes), with a second dose of 1 g IV if bleeding continues after 30 minutes, or if bleeding restarts within 24 hours of completing the first dose.
- The WOMAN Trial defined "clinically diagnosed postpartum haemorrhage" as clinically estimated blood loss of more than 500 ml after a vaginal birth or 1000 ml after caesarean section, or any blood loss sufficient to compromise haemodynamic stability.
- Based on evidence from the WOMAN trial, the reference point for the start of the 3-hour window for starting TXA administration is time of birth. If time of birth is unknown, the best estimate of time of birth should be used as the reference point. As most deaths due to postpartum haemorrhage occur within the first 2 to 3 hours after birth, it is critical that TXA is given as soon as possible to achieve clinical benefits.
- Analysis of the effects of timing of administration in the WOMAN trial, as well as an individual participant data (IPD) meta-analysis of 40 138 bleeding patients (including WOMAN trial participants), indicates that TXA administration beyond 3 hours does not confer any clinical benefit. Furthermore, the point estimates of effect of TXA use beyond 3 hours on death for trauma or after PPH were both in the direction of harm, albeit not statistically significant for women with PPH. In view of this evidence, the GDG does not support the use of TXA more than 3 hours after birth.
- Administration of TXA should be considered as part of the standard postpartum haemorrhage treatment package. Standard care in the context of this recommendation includes routine care for PPH treatment, including fluid replacement, medical (uterotonics), monitoring of vital signs, nonsurgical (e.g. bimanual compression, intrauterine balloon tamponade, nonpneumatic antishock garment, aortic compression) and surgical interventions (e.g. brace sutures, arterial ligation or hysterectomy) in accordance with WHO guidelines or adapted local PPH treatment protocols.
- TXA should be used in all cases of PPH regardless of whether the bleeding is due to genital tract trauma or other causes.
- The use of TXA should be avoided in women with a clear contraindication to antifibrinolytic therapy (including TXA) (e.g. a known thromboembolic event during pregnancy).
- This recommendation applies only to IV use. The evaluation of benefits and potential harms of other routes of TXA administration is a research priority.
- Regardless of the level of health system resources, TXA should be recognized as a life-saving intervention and be made readily available for the management of postpartum haemorrhage in settings where emergency obstetric care is provided.

A. Review Question

- For women with postpartum haemorrhage (P), does administration of tranexamic acid in addition to standard care (I) compared to standard care alone (C), improve outcomes (O)?
  - If so, when is the most appropriate period to administer tranexamic acid to improve outcomes?

B. Assessment

Effects of the intervention

What are the anticipated effects of administration of TXA in addition to standard care for PPH treatment?

Research evidence

Evidence on the use of TXA for treatment of PPH was extracted from a forthcoming Cochrane systematic review of two trials (20 212 women).[12] This review included trials that compared the use of any fibrinolytic drug with no treatment in women with PPH. However, no evidence was identified for interventions other than TXA.

One multicentre trial was conducted in eight obstetric units in France with recruitment between 2005 and 2008.[14] This trial randomized 152 women with PPH > 800 ml after a vaginal birth. The intervention group received a loading dose of 4 g TXA mixed with 50 ml saline, administered IV over 1 hour, followed by a maintenance dose of 1 g/hour for 6 hours. Women in the control group were given standard care only, as per the routine practice in participating facilities. The primary outcome was blood loss between randomization and 6 hours.

The second (WOMAN trial) was a multicountry, multicentre, placebo-controlled randomised trial of 20 060 women in 193 hospitals, across 21 high-, middle- and low-income countries conducted between March 2010 and April 2016.[9] The trial randomized women with clinically diagnosed PPH, defined as clinically estimated blood loss after a vaginal birth of > 500 ml, or > 1000 ml following a caesarean section, or any blood loss sufficient to compromise haemodynamic stability and where the clinician responsible for care was uncertain as to whether or not to use TXA. In addition to usual care, women in the experimental group were initially given 1 g TXA IV in a 10 ml solution, at an approximate rate of 1 ml/minute, as soon as possible after randomization. A second dose was used if bleeding continued after 30 minutes or if it stopped and restarted within 24 hours after the first dose. The control arm received placebo (normal saline) using the same regimen. When the trial protocol was registered, the primary outcome was a composite of death from all causes or hysterectomy within 42 days. During the course of the study (but before results were available or any unblinding), the primary outcome was revised to maternal death due to bleeding, and the sample size increased.

Evidence regarding this intervention is almost entirely derived from the WOMAN trial.

Comparison: TXA (in addition to standard care) versus standard care alone

The effects of TXA on critical outcomes for all women with PPH, regardless of how PPH was defined, the mode of birth or timing of PPH administration, are described below.

- **Maternal mortality (all causes):** Moderate certainty evidence suggests slightly fewer deaths in the group receiving TXA although this difference was not statistically significant (two studies, 20 172 women; 227/10 113 (2.2%) vs 256/10 059 (2.5%); RR 0.88, 95% CI 0.74 to 1.05).

- **Maternal mortality due to PPH:** In both trials, clinicians were asked to record the primary cause of death. Moderate certainty evidence suggests that deaths that were considered to be due to bleeding were probably reduced in the TXA group (two studies, 20 172 women, 155/10 113 (1.5%) vs 191/10 059 (1.9%), RR 0.81, 95% CI 0.65 to 1.00). The number needed to treat (NNT) to prevent one maternal death due to bleeding is 258 (95% CI 133.2 to 4051.8).
- **Severe maternal morbidity:** The French trial reported multiple organ failure; there were no events in either arm and very few admissions to intensive care (one study, 152 women, 3/77 (3.9%) vs 5/74 (6.8%), RR 0.58 (95% CI 0.14 to 2.33). The number of women suffering any severe morbidity was not reported in the WOMAN trial report, but specific morbidities were reported. Moderate certainty evidence suggested little or no difference between groups for any of morbidity outcomes reported (respiratory failure: RR 0.87, 95% CI 0.67 to 1.12; seizure: two studies; RR 0.76, 95% CI 0.49 to 1.20; hepatic failure RR 0.96, 95% CI 0.58 to 1.60; cardiac failure: RR 0.95, 95% CI 0.73 to 1.23; renal failure: two studies; RR 1.09, 95% CI 0.85 to 1.39).
- **Blood products transfusion (all):** Moderate certainty evidence suggests there is very little or no difference between groups for transfusion of blood products, with more than half of the women in both arms of the WOMAN trial receiving a transfusion (two studies; RR 1.00, 95% CI 0.97 to 1.03).
- **Additional blood loss:** The French trial reported additional blood loss > 500 ml or > 1000 ml. Low-quality evidence suggests TXA probably reduces blood loss > 500 ml (RR 0.50, 95% CI 0.27 to 0.93, 151 women). Although the direction of effect was the same for loss > 1000 ml, the study had insufficient power to demonstrate a difference between groups (4/77 women versus 8/74).
- **Additional uterotonics:** The vast majority of women in the WOMAN trial received uterotonics (99.3% vs 99.1%, two studies; RR 1.00, 95% CI 1.0 to 1.0).
- **Surgical interventions:** High or moderate certainty evidence suggests there is probably little difference between groups for most surgical interventions to control bleeding (hysterectomy (all): two studies; RR 1.01, 95% CI 0.88 to 1.17; ligature: RR 0.88, 95% CI 0.74 to 1.05; embolization: RR 0.82, 95% CI 0.42 to 1.62). High certainty evidence suggests laparotomy to control bleeding is reduced for women in the TXA group (0.8% vs 1.3%) (RR 0.64, 95% CI 0.49 to 0.85) while brace sutures are increased (RR 1.19, 95% CI 1.01 to 1.41).
- **Invasive nonsurgical interventions:** High certainty evidence suggests there is probably little or no difference in intrauterine tamponade (one study; RR 0.96, 95% CI 0.87 to 1.06) or manual removal of placenta: (one study; RR 0.95, 95% CI 0.87 to 1.04).
- **Procedure-related complications:** Moderate certainty evidence suggests there is probably little or no difference between groups for thromboembolic events (any maternal thromboembolic event: RR 0.88, 95% CI 0.54 to 1.43; deep venous thrombosis: two studies; RR 0.62 95% CI 0.20 to 1.88; pulmonary embolism RR 0.85, 95% CI 0.44 to 1.61; myocardial infarction: RR 0.66, 95% CI 0.11 to 3.97; stroke: RR 1.33, 95% CI 0.46 to 3.82).
- **Neonatal adverse effects**: Available neonatal outcome data were limited (data from WOMAN trial only). There were no neonatal thromboembolic events and no clear differences in deaths in breastfed neonates (eight deaths with TXA vs seven deaths with placebo) in the WOMAN trial.
- **Longer-term outcomes:** Available data on longer-term outcomes was limited (data from the WOMAN trial only). Outcomes in the WOMAN trial were measured up to hospital discharge or 42 days if still in hospital. There was no information on longer-term outcomes in women or babies.
- Subgroup analysis examining treatment effect by mode of birth (vaginal or caesarean) suggests no clear difference in effect on maternal death (all causes) and maternal death due to PPH for type of birth (moderate certainty of evidence).

Comparison: TXA (in addition to standard care) versus standard care alone, by timing of TXA administration

Evidence for this subgroup comparison was derived from a pre-planned subgroup analysis of the WOMAN trial.

- **Maternal mortality due to PPH:** There are subgroup differences for the timing of drug administration. Women receiving TXA less than 1 hour after birth had reduced risk of death from bleeding, but the confidence interval crossed the line of no effect (less than 1 hour: RR 0.80, 95% CI 0.55 to 1.16). Women receiving TXA 1 to 3 hours after birth were at reduced risk of death from bleeding (1 to 3 hours: RR 0.60, 95% CI 0.41 to 0.88) compared with women where more than 3 hours had elapsed before TXA was administered (more than 3 hours: RR 1.07, 95% CI 0.76 to 1.51).
- **Maternal mortality (all cause):** Compared to the control group, women receiving TXA less than 1 hour after birth had similar risks of death (any cause) (less than 1 hour: RR 0.98, 95% CI 0.72 to 1.33), as did women receiving TXA more than 3 hours after birth (more than 3 hours: RR 1.00, 95% CI 0.75 to 1.33). However, women receiving TXA 1 to 3 hours after birth were at reduced risk of death from all causes (1 to 3 hours: RR 0.69, 95% CI 0.49 to 0.96).
- **Death or hysterectomy:** Compared to the control group, women receiving TXA less than 1 hour after birth had similar risks of death or hysterectomy (less than 1 hour: RR 1.08, 95% CI 0.91 to 1.28), as did women receiving TXA more than 3 hours after birth (more than 3 hours: RR 1.01, 95% CI 0.82 to 1.25). However, women receiving TXA 1 to 3 hours after birth were at reduced risk of death or hysterectomy (1 to 3 hours: RR 0.80, 95% CI 0.63 to 1.00).
- **Laparotomy for bleeding:** Compared to the control group, women receiving TXA less than 1 hour after birth had reduced risk of laparotomy for bleeding (less than 1 hour: RR 0.48, 95% CI 0.29 to 0.79), as did women receiving TXA at 1 to 3 hours after birth (1 to 3 hours: RR 0.54, 95% CI 0.31 to 0.95). Women receiving TXA more than 3 hours after birth were not at reduced risk of laparotomy for bleeding (more than 3 hours: RR 0.89, 95% CI 0.59 to 1.35).

Desirable effects

How substantial are the desirable anticipated effects of TXA + standard care vs standard care alone?

Judgement					
☐ Don't know	☐ Varies	☐ Trivial	☐ Small	☐ Moderate	☒ Large

Undesirable effects

How substantial are the undesirable anticipated effects TXA + standard care vs standard care alone?

Judgement					
☐ Don't know	☐ Varies	☐ Large	☐ Moderate	☐ Small	☒ Trivial

Certainty of the evidence

What is the overall certainty of the evidence of effects?

Judgement				
☐ No included studies	☐ Very low	☐ Low	☒ Moderate	☐ High

Additional considerations
Additional evidence was obtained from a forthcoming individual patient data (IPD) on the impact of treatment delay on the effectiveness and safety of antifibrinolytics in acute, severe haemorrhage.[15] The IPD meta-analysed 40 138 bleeding patients (with 3 558 deaths recorded) who received TXA or placebo from WOMAN and CRASH-2 trials combined. The authors reported that deaths from PPH peaked at 2 to 3 hours after childbirth, and immediate treatment improved bleeding survival. Treatment delay appears to reduce benefit – the benefit appears to decrease by 10% for every 15 minutes' delay, with no benefit seen after 3 hours. The point estimates of effect of TXA use beyond 3 hours on death for trauma or after PPH were both in the direction of harm, albeit not statistically significant for women with PPH.

Values and preferences

Is there important uncertainty about, or variability in, how much women value the main outcomes?

Typically, women, healthcare providers and policy-makers place a higher value on avoiding a maternal death, even when potentially associated with an increase in invasive surgical interventions, such as brace sutures. Therefore, women, healthcare providers and policy-makers in all settings are likely to place a high value on the reduction in the risk of maternal death due to bleeding. The GDG is confident that women, healthcare providers and policy-makers in any setting will invariably place a higher value on this benefit, compared to any inconvenience (or drawbacks) that TXA use might cause to the woman, her baby or the health system. Stakeholders with different values in different contexts are unlikely to make different decisions when presented with these choices.

Judgement			
☐ Important uncertainty or variability	☐ Possibly important uncertainty or variability	☐ Probably no important uncertainty or variability	☒ No important uncertainty or variability

Balance of effects

Does the balance between desirable and undesirable effects favour use of TXA in addition to standard care (intervention) or standard care alone (comparison)?

There is evidence that TXA is probably beneficial in reducing maternal deaths due to bleeding and reducing the need for laparotomy to stop bleeding. Early treatment appears to optimize benefit. There does not appear to be evidence of maternal or newborn harms, or significant side-effects. While no difference in newborn thromboembolic events were seen, in the WOMAN trial most women and babies were followed until discharge from the health facility, thus this evidence is more likely representative of the first few days after birth.

Judgement						
☐ Don't know	☐ Varies	☐ Favours the standard care alone	☐ Probably favours the standard care alone	☐ Does not favour TXA + standard care or standard care alone	☐ Probably favours TXA + standard care	☒ Favours TXA + standard care

Resources required

What are the resource requirements for administering TXA in addition to standard care for PPH treatment?

Research evidence

None of the studies included in the Cochrane systematic review conducted a formal cost-effectiveness analysis.

Main resource requirements

The use of TXA in addition to standard PPH treatment requires the existence of healthcare providers who have been trained in how to administer intravenous drugs.

Resource	Description
Training	2 to 3 day practice-based training/practice drills for PPH management
Supplies	1 to 2 g of TXA (varies between settings, with an approximate range of $1.00 to $5.70 per g) [16] IV infusion set Syringe/needle/swabs = approximately US$0.08 to $0.10
Equipment	None required.
Time	Average time needed is 10 to 15 minutes for gaining IV access and administration of the drug (depending on other factors such as provider skills). However, sufficient time is needed for monitoring the response of the woman to treatment as required for all cases of PPH.
Supervision and monitoring	Regular supervision and review by labour ward lead, especially when first introduced.

Additional considerations
• TXA is relatively cheap in most contexts, easy to administer, and it is often available in healthcare settings due to its use in trauma and surgery. Research evidence on cost-effectiveness can be extrapolated from cost-effectiveness analysis of TXA for bleeding trauma patients.16 The study found that administering TXA to bleeding trauma patients within 3 hours of injury saved an estimated 372, 315 and 755 life-years (LYs) per 1 000 trauma patients in Tanzania, India and the UK respectively. The cost of giving TXA to 1 000 patients was $17 483 in Tanzania, $19 550 in India and $30 830 in the UK. The incremental cost of giving TXA versus not giving TXA was $18 025 in Tanzania, $20 670 in India and $48 002 in the UK. The estimated incremental cost per LY gained of administering TXA is $48, $66 and $64 in Tanzania, India and the UK respectively. Early administration of TXA to bleeding trauma patients is likely to be highly cost-effective in low-, middle- and high-income settings.
• The use of TXA may also reduce subsequent costs related to surgical procedures for PPH treatment (such as laparotomy) as well as any complications associated with surgery.
• Out-of-pocket costs to individual women might be higher when TXA is added to standard care for PPH in settings where women incur financial costs for births.

Resource requirements

How large are the resource requirements for administering TXA in addition to standard care for PPH treatment compared to standard care alone?

Judgement						
☐ Don't know	☐ Varies	☐ Large costs	☐ Moderate costs	☒ Negligible costs or savings	☐ Moderate savings	☐ Large savings

Certainty of evidence on required resources

What is the certainty of the evidence on costs?

Judgement				
☒ No included studies	☐ Very low	☐ Low	☐ Moderate	☐ High

Cost-effectiveness

Does cost-effectiveness favour TXA + standard care or standard care alone?

Judgement						
☐ Don't know	☐ Varies	☐ Favours the standard care alone	☐ Probably favours the standard care alone	☐ Does not favour either the TXA + standard care or the standard care alone	☒ Probably favours TXA + standard care	☐ Favours TXA +standard care

Equity

What would be the impact on health equity of TXA administration in addition to standard care for PPH treatment?

Research evidence

- No direct evidence of the impact of the TXA administration in addition to standard care for PPH treatment on equity was found. However, indirect evidence from a review of barriers and facilitators to facility-based birth indicates that poor quality of care, as evident by poor birth outcomes, is probably a significant barrier to the uptake of facility birth by women in LMICs.[17]

Additional considerations

- The 2015 WHO State of Inequality report indicates that women who are poor, least-educated, and reside in rural areas have lower health intervention coverage and worse health outcomes than more advantaged women.[18] Therefore, reducing maternal deaths due to bleeding through scaling up of TXA for PPH treatment could have a positive impact on health equity and improve outcomes among disadvantaged women, especially in LMICs where these women are at significantly higher risk of PPH-related maternal deaths.
- Reducing the need for expensive, life-saving surgical interventions (such as laparotomy to stop bleeding in women with vaginal birth) through an IV medication would probably reduce inequities, especially in contexts where health services are covered through out-of-pocket means.

Judgement

☐ Don't know	☐ Varies	☐ Reduced	☐ Probably reduced	☐ Probably no impact	☒ Probably increased	☐ Increased

Acceptability

Is TXA (in addition to standard care) acceptable to key stakeholders (women and healthcare providers) for PPH treatment?

The intervention is likely to be acceptable to both women and healthcare providers. TXA is administered in adequately equipped health facilities (providing emergency obstetric care) by a skilled healthcare provider via a standard IV infusion over a short period of time. There is no evidence of adverse maternal or neonatal effects. The balance between benefits and harms suggests that TXA will be acceptable to key stakeholders (women, providers and policy makers) across settings. An incremental cost with substantial benefits in terms of saving lives would be generally acceptable.

Judgement

☐ Don't know	☐ Varies	☐ No	☐ Probably No	☒ Probably Yes	☐ Yes

Feasibility

Is TXA feasible to implement in addition to standard care for PPH treatment?

The use of IV TXA for treatment of PPH in healthcare facilities was regarded by the GDG as feasible. Standard IV infusion equipment is required, as well as healthcare providers with sufficient training to safely administer IV bolus infusions (similar to oxytocin infusion). Many hospitals already have access to TXA due to its common use for trauma and surgery. Available preparations are compatible with recommended dosing regimens for PPH treatment. In many healthcare facilities (including in LMICs) no (or minimal) additional resources, infrastructure or training is required to commence using TXA for this indication. Administration of TXA should be relatively easy to integrate into standard PPH treatment packages. It is listed on the WHO Model List of Essential Medicines under medicines affecting coagulation.

The successful implementation of the WOMAN trial in 193 hospitals in 21 countries, which recruited over 20 000 women, in itself can be considered a potential demonstration of the feasibility of implementing this intervention.[9] The pragmatic nature of the trial, coupled with the variations in the capacities of participating institutions (from low to very high) also supports feasibility across low-, middle- and high-income settings. These hospitals are likely to implement a recommendation of TXA easily.

However, given that evidence currently supports IV TXA for treatment, the intervention may not be feasible in settings where IV administrations are restricted to doctors working in high-level or referral facilities.

Judgement					
☐ Don't know	☐ Varies	☐ No	☐ Probably No	☒ Probably Yes	☐ Yes

4. Research implications

- The GDG identified that further research on the use of TXA for PPH is a priority. While the large, multicountry WOMAN trial has assessed the benefits and harms of IV TXA for PPH treatment, other research priorities include:
- What are the effects of TXA by other routes of administration (for example, oral, intramuscular, topical, buccal) when used for PPH treatment?
- What is the cost-effectiveness of TXA when used for PPH treatment?
- What is the optimal dosing regimen of TXA for PPH treatment?
- What are the longer-term effects (on women and breastfed newborns) of TXA when used for PPH treatment?
- What are the effects of oral or intravenous TXA when used for PPH prevention? [19]

5. Dissemination and implementation of the recommendation

Dissemination and implementation of the recommendation is to be considered by all actors involved in the provision of care for pregnant women at the international, national and local levels. There is a vital need to increase access and strengthen the capacity of health centres to provide high quality services for all women giving birth. It is therefore crucial that this recommendation is translated into PPH treatment packages and programmes at country and health-facility levels.

Recommendation dissemination and evaluation

The recommendation will be disseminated through WHO regional and country offices, ministries of health, professional organizations, WHO collaborating centres, other United Nations agencies and nongovernmental organizations, among others. This recommendation will be also available on the WHO website and in the WHO Reproductive Health Library. To increase awareness of the recommendation, a short commentary will be published in a peer-reviewed journal. The recommendation will be also disseminated during meetings or scientific conferences attended by WHO staff. The executive summary will be translated into the six UN languages and disseminated through the WHO regional offices. Technical assistance will be provided to any WHO regional office willing to translate the full recommendation into any of the six UN languages.

Implementation considerations

The successful introduction of evidence-based policies (related to the prevention and management of PPH) into national programmes and healthcare services depends on well planned and participatory, consensus-driven processes of adaptation and implementation. These processes may include the development or revision of existing national guidelines or protocols based on this document. TXA should be included as part of the standard package for PPH treatment. It should therefore be available at all times in the labour room of facilities providing emergency obstetric care.

Due consideration should be given to any specific manufacturer's instructions on precautions and contraindications. TXA for injection may be mixed with most solutions for infusion, such as electrolyte solutions, carbohydrate solutions, amino acid solutions and dextran solutions.[20] TXA should be administered as a bolus IV injection over 10 minutes, as there is a potential risk of transient lowering of blood pressure. TXA should not be mixed with blood for transfusion, solutions containing penicillin or mannitol.[20] It can be administered via the same IV cannula used for IV hydration or uterotonic administration.

An enabling environment should be created for the use of TXA (for example, by widening its availability) in order to support changes in the behaviour of healthcare practitioners to enable the use of evidence-based practice. This includes technical support for local guideline implementers in the development of training manuals, flowcharts and quality indicators as well as their participation in stakeholders' meetings. Local professional societies play important roles in this process, and an inclusive and participatory process should be encouraged.

Health facilities where emergency obstetric care is provided need to have the necessary supplies and equipment, as well as the necessary training for staff attending births, so that TXA can be administered safely by IV infusion. The shelf life of TXA is generally three years, and can be stored at room temperature (15 to 30 degrees Celsius). The opened product must be used immediately. The manufacturer's instructions on storage and use, however, should always be given precedence.

The recommendation should be adapted into locally appropriate documents that are able to meet the specific needs of each country and health service. Modifications to the recommendation should be justified in an explicit and transparent manner.

6. Applicability issues

Anticipated impact on the organization of care and resources

Implementing this evidence-based recommendation can be achieved without substantive additional resources. The GDG noted that updating training curricula and providing training on the updated recommendation would increase the recommendation's impact and facilitate its implementation. Standardizing PPH treatment by including this recommendation into existing packages of care can encourage healthcare provider behaviour change.

Monitoring and evaluating guideline implementation

Implementation should be monitored at the health-service level as part of broader efforts to monitor and improve the quality of maternal and newborn care. For example, interrupted time series, clinical audits or criterion-based clinical audits can be used to obtain relevant data related to the management of PPH. Clearly defined review criteria and indicators are needed and these could be associated with locally agreed targets. These can be aligned with the standards and indicators described in the WHO document *Standards for improving quality of maternal and newborn care in health facilities*.[21]

In 2012, the GDG of the WHO recommendations on prevention and treatment of PPH strongly recommended the use of coverage of prophylactic uterotonics as a process indicator for the monitoring of PPH prevention.[5] This indicator provides an overall assessment of adherence to a key recommendation within all of WHO's recommendations on PPH prevention and treatment. The use of other locally agreed and more specific indicators (for example, the assessment of the use of specific uterotonics or use of TXA for PPH treatment) may be necessary to obtain a more complete assessment of the quality of care related to the prevention and treatment of PPH. WHO has developed specific guidance for evaluating the quality of care for severe maternal complications (including PPH) based on the near-miss and criterion-based clinical audit concepts.[22]

In collaboration with the WHO RHR and MCA Departments' monitoring and evaluation team, data on country and regional level implementation of the recommendation will be collected and evaluated in the short- to medium-term to evaluate the recommendation's impact on the national policy of individual WHO Member States.

Information on recommended indicators can also be obtained at the local level by interrupted time series or clinical audits.

7. Updating the recommendation

The Executive GSG will convene annually to review WHO's current portfolio of maternal and perinatal health recommendations, and to prioritize new and existing questions for recommendation development and updating. Accordingly, the recommendation on TXA use for the treatment of PPH will be reviewed and prioritized by the Executive GSG. In the event that new evidence (that could potentially impact the current evidence base) is identified, the recommendation may be updated. If no new reports or information is identified, the recommendation may be revalidated.

Following publication and dissemination of the updated recommendation, any concern about validity of the recommendation will be promptly communicated to the guideline implementers, in addition to plans to update the recommendation.

WHO welcomes suggestions regarding additional questions for inclusion in the updated recommendation. Please email your suggestions to mpa-info@who.int.

References

1. Souza JP, Gülmezoglu AM, Vogel J, et al. Moving beyond essential interventions for reduction of maternal mortality (the WHO Multicountry Survey on Maternal and Newborn Health): a cross-sectional study. Lancet. 2013;381(9879):1747-55.
2. Carroli G, Cuesta C, Abalos E, Gulmezoglu AM. Epidemiology of postpartum haemorrhage: a systematic review. Best Pract Res Clin Obstet Gynaecol. 2008;22(6):999-1012.
3. Say L, Chou D, Gemmill A, et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014;2(6):e323-33.
4. Oyelese Y, Ananth CV. Postpartum hemorrhage: epidemiology, risk factors, and causes. Clin Obstet Gynecol. 2010;53(1):147-56.
5. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva: World Health Organization, 2012.
6. National Center for Biotechnology Information PCD, CID=5526. Tranexamic acid – compound summary for CID 5526. 2017 (https://pubchem.ncbi.nlm.nih.gov/compound/5526, accessed 31 August 2017).
7. Report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2017 (including the 20th WHO Model List of Essential Medicines and the 6th WHO Model List of Essential Medicines for Children). Geneva: World Health Organization, 2017.
8. Shakur H, Elbourne D, Gülmezoglu M, et al. The WOMAN Trial (World Maternal Antifibrinolytic Trial): tranexamic acid for the treatment of postpartum haemorrhage: an international randomised, double blind placebo controlled trial. Trials. 2010:11:40.
9. WOMAN Trial Collaborators. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial. Lancet. 2017;389(10084):2105-16.
10. WHO handbook for guideline development (second edition). Geneva: World Health Organization; 2014.
11. Mousa HA, Blum J, Abou El Senoun G, Shakur H, Alfirevic Z. Treatment for primary postpartum haemorrhage. Cochrane Database Syst Rev. 2014;(2):CD003249.
12. Shakur H, Beaumont D, Pavord S, Gayet-Ageron A, Ker K, Dowswell T, Mousa H. Antifibrinolytic drugs for treating primary postpartum haemorrhage. Cochrane Database Syst Rev. 2017;(unpublished).
13. Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011;64(4):401-6.
14. Ducloy-Bouthors AS, Jude B, Duhamel A, et al. High-dose tranexamic acid reduces blood loss in postpartum haemorrhage. Crit Care. 2011;15(2):R117.

15. Gayet-Ageron A, Prieto-Merino D, Ker K, Shakur H, Ageron F-X, Roberts I. Impact of treatment delay on the effectiveness and safety of anti-fibrinolytics in acute severe haemorrhage: an individual patient data meta-analysis in 40 138 bleeding patients. Lancet. 2017; accepted for publication.

16. Guerriero C, Cairns J, Perel P, Shakur H, Roberts I, collaborators Ct. Cost-effectiveness analysis of administering tranexamic acid to bleeding trauma patients using evidence from the CRASH-2 trial. PLoS One. 2011;6(5):e18987.

17. Bohren MA, Hunter EC, Munthe-Kaas HM, Souza JP, Vogel JP, Gülmezoglu AM. Facilitators and barriers to facility-based delivery in low- and middle-income countries: a qualitative evidence synthesis. Reprod Health. 2014;11(1):71.

18. State of inequality: reproductive, maternal, newborn and child health. Geneva: World Health Organization; 2015.

19. Novikova N, Hofmeyr GJ, Cluver C. Tranexamic acid for preventing postpartum haemorrhage. Cochrane Database Syst Rev. 2015;(6):CD007872.

20. EMC. Cyclokapron Injection. 15 March 2016 (https://www.medicines.org.uk/emc/medicine/1489w5, accessed September 2017).

21. Standards for improving quality of maternal and newborn care in health facilities. Geneva: World Health Organization; 2016.

22. Evaluating the quality of care for severe pregnancy complications: The WHO near-miss approach for maternal health. Geneva: World Health Organization; 2011.

Annex 1. External experts and WHO staff involved in the preparation of the guideline

A. Participants at the who technical consultation on TXA for the treatment of PPH

Guideline Development Group

Edgardo Abalos (unable to attend)
Centro Rosarino de Estudios Perinatales (CREP)
Rosario, Argentina

Yap-Seng Chong
Department of Obstetrics and Gynaecology
National University Hospital
Singapore

Catherine Deneux-Tharaux
Inserm U1153
Obstetrical, Perinatal and Pediatric Epidemiology Research Team
Centre of Research in Epidemiology and Statistics
Sorbonne Paris Cité
Université Paris Descartes
Paris, France

Bukola Fawole
Department of Obstetrics & Gynaecology
College of Medicine
University of Ibadan
Ibadan, Nigeria

Justus Hofmeyr
Universities of the Witwatersrand
and Walter Sisulu/Eastern Cape Department of Health
East London, South Africa

Caroline Homer (unable to attend)
WHO Collaborating Centre for Nursing, Midwifery and Health Development
Faculty of Health
University of Technology
Sydney, Australia

Pisake Lumbiganon
Department of Obstetrics and Gynaecology
Faculty of Medicine
Khon Kaen University
Khon Kaen, Thailand

Suellen Miller
Department of Obstetrics, Gynecology & Reproductive Sciences
Director, Safe Motherhood Program
Bixby Center for Global Reproductive Health
San Francisco, United States

Ashraf Nabhan
Department of Obstetrics and Gynecology
Faculty of Medicine
Ain Shams University
Abbasia, Cairo, Egypt

James Neilson
Department of Women's and Children's Health
The University of Liverpool
Women's NHS Foundation Trust
Liverpool, United Kingdom

Hiromi Obara
JICA Health Policy Advisor
Lao People's Democratic Republic

Zahida Qureshi
Department of Obstetrics and Gynaecology
School of Medicine
University of Nairobi
Nairobi, Kenya

Rahat Qureshi
Aga Khan University
Department of Obstetrics and Gynecology
Karachi, Pakistan

Helen West
The University of Liverpool
Women's NHS Foundation Trust
Liverpool, United Kingdom

Observers

Deborah Armbruster
United States Agency for International Development (USAID)
Bureau for Global Health
Washington DC, United States

Kusum Thapa
MCSP/Jhpiego
USAID Grantee
1776 Massachusetts Ave
Washington DC, United States

Janna Patterson
Maternal, Neonatal & Child Health
Global Development Program
Bill & Melinda Gates Foundation
Seattle, Washington, United States

Haleema Shakur-Still
London School of Hygiene and Tropical Medicine
London, United Kingdom

Sally Tracy
International Confederation of Midwives (ICM)
Sydney University
Sydney, Australia

Gerard H.A. Visser
International Federation of Gynecology and Obstetrics (FIGO)
London, United Kingdom

Beverley Winikoff
Gynuity Health Projects
New York, United States

Systematic Review Team

Therese Dowswell
Department of Women's and Children's Health
The University of Liverpool
Women's NHS Foundation Trust
Crown Street
Liverpool, United Kingdom

WHO Regional Offices

Mavjuda Babamuradova
Sexual and Reproductive Health
Noncommunicable diseases and life-course
WHO Regional Office for Europe
Copenhagen, Denmark

Anoma Jayathilaka
Family Health, Gender and Life Course
WHO Regional Office for South-East Asia
New Delhi, India

Ramez Khairi Mahaini (unable to attend)
Reproductive and Maternal Health
WHO Regional Office for the Eastern Mediterranean
Cairo, Egypt

Bremen De Mucio
Sexual and Reproductive Health
WHO Regional Office of the Americas
Montevideo, Uruguay

Mari Nagai (unable to attend)
Reproductive, Maternal, Newborn, Child and Adolescent Health Division of NCD and Health through Life-Course
Regional Office for the Western Pacific
Manila, Philippines

Léopold Ouedraogo (unable to attend)
Reproductive Health
Health Promotion Cluster (HPR)
WHO Regional Office for Africa
Brazzaville, Republic of Congo

Claudio Sosa
Sexual and Reproductive Health
WHO Regional Office of the Americas
Montevideo, Uruguay

WHO Secretariat

A. Metin Gülmezoglu
Coordinator, RHR/MPA
Maternal and Perinatal Health & Preventing Unsafe Abortion
Department of Reproductive Health and Research

Mercedes Bonet
Medical Officer, RHR/MPA
Maternal and Perinatal Health & Preventing Unsafe Abortion
Department of Reproductive Health and Research

Olufemi T. Oladapo
Medical Officer, RHR/MPA
Maternal and Perinatal Health & Preventing Unsafe Abortion
Department of Reproductive Health and Research

Joao Paulo Souza (unable to attend)
Medical Officer, RHR/MPA
Maternal and Perinatal Health & Preventing Unsafe Abortion
Department of Reproductive Health and Research

Joshua P. Vogel
Technical Officer, RHR/MPA
Maternal and Perinatal Health & Preventing Unsafe Abortion
Department of Reproductive Health and Research

Maurice Bucagu (unable to attend)
Medical Officer, MCA/PPP
Policy, Planning and Programmes
Department of Maternal, Newborn, Child and Adolescent Health

Fran McConville (unable to attend)
Technical Officer, MCA/PPP
Policy, Planning and Programmes
Department of Maternal, Newborn, Child and Adolescent Health

Anayda Portela
Technical Officer, MCA/MRD
Research and Development
Department of Maternal, Newborn, Child and Adolescent Health

B. WHO Steering Group

A. Metin Gülmezoglu
(WHO Department of Reproductive Health and Research)

Olufemi T. Oladapo
(WHO Department of Reproductive Health and Research)

Anayda Portela
(WHO Department of Maternal, Newborn, Child and Adolescent Health)

Joshua Vogel
(WHO Department of Reproductive Health and Research)

C. External Review Group

Richard M.K. Adanu
School of Public Health
University of Ghana
Accra, Ghana

Fernando Althabe
Department of Maternal and Child Health Research
Institute for Clinical Effectiveness and Health Policy
Buenos Aires, Argentina

Sue Fawcus
Department of Obstetrics and Gynaecology
University of Cape Town
Cape Town, South Africa

Jamilu Tukur
Department of Obstetrics and Gynaecology
Bayero University
Kano, Nigeria

Dilys Walker
Department of Obstetrics, Gynecology & Reproductive Sciences
UCSF School of Medicine
University of California
San Francisco, United States

Annex 2. Critical and important outcomes for decision-making

Key question	Priority Outcomes
For women with postpartum haemorrhage (P), does administration of tranexamic acid in addition to standard care (I) compared to standard care alone (C), improve outcomes (O)?	**Critical outcomes** • Maternal death (all cause)* • Maternal death due to bleeding* • Additional blood loss ≥ 500 ml • Additional blood loss ≥ 1000 ml • Blood transfusion • Additional uterotonics • Invasive nonsurgical interventions • Surgical interventions (including hysterectomy) • Maternal temperature ≥ 40 °C • Procedure-related complications • Infections • Severe morbidity • Maternal transfer • Reduction of time from decision-making to implementation • Availability of drugs and treatment
	Important outcomes • Accuracy in blood loss assessment • Mean blood loss • Postpartum anaemia • Additional nonsurgical interventions (e.g. external aortic compression and compression garments) • Artery embolization • Nausea, vomiting or shivering • Maternal temperature ≥ 38 °C • Delayed initiation of breastfeeding • Prolonged hospitalization

* Maternal death (all cause) and maternal death due to bleeding were added as critical outcomes for the update of this recommendation.

Annex 3: Summary and management of declared interests from GDG members

Name and expertise contributed to the guideline development	Declared interest	Management of conflict of interest
Edgardo Abalos Content expert and end-user	None declared	Not applicable
Yap-Seng Chong Content expert and end-user	None declared	Not applicable
Catherine Deneux-Tharaux Content expert and end-user	None declared	Not applicable
Therese Dowswell Guideline methodologist	None declared	As one of the methodologists for this guideline, Therese Dowswell did not have voting rights at the meeting.
Bukola Fawole Content expert and end-user	Professor Fawole was a country investigator (Nigeria) on the WOMAN trial. He has participated in previous GDGs, including the previous WHO GDG on prevention and treatment of postpartum haemorrhage (2012).	The conflict was not considered serious enough to affect GDG membership or participation in the Technical Consultation. His perspectives on implementation of this intervention (resulting from WOMAN trial) were regarded as important.
Justus Hofmeyr Content expert and end-user	None declared	Not applicable
Caroline Homer Content expert and end-user	Co-Chair of National Antenatal Guidelines Expert Advisory Committee in Australia (2008 onwards)	The conflict was not considered serious enough to affect GDG membership or participation in the Technical Consultation
Pisake Lumbiganon Content expert and end-user	Was a DSMB member of the WOMAN trial	The conflict was not considered serious enough to affect GDG membership or participation in the Technical Consultation
Suellen Miller Content expert and end-user	Prof Miller's employer (University of California, San Francisco) holds the trademark on a nonpneumatic antishock device (NASG) for PPH management	The conflict was not considered serious enough to affect GDG membership or participation in the Technical Consultation
Ashraf Nabhan Content expert and end-user	None declared	Not applicable

Name and expertise contributed to the guideline development	Declared interest	Management of conflict of interest
James Neilson Content expert and end-user	None declared	Not applicable
Hiromi Obara Content expert and implementer	None declared	Not applicable
Zahida Qureshi Content expert and end-user	Professor Qureshi was a country investigator (Kenya) on the WOMAN trial. She has participated in previous GDGs, including the previous WHO GDG on prevention and treatment of postpartum haemorrhage (2012).	The conflict was not considered serious enough to affect GDG membership or participation in the Technical Consultation. Her perspectives on implementation of this intervention (resulting from WOMAN trial) were regarded as important.
Rahat Qureshi Content expert and end-user	None declared	Not applicable
Helen West Consumer representative	None declared	Not applicable

Annex 4. Summary of the considerations related to the strength of the recommendations

Desirable effects	- Don't know	- Varies		- Trivial	- Small	- Moderate	✓ Large
Undesirable effects	- Don't know	- Varies		- Large	- Moderate	- Small	✓ Trivial
Certainty of the evidence	- No included studies			- Very low	- Low	✓ Moderate	- High
Values and preferences				- **Important uncertainty or variability**	- Possibly important uncertainty or variability	- Probably no important uncertainty or variability	✓ No important uncertainty or variability
Balance of effects	- Don't know	- Varies	- Favours the comparison	- Probably favours the comparison	- Does not favour either the intervention or the comparison	- Probably favours the intervention	✓ Favours the intervention
Resources required	- Don't know	- Varies	- Large costs	- Moderate costs	✓ Negligible costs or savings	- Moderate savings	- Large savings
Certainty of evidence of required resources	✓ No included studies			- Very low	- Low	- Moderate	- High
Cost-effectiveness	- Don't know	- Varies	- Favours the comparison	- Probably favours the comparison	- Does not favour either the intervention or the comparison	✓ Probably favours the intervention	- Favours the intervention
Equity	- Don't know	- Varies	- Reduced	- Probably reduced	- Probably no impact	✓ Probably increased	- Increased
Acceptability	- Don't know	- Varies		- No	- Probably No	✓ Probably Yes	- Yes
Feasibility	- Don't know	- Varies		- No	- Probably No	- Probably Yes	✓ Yes

Annex 5. GRADE Tables

Question: Standard care plus tranexamic acid compared to standard care alone for treating primary postpartum haemorrhage

Setting: Data from two studies, one conducted in France (5 tertiary care centres and 3 secondary care obstetric centres: 152 women) and one multicentre RCT with 20 060 women (WOMAN trial).

WOMAN trial: Labour ward settings in high- (United Kingdom: 569 women), and low- and middle-income countries (Nigeria: 5711 women; Pakistan: 5282 women; Uganda: 2235 women; Kenya: 1031 women; Cameroon: 893 women; Sudan: 860 women; Tanzania: 538 women; Nepal: 533 women; Zambia: 496 women; Albania: 485 women; Democratic Republic of Congo: 457 women; Bangladesh: 325 women; Ethiopia: 302 women; Burkina Faso: 142 women; Jamaica: 73 women; Ghana: 41 women; Papua New Guinea: 38 women; Egypt: 33 women; Colombia: 8 women; Côte d'Ivoire: 8 women).

Bibliography: Shakur H, Beaumont D, Pavord S, Gayet-Ageron A, Ker K, Dowswell T, Mousa H. Antifibrinolytic drugs for treating primary postpartum haemorrhage. Cochrane Database Syst Rev. 2017;(unpublished).

Quality assessment							No. of patients		Effect		Certainty	Importance
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other consider-ations**	**Standard care plus tranexamic acid**	**Placebo or standard care alone**	**Relative (95% CI)**	**Absolute (95% CI)**		
Maternal mortality (all causes)												
2	randomised trials	not serious	not serious	not serious	serious [a]	none	227/10113 (2.2%)	256/10059 (2.5%)	**RR 0.88** (0.74 to 1.05)	**3 fewer per 1000** (from 1 more to 7 fewer)	⊕⊕⊕○ MODERATE	CRITICAL
Maternal mortality (due to PPH)												
2	randomised trials	not serious	not serious	not serious	serious [b]	none	155/10113 (1.5%)	191/10059 (1.9%)	**RR 0.81** (0.65 to 1.00)	**4 fewer per 1000** (from 0 fewer to 7 fewer)	⊕⊕⊕○ MODERATE	CRITICAL
Severe maternal morbidity (maternal intensive care admission)												
1	randomised trials	serious [c]	not serious	not serious	very serious [d]	none	3/77 (3.9%)	5/74 (6.8%)	**RR 0.58** (0.14 to 2.33)	**28 fewer per 1000** (from 58 fewer to 90 more)	⊕○○○ VERY LOW	CRITICAL

Quality assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consider-ations	Standard care plus tranexamic acid	Placebo or standard care alone	Relative (95% CI)	Absolute (95% CI)		
Severe maternal morbidity (maternal respiratory failure)												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	108/10033 (1.1%)	124/9985 (1.2%)	**RR 0.87** (0.67 to 1.12)	**2 fewer per 1000** (from 1 more to 4 fewer)	⊕⊕⊕○ MODERATE	CRITICAL
Severe maternal morbidity (maternal seizure)												
2	randomised trials	not serious	not serious	not serious	serious [a]	none	33/10110 (0.3%)	43/10059 (0.4%)	**RR 0.76** (0.49 to 1.20)	**1 fewer per 1000** (from 1 more to 2 fewer)	⊕⊕⊕○ MODERATE	CRITICAL
Severe maternal morbidity (hepatic failure)												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	29/10033 (0.3%)	30/9985 (0.3%)	**RR 0.96** (0.58 to 1.60)	**0 fewer per 1000** (from 1 fewer to 2 more)	⊕⊕⊕○ MODERATE	CRITICAL
Severe maternal morbidity (cardiac failure)												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	110/10033 (1.1%)	115/9985 (1.2%)	**RR 0.95** (0.73 to 1.23)	**1 fewer per 1000** (from 3 fewer to 3 more)	⊕⊕⊕○ MODERATE	CRITICAL
Severe maternal morbidity (maternal renal failure)												
2	randomised trials	not serious	not serious	not serious	serious [a]	none	129/10110 (1.3%)	118/10059 (1.2%)	**RR 1.09** (0.85 to 1.39)	**1 more per 1000** (from 2 fewer to 5 more)	⊕⊕⊕○ MODERATE	CRITICAL
Blood Products transfusion (all)												
2	randomised trials	not serious	serious [e]	not serious	not serious	none	5474/10113 (54.1%)	5446/10059 (54.1%)	**RR 1.00** (0.97 to 1.03)	**0 fewer per 1000** (from 16 fewer to 16 more)	⊕⊕⊕○ MODERATE	CRITICAL

Quality assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consider-ations	Standard care plus tranexamic acid	Placebo or standard care alone	Relative (95% CI)	Absolute (95% CI)		
Additional blood loss > 500 ml												
1	randomised trials	serious [c]	not serious	not serious	serious [f]	none	12/77 (15.6%)	23/74 (31.1%)	**RR 0.50** (0.27 to 0.93)	**155 fewer per 1000** (from 22 fewer to 227 fewer)	⨁⨁◯◯ LOW	CRITICAL
Additional blood loss > 1000 ml												
1	randomised trials	serious [c]	not serious	not serious	very serious [d]	none	4/77 (5.2%)	8/74 (10.8%)	**RR 0.48** (0.15 to 1.53)	**56 fewer per 1000** (from 57 more to 92 fewer)	⨁◯◯◯ VERY LOW	CRITICAL
Additional uterotonics												
2	randomised trials	not serious	not serious	not serious	not serious	none	10032/10106 (99.3%)	9964/10058 (99.1%)	**RR 1** (1 to 1)	**0 fewer per 1000** (from 0 fewer to 0 fewer)	⨁⨁⨁⨁ HIGH	CRITICAL
Surgical intervention (hysterectomy)												
2	randomised trials	not serious	not serious	not serious	not serious	none	358/10109 (3.5%)	352/10059 (3.5%)	**RR 1.01** (0.88 to 1.17)	**0 fewer per 1000** (from 4 fewer to 6 more)	⨁⨁⨁⨁ HIGH	CRITICAL
Surgical intervention (ligature)												
2	randomised trials	not serious	not serious	not serious	serious [a]	none	225/10109 (2.2%)	255/10059 (2.5%)	**RR 0.88** (0.74 to 1.05)	**3 fewer per 1000** (from 1 more to 7 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
Surgical intervention (embolization)												
2	randomised trials	not serious	not serious	not serious	serious [a]	none	15/10109 (0.1%)	18/10059 (0.2%)	**RR 0.82** (0.42 to 1.62)	**0 fewer per 1000** (from 1 fewer to 1 more)	⨁⨁⨁◯ MODERATE	CRITICAL

Quality assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consider-ations	Standard care plus tranexamic acid	Placebo or standard care alone	Relative (95% CI)	Absolute (95% CI)		
Surgical intervention (laparotomy)												
1	randomised trials	not serious	not serious	not serious	not serious	none	82/10032 (0.8%)	127/9985 (1.3%)	**RR 0.64** (0.49 to 0.85)	**5 fewer per 1000** (from 2 fewer to 6 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL
Surgical intervention (brace sutures)												
1	randomised trials	not serious	not serious	not serious	not serious	none	300/10032 (3.0%)	250/9985 (2.5%)	**RR 1.19** (1.01 to 1.41)	**5 more per 1000** (from 0 fewer to 10 more)	⊕⊕⊕⊕ HIGH	CRITICAL
Invasive non-surgical intervention (intrauterine tamponade)												
1	randomised trials	not serious	not serious	not serious	not serious	none	705/10032 (7.0%)	729/9985 (7.3%)	**RR 0.96** (0.87 to 1.06)	**3 fewer per 1000** (from 4 more to 9 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL
Invasive non-surgical intervention (manual removal of placenta)												
1	randomised trials	not serious	not serious	not serious	not serious	none	918/10032 (9.2%)	961/9985 (9.6%)	**RR 0.95** (0.87 to 1.04)	**5 fewer per 1000** (from 4 more to 13 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL
Procedure-related complication (any maternal thromboembolic event)												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	30/10033 (0.3%)	34/9985 (0.3%)	**RR 0.88** (0.54 to 1.43)	**0 fewer per 1000** (from 1 more to 2 fewer)	⊕⊕⊕◯ MODERATE	CRITICAL
Procedure-related complication (deep venous thrombosis)												
2	randomised trials	not serious	not serious	not serious	serious [a]	none	5/10110 (0.0%)	8/10059 (0.1%)	**RR 0.62** (0.20 to 1.88)	**0 fewer per 1000** (from 1 fewer to 1 more)	⊕⊕⊕◯ MODERATE	CRITICAL

Quality assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consider-ations	Standard care plus tranexamic acid	Placebo or standard care alone	Relative (95% CI)	Absolute (95% CI)		
Procedure-related complication (pulmonary embolism)												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	17/10033 (0.2%)	20/9985 (0.2%)	**RR 0.85** (0.44 to 1.61)	**0 fewer per 1000** (from 1 fewer to 1 more)	⊕⊕⊕○ MODERATE	CRITICAL
Procedure-related complication (myocardial infarction)												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	2/10033 (0.0%)	3/9985 (0.0%)	**RR 0.66** (0.11 to 3.97)	**0 fewer per 1000** (from 0 fewer to 1 more)	⊕⊕⊕○ MODERATE	CRITICAL
Procedure-related complication (stroke)												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	8/10033 (0.1%)	6/9985 (0.1%)	**RR 1.33** (0.46 to 3.82)	**0 fewer per 1000** (from 0 fewer to 2 more)	⊕⊕⊕○ MODERATE	CRITICAL
Procedure-related complication (neonatal thromboembolic event)												
1	randomised trials	not serious	not serious	not serious	very serious [g]	none	0/10033	0/9985	No events	No events	⊕⊕○○ LOW	CRITICAL
Procedure-related complication (death of breastfed baby)												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	8/10033 (0.1%)	7/9985 (0.1%)	**RR 1.14** (0.41 to 3.14)	**0 fewer per 1000** (from 0 fewer to 2 more)	⊕⊕⊕○ MODERATE	No baby outcomes in WHO but this could be seen as a procedure related complica-tion

CI: Confidence interval; **RR:** Risk ratio; **MD:** Mean difference

Explanations

a. Wide confidence interval crossing the line of no effect

b. Wide confidence interval that includes the line of no effect

c. Single study with design limitations (no blinding)

d. Few events, small sample size, and wide confidence interval crossing the line of no effect

e. Moderate statistical heterogeneity and may be clinical heterogeneity

f. Single study with small sample size

g. No events

Question: Standard care plus tranexamic acid compared to placebo or standard care alone for treating primary postpartum haemorrhage (subgroup time from birth)

Setting: Data from one multicentre RCT with 20 060 women (WOMAN trial). Labour ward settings in high- (United Kingdom: 569 women), and low- and middle-income countries (Nigeria: 5711 women; Pakistan: 5282 women; Uganda: 2235 women; Kenya: 1031 women; Cameroon: 893 women; Sudan: 860 women; Tanzania: 538 women; Nepal: 533 women; Zambia: 496 women; Albania: 485 women; Democratic Republic of Congo: 457 women; Bangladesh: 325 women; Ethiopia: 302 women; Burkina Faso: 142 women; Jamaica: 73 women; Ghana: 41 women; Papua New Guinea: 38 women; Egypt: 33 women; Colombia: 8 women; Côte d'Ivoire: 8 women).

Bibliography: Shakur H, Beaumont D, Pavord S, Gayet-Ageron A, Ker K, Dowswell T, Mousa H. Antifibrinolytic drugs for treating primary postpartum haemorrhage. Cochrane Database Syst Rev. 2017;(unpublished).

Quality assessment							No. of patients		Effect		Certainty	Importance
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other consider-ations**	**Standard care plus tranexamic acid**	**Placebo or standard care alone**	**Relative (95% CI)**	**Absolute (95% CI)**		
Maternal mortality due to bleeding (subgroup time from birth) – less than 1 hour												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	49/4846 (1.0%)	60/4726 (1.3%)	**RR 0.80** (0.55 to 1.16)	**3 fewer per 1000** (from 2 more to 6 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
Maternal mortality due to bleeding (subgroup time from birth) – 1 to 3 hours												
1	randomised trials	not serious	not serious	not serious	not serious	none	40/2674 (1.5%)	67/2682 (2.5%)	**RR 0.60** (0.41 to 0.88)	**10 fewer per 1000** (from 3 fewer to 15 fewer)	⨁⨁⨁⨁ HIGH	CRITICAL
Maternal mortality due to bleeding (subgroup time from birth) – more than 3 hours												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	66/2514 (2.6%)	63/2569 (2.5%)	**RR 1.07** (0.76 to 1.51)	**2 more per 1000** (from 6 fewer to 13 more)	⨁⨁⨁◯ MODERATE	CRITICAL

Quality assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consider-ations	Standard care plus tranexamic acid	Placebo or standard care alone	Relative (95% CI)	Absolute (95% CI)		
Maternal mortality (all cause) (subgroup time from birth) – less than 1 hour												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	80/4846 (1.7%)	80/4726 (1.7%)	**RR 0.98** (0.72 to 1.33)	**0 fewer per 1000** (from 5 fewer to 6 more)	⨁⨁⨁◯ MODERATE	CRITICAL
Maternal mortality (all cause) (subgroup time from birth) – 1 to 3 hours												
1	randomised trials	not serious	not serious	not serious	not serious	none	57/2674 (2.1%)	83/2682 (3.1%)	**RR 0.69** (0.49 to 0.96)	**10 fewer per 1000** (from 1 fewer to 16 fewer)	⨁⨁⨁⨁ HIGH	CRITICAL
Maternal mortality (all cause) (subgroup time from birth) – more than 3 hours												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	90/2514 (3.6%)	92/2569 (3.6%)	**RR 1.00** (0.75 to 1.33)	**0 fewer per 1000** (from 9 fewer to 12 more)	⨁⨁⨁◯ MODERATE	CRITICAL
Composite outcome: death or hysterectomy by subgroups (timing) – less than 1 hour												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	253/4844 (5.2%)	229/4726 (4.8%)	**RR 1.08** (0.91 to 1.28)	**4 more per 1000** (from 4 fewer to 14 more)	⨁⨁⨁◯ MODERATE	CRITICAL
Composite outcome: death or hysterectomy by subgroups (timing) – 1 to 3 hours												
1	randomised trials	not serious	not serious	not serious	serious [b]	none	122/2672 (4.6%)	154/2682 (5.7%)	**RR 0.80** (0.63 to 1.00)	**11 fewer per 1000** (from 0 fewer to 21 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
Composite outcome: death or hysterectomy by subgroups (timing) – more than 3 hours												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	159/2514 (6.3%)	161/2569 (6.3%)	**RR 1.01** (0.82 to 1.25)	**1 more per 1000** (from 11 fewer to 16 more)	⨁⨁⨁◯ MODERATE	CRITICAL

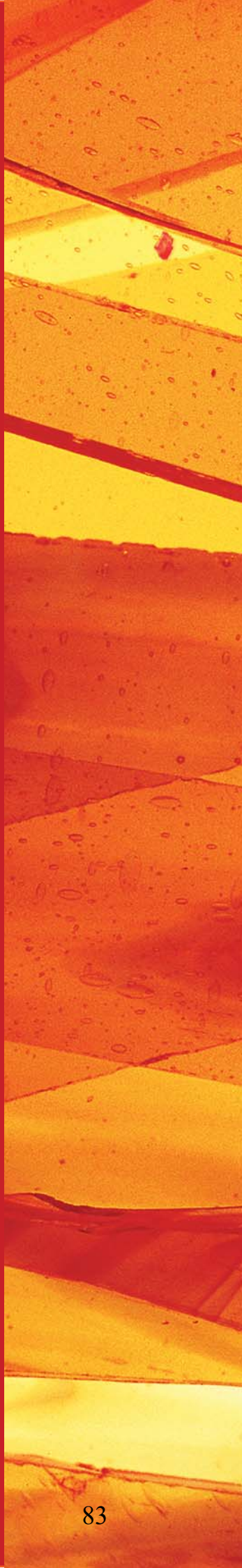
Quality assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consider-ations	Standard care plus tranexamic acid	Placebo or standard care alone	Relative (95% CI)	Absolute (95% CI)		
Laparotomy for bleeding (subgroups by timing) - less than 1 hour												
1	randomised trials	not serious	not serious	not serious	not serious	none	22/4844 (0.5%)	45/4726 (1.0%)	**RR 0.48** (0.29 to 0.79)	**5 fewer per 1000** (from 2 fewer to 7 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL
Laparotomy for bleeding (subgroups by timing) - 1 to 3 hours												
1	randomised trials	not serious	not serious	not serious	not serious	none	19/2672 (0.7%)	35/2682 (1.3%)	**RR 0.54** (0.31 to 0.95)	**6 fewer per 1000** (from 1 fewer to 9 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL
Laparotomy for bleeding (subgroups by timing) - more than 3 hours												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	41/2514 (1.6%)	47/2569 (1.8%)	**RR 0.89** (0.59 to 1.35)	**2 fewer per 1000** (from 6 more to 8 fewer)	⊕⊕⊕○ MODERATE	CRITICAL

CI: Confidence interval; **RR:** Risk ratio

Explanations

a. Wide 95% CI crossing the line of no effect

b. Wide 95% CI including the line of no effect



For more information, please contact:

Department of Reproductive Health and Research
E-mail: reproductivehealth@who.int
www.who.int/reproductivehealth

Maternal, Newborn, Child and Adolescent Health
E-mail: mncah@who.int
www.who.int/maternal_child_adolescent

World Health Organization
Avenue Appia 20, CH-1211 Geneva 27
Switzerland

ISBN 978 92 4 155015 4

(k) Failed to provide a home inspection report to a client by the date agreed on by the home inspector and the client or, if no date was agreed on, within a reasonable time after completing the inspection.

(m) Violated this subchapter or any rule promulgated under this subchapter.

(3) In addition to or in lieu of proceeding under sub. (2), the department may assess against a person who has engaged in any of the practices specified in sub. (2) a forfeiture of not more than $1,000 for each separate offense.

(5) The department may, as a condition of removing a limitation on a certificate issued under this subchapter or of reinstating a certificate that has been suspended or revoked under this subchapter, do any of the following:

(a) Require the home inspector to obtain insurance against loss, expense and liability resulting from errors and omissions or neglect in the performance of services as a home inspector.

(b) Require the home inspector to file with the department a bond that is furnished by a company authorized to do business in this state and is in an amount approved by the department.

History: 1997 a. 81; 2021 a. 17.
Cross-reference: See also ch. SPS 131, Wis. adm. code.

440.979 Report by department. The department shall submit an annual report to the legislature under s. 13.172 (2) that describes all of the following:

(1) The number of home inspectors who are registered under this subchapter.

(2) The number and nature of complaints regarding home inspections that are received by the department from clients of home inspectors.

(3) The number and nature of complaints regarding home inspections that are received by the department from persons who are not clients of home inspectors.

(4) An estimate of the cost of complying with this subchapter that is incurred by home inspectors.

(5) The cost incurred by the department in carrying out its duties under this subchapter.

History: 1997 a. 81; 1999 a. 32 s. 311.
Cross-reference: See also ch. SPS 131, Wis. adm. code.

SUBCHAPTER XII

SANITARIANS

440.98 Sanitarians; qualifications, duties, registration. (1) DEFINITIONS. In this section:

(a) "Municipality" means a county, city or village.

(b) "Sanitarian" means an individual who, through education, training or experience in the natural sciences and their application and through technical knowledge of prevention and control of preventable diseases, is capable of applying environmental control measures so as to protect human health, safety and welfare.

(2) REGISTRATION QUALIFICATIONS. In order to safeguard life, health and property, to promote public welfare and to establish the status of those persons whose duties in environmental sanitation call for knowledge of the natural sciences, the department may establish minimum standards and qualifications for the registration of sanitarians.

(3) SANITARIANS; EMPLOYMENT OR CONTRACTUAL SERVICES. Any agency of the state may employ or contract for the services of sanitarians, registered under this section, who shall enforce the public health statutes under chs. 250 to 256 or rules promulgated under those statutes.

(5) REGISTRATION. Except as provided in s. 440.12 or 440.13, the department shall register as a sanitarian any person who satisfies the conditions in sub. (6) and who has presented evidence satisfactory to the department that sanitarian registration standards and qualifications of the department, as established by rule, have been met.

(6) APPLICATIONS. An application for a sanitarian registration under this section shall be made on a form provided by the department and filed with the department and shall be accompanied by the initial credential fee determined by the department under s. 440.03 (9) (a). The renewal date for a sanitarian registration is specified under s. 440.08 (2) (a), and the renewal fee for such registration is determined by the department under s. 440.03 (9) (a).

(7) RECIPROCITY. The department may by rule set standards for sanitarians registered in other states to practice as registered sanitarians in this state.

(8) REVOCATION OF REGISTRATION. The department may, after a hearing held in conformance with ch. 227, revoke, deny, suspend, or limit under this subchapter the registration of any sanitarian, or reprimand the sanitarian, for practice of fraud or deceit in obtaining the registration or any unprofessional conduct, incompetence, or professional negligence.

(9) FORFEITURE. In addition to or in lieu of a reprimand or a denial, limitation, suspension, or revocation of a registration under sub. (8), the department may assess against any person a forfeiture of not less than $100 nor more than $1,000 for each violation under sub. (8).

History: 1975 c. 414 s. 28; 1977 c. 29, 418; 1983 a. 189; 1985 a. 182 s. 57; 1987 a. 27; 1993 a. 27 s. 223; Stats. 1993 s. 250.05; 1997 a. 191, 237; 1999 a. 9; 2005 a. 25 ss. 2120 to 2128; Stats. 2005 s. 440.70; 2005 a. 25 ss. 2121 to 2130, 2336m, 2337; 2005 a. 254 s. 35; 2007 a. 20, 130.
Cross-reference: See also chs. SPS 174, 175, 176, and 177, Wis. adm. code.

SUBCHAPTER XIII

LICENSED MIDWIVES

Cross-reference: See also chs. SPS 180, 181, 182, and 183, Wis. adm. code.

440.9805 Definitions. In this subchapter:

(1) "Health care provider" means a health care provider, as defined in s. 146.81 (1) (a) to (p), a person licensed or issued a training permit as an emergency medical services practitioner under s. 256.15, or a person certified as an emergency medical responder under s. 256.15 (8) (a).

(2) "Licensed midwife" means a person who has been granted a license under this subchapter to engage in the practice of midwifery.

(3) "Practice of midwifery" means providing maternity care during the antepartum, intrapartum, and postpartum periods.

History: 2005 a. 292; 2007 a. 97 s. 185; 2007 a. 130; 2009 a. 28; 2017 a. 12.

440.981 Use of title; penalty. (1) No person may use the title "licensed midwife," describe or imply that he or she is a licensed midwife, or represent himself or herself as a licensed midwife unless the person is granted a license under this subchapter or is licensed as a nurse-midwife under s. 441.15.

(2) Any person who violates sub. (1) may be fined not more than $250, imprisoned not more than 3 months, or both.

History: 2005 a. 292.

440.982 Licensure. (1) No person may engage in the practice of midwifery unless the person is granted a license under this subchapter, is granted a temporary permit pursuant to a rule promulgated under s. 440.984 (2m), or is licensed as a nurse-midwife under s. 441.15.

(1m) Except as provided in sub. (2), the department may grant a license to a person under this subchapter if all of the following apply:

(a) The person submits an application for the license to the department on a form provided by the department.

(b) The person pays the initial credential fee determined by the department under s. 440.03 (9) (a).

(c) The person submits evidence satisfactory to the department of one of the following:

1. The person holds a valid certified professional midwife credential granted by the North American Registry of Midwives or a successor organization.

2. The person holds a valid certified nurse-midwife credential granted by the American College of Nurse Midwives or a successor organization.

(d) The person submits evidence satisfactory to the department that the person 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) to provide such instruction.

(2) The department may not grant a license under this subchapter to any person who has been convicted of an offense under s. 940.22, 940.225, 944.06, 944.15, 944.17, 944.30 (1m), 944.31, 944.32, 944.33, 944.34, 948.02, 948.025, 948.051, 948.06, 948.07, 948.075, 948.08, 948.081, 948.09, 948.095, 948.10, 948.11, 948.12, or 948.125 or under s. 940.302 (2) if s. 940.302 (2) (a) 1. b. applies.

History: 2005 a. 292; 2007 a. 20, 104, 116; 2013 a. 362; 2017 a. 128; 2023 a. 224.

Cross-reference: See also ch. SPS 181, Wis. adm. code.

440.983 Renewal of licensure. (1) The renewal date for licenses granted under this subchapter is specified in s. 440.08 (2) (a). Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee determined by the department under s. 440.03 (9) (a).

(2) A licensed midwife shall, at the time that he or she applies for renewal of a license under sub. (1), submit proof satisfactory to the department of all of the following:

(a) He or she 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.

(b) He or she 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) to provide such instruction.

History: 2005 a. 292; 2007 a. 20, 104.

440.984 Rule making. (1) The department shall promulgate rules necessary to administer this subchapter. Except as provided in subs. (2), (2m), and (3), any rules regarding the practice of midwifery shall be consistent with standards regarding the practice of midwifery established by the National Association of Certified Professional Midwives or a successor organization.

(2) The rules shall allow a licensed midwife to administer oxygen during the practice of midwifery.

(2m) The rules shall provide for the granting of temporary permits to practice midwifery pending qualification for licensure.

(3) The rules may allow a midwife to administer, during the practice of midwifery, oxytocin (Pitocin) as a postpartum antihemorrhagic agent, intravenous fluids for stabilization, vitamin K, eye prophylactics, and other drugs or procedures as determined by the department.

(4) The rules may not do any of the following:

(a) Require a licensed midwife to have a nursing degree or diploma.

(b) Require a licensed midwife to practice midwifery under the supervision of, or in collaboration with, another health care provider.

(c) Require a licensed midwife to enter into an agreement, written or otherwise, with another health care provider.

(d) Limit the location where a licensed midwife may practice midwifery.

(e) Permit a licensed midwife to use forceps or vacuum extraction.

History: 2005 a. 292.

Cross-reference: See also chs. SPS 180, 181, 182, and 183, Wis. adm. code.

440.985 Informed consent. A licensed midwife shall, at an initial consultation with a client, provide a copy of the rules promulgated by the department under this subchapter and disclose to the client orally and in writing all of the following:

(1) The licensed midwife's experience and training.

(2) Whether the licensed midwife has malpractice liability insurance coverage and the policy limits of any such coverage.

(3) A protocol for medical emergencies, including transportation to a hospital, particular to each client.

(4) Any other information required by department rule.

History: 2005 a. 292.

Cross-reference: See also s. SPS 182.01, Wis. adm. code.

440.986 Disciplinary proceedings and actions. (1) Subject to the rules promulgated under s. 440.03 (1), the department may conduct investigations and hearings to determine whether a violation of this subchapter or any rule promulgated under this subchapter has occurred.

(2) Subject to the rules promulgated under s. 440.03 (1), the department may reprimand a licensed midwife or deny, limit, suspend, or revoke a license granted under this subchapter if the department finds that the applicant or the licensed midwife has done any of the following:

(a) Intentionally made a material misstatement in an application for a license or for renewal of a license.

(b) Subject to ss. 111.321, 111.322, and 111.34, practiced midwifery while his or her ability to engage in the practice was impaired by alcohol or other drugs.

(c) Advertised in a manner that is false or misleading.

(d) In the course of the practice of midwifery, made a substantial misrepresentation that was relied upon by a client.

(e) In the course of the practice of midwifery, engaged in conduct that evidences an inability to apply the principles or skills of midwifery.

(f) Obtained or attempted to obtain compensation through fraud or deceit.

(g) Allowed another person to use a license granted under this subchapter.

(h) Violated any law of this state or federal law that substantially relates to the practice of midwifery, violated this subchapter, or violated any rule promulgated under this subchapter.

(3) Subject to the rules promulgated under s. 440.03 (1), the department shall revoke a license granted under this subchapter if the licensed midwife is convicted of any of the offenses specified in s. 440.982 (2).

History: 2005 a. 292.

Cross-reference: See also ch. SPS 183, Wis. adm. code.

440.987 Advisory committee. If the department appoints an advisory committee under s. 440.042 to advise the department

on matters relating to the regulation of licensed midwives, the committee shall consist of only the following:

(1) Two members who are licensed midwives.

(2) One member who is licensed as a nurse-midwife under s. 441.15 and who practices in an out-of-hospital setting.

(3) One member who is a physician specializing in obstetrics and gynecology.

(4) One public member who has received midwifery care in an out-of-hospital setting.

History: 2005 a. 292.

440.988 Vicarious liability. No health care provider shall be liable for an injury resulting from an act or omission by a licensed midwife, even if the health care provider has consulted with or accepted a referral from the licensed midwife.

History: 2005 a. 292.

SUBCHAPTER XIV

UNIFORM ATHLETE AGENTS ACT

440.99 Definitions. In this subchapter:

(1) "Agency contract" means an agreement in which a student athlete authorizes a person to negotiate or solicit on behalf of the student athlete a professional-sports-services contract or an endorsement contract.

(2) (a) "Athlete agent" means an individual, whether or not registered under this subchapter, who does any of the following:

1. Directly or indirectly recruits or solicits or, for compensation, procures employment or offers, promises, attempts, or negotiates to obtain employment for a student athlete as a professional athlete or member of a professional sports team or organization.

2. For compensation or in anticipation of compensation in connection with a student athlete's participation in athletics, does any of the following:

a. Serves the student athlete in an advisory capacity on a matter related to finances, business pursuits, or career management decisions, unless the individual is an employee of an educational institution acting exclusively as an employee of the educational institution for the benefit of the educational institution.

b. Manages the business affairs of the student athlete by providing assistance with bills, payments, contracts, or taxes.

3. In anticipation of representing a student athlete for a purpose related to the student athlete's participation in athletics, does any of the following:

a. Gives consideration to the student athlete or another person.

b. Serves the student athlete in an advisory capacity on a matter related to finances, business pursuits, or career management decisions.

c. Manages the business affairs of the student athlete by providing assistance with bills, payments, contracts, or taxes.

(b) "Athlete agent" does not include the following:

1. An individual who acts solely on behalf of a professional sports team or organization.

2. An individual who is a licensed, registered, or certified professional and offers or provides services to a student athlete customarily provided by members of the profession, unless the individual does any of the following:

a. Recruits or solicits.

b. For compensation, procures employment or offers, promises, attempts, or negotiates to obtain employment for the student athlete as a professional athlete or member of a professional sports team or organization.

c. Receives consideration for providing the services, and the consideration is calculated using a different method than for an individual who is not a student athlete.

(3) "Athletic director" means an individual responsible for administering the overall athletic program of an educational institution or, if an educational institution has separately administered athletic programs for male students and female students, the athletic program for males or the athletic program for females, as appropriate.

(4r) "Educational institution" includes all of the following, whether public or private:

(a) An elementary school.

(b) A secondary school.

(c) A technical or vocational school.

(d) A community college.

(e) A college.

(f) A university.

(5) "Endorsement contract" means an agreement under which a student athlete is employed or receives consideration to use on behalf of the other party any value that the student athlete may have because of publicity, reputation, following, or fame obtained because of athletic ability or performance.

(5d) "Enrolled" means registered for courses and attending athletic practice or class. "Enrolls" has a corresponding meaning.

(6) "Intercollegiate sport" means a sport played at the collegiate level for which eligibility requirements for participation by a student athlete are established by a national association that promotes or regulates collegiate athletics.

(6c) "Interscholastic sport" means a sport played between educational institutions that are not community colleges, colleges, or universities.

(6r) "Licensed, registered, or certified professional" means an individual licensed, registered, or certified as an attorney, dealer in securities, financial planner, insurance agent, real estate broker or sales agent, tax consultant, accountant, or other member of a profession, other than that of athlete agent, who is licensed, registered, or certified by this state or a nationally recognized organization that licenses, registers, or certifies members of the profession on the basis of experience, education, or testing.

(7) "Professional-sports-services contract" means an agreement under which an individual is employed as a professional athlete or agrees to render services as a player on a professional sports team or with a professional sports organization.

(8) "Record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.

(8c) "Recruit or solicit" means attempt to influence the choice of an athlete agent or the choice to enter into an agency contract or both by a student athlete or, if the student athlete is a minor, a parent or guardian of the student athlete. The term does not include giving advice with respect to the selection of a particular athlete agent or with respect to entering into an agency contract if the advice is given in a family, coaching, or social situation, unless the individual giving the advice does so because of the receipt or anticipated receipt of an economic benefit, directly or indirectly, from an athlete agent.

(9) "Registration" means registration as an athlete agent under this subchapter.

(9m) "Sign" means any of the following, with present intent to authenticate or adopt a record:

(a) To execute or adopt a tangible symbol.

(b) To attach to or logically associate with the record an electronic symbol, sound, or process.

Chapter SPS 180

AUTHORITY AND 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.

History: CR 06-096: cr. Register December 2006 No. 612, eff. 5-1-07; correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671; CR 19-066: am. Register January 2020 No. 769, eff. 2-1-20.

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.

History: CR 06-096: cr. Register December 2006 No. 612, eff. 5-1-07; CR 08-087: cr. (1m), (3m), (11) Register August 2011 No. 668, eff. 9-1-11; corrections in (4) and (6) made under s. 13.92 (4) (b) 6. and 7., Stats., Register August 2011 No. 668; correction in (intro.), (9), (10) made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671; CR 19-066: am. (intro.), renum. (1m) (intro.) to (1m) and am., r. (1m) (a) to (c), am. (3m), r. (6), am. (8), (11) Register January 2020 No. 769, eff. 2-1-20.

Chapter SPS 181

APPLICATIONS FOR LICENSURE, RENEWAL OF LICENSES AND TEMPORARY PERMITS

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.

(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: 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 the department's website at: http://dsps.wi.gov.

(1m) RECIPROCITY FOR SERVICE MEMBERS, FORMER SERVICE 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: Application forms are available on the department's website at 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: 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 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, 1-888-842-4784. The American College of Nurse-Midwives may be contacted at 8403 Colesville Road, Suite 1550, Silver Spring, MD 20910, (240) 485-1800.

History: CR 06-096: cr. Register December 2006 No. 612, eff. 5-1-07; CR 08-087: cr. (1) (d), (2) (c) 1., 2., renum. (2) (c) to be (2) (c) (intro.) and am., am. (4) (b) 4. Register August 2011 No. 668, eff. 9-1-11; CR 19-066: am. (1) (a), (c), (2) (a), (4) (a) 2. b., f. Register January 2020 No. 769, eff. 2-1-20; CR 21-056: cr. (1m) Register July 2023 No. 811, eff. 8-1-23.

Chapter SPS 182

STANDARDS OF 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.

History: CR 06-096: cr. Register December 2006 No. 612, eff. 5-1-07.

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 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).

History: CR 06-096: cr. Register December 2006 No. 612, eff. 5-1-07; CR 19-066: am. (1) (intro.), (e), (1m) Register January 2020 No. 769, eff. 2-1-20.

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.

(e) Vitamin K for the prophylaxis of hemorrhagic disease of the newborn.

(f) RHo (D) immune globulin for the prevention of RHo (D) sensitization in RHo (D) negative women.

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

(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 and advanced practice nurses, 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), 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:

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
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
5% dextrose in lactated Ringer's solution (D5LR), unless unavailable or impractical in which case 0.9% sodium chloride may be administered	To achieve maternal stabilization during uncontrolled postpartum hemorrhage or anytime blood loss is accompanied by tachycardia, hypotension, decreased level of consciousness, pallor or diaphoresis	First liter run in at a wide-open rate, the second liter titrated to client's condition	IV catheter 18 gauge or greater (2 if hemorrhage is severe)	Until maternal stabilization is achieved or transfer to a hospital is complete

(4) CONSULTATION AND REFERRAL. (a) A licensed midwife shall consult with a licensed physician 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.

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 licensed physician or certified 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. Hyperemisis 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. Insulin requiring diabetes mellitus.

5. Known maternal congenital abnormalities 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 affecting normal vaginal births, including tumors and malformations.

11. Alcoholism or abuse.

12. Drug addiction or abuse.

13. Confirmed AIDS status.

14. Uncontrolled current serious psychiatric illness.

15. Social or familial conditions unsatisfactory for out-of-hospital maternity care services.

16. Fetus with suspected or diagnosed congenital abnormalities that may require immediate medical intervention.

History: CR 06-096: cr. Register December 2006 No. 612, eff. 5-1-07; renumbers to (4) (b) 1. za., zb. and zc. made under s. 13.93 (2m) (b) 1., Stats., Register November 2007 No. 623.

Chapter SPS 183

GROUNDS FOR DISCIPLINE

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 midwife 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.

History: CR 06-096: cr. Register December 2006 No. 612, eff. 5-1-07; CR 19-066: am. (1) (intro.), (g), (v), (2) to (4) Register January 2020 No. 769, eff. 2-1-20.

Chapter SPS 183

APPENDIX I

ESSENTIAL DOCUMENTS OF THE NATIONAL ASSOCIATION OF CERTIFIED PROFESSIONAL MIDWIVES

Contents

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

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

COMMITTEE OPINION

Number 697 • April 2017
(Reaffirmed 2020)

(Replaces Committee Opinion Number 669, August 2016)

Committee on Obstetric Practice

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Obstetric Practice in collaboration with committee members Joseph R. Wax, MD, and William H. Barth Jr, MD.

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

INTERIM UPDATE: This Committee Opinion is updated as highlighted to reflect a limited, focused change in the presentation of data regarding perinatal mortality in planned home births.

Planned Home Birth

ABSTRACT: In the United States, approximately 35,000 births (0.9%) per year occur in the home. Approximately one fourth of these births are unplanned or unattended. Although the American College of Obstetricians and Gynecologists believes that hospitals and accredited birth centers are the safest settings for birth, each woman has the right to make a medically informed decision about delivery. Importantly, women should be informed that several factors are critical to reducing perinatal mortality rates and achieving favorable home birth outcomes. These factors include the appropriate selection of candidates for home birth; the availability of a certified nurse–midwife, certified midwife or midwife whose education and licensure meet International Confederation of Midwives' Global Standards for Midwifery Education, or physician practicing obstetrics within an integrated and regulated health system; ready access to consultation; and access to safe and timely transport to nearby hospitals. The Committee on Obstetric Practice considers fetal malpresentation, multiple gestation, or prior cesarean delivery to be an absolute contraindication to planned home birth.

Recommendations

- Women inquiring about planned home birth should be informed of its risks and benefits based on recent evidence. Specifically, they should be informed that although planned home birth is associated with fewer maternal interventions than planned hospital birth, it also is associated with a more than twofold increased risk of perinatal death (1–2 in 1,000) and a threefold increased risk of neonatal seizures or serious neurologic dysfunction (0.4–0.6 in 1,000). These observations may reflect fewer obstetric risk factors among women planning home birth compared with those planning hospital birth. Although the American College of Obstetricians and Gynecologists (the College) believes that hospitals and accredited birth centers are the safest settings for birth, each woman has the right to make a medically informed decision about delivery.
- Women should be informed that several factors are critical to reducing perinatal mortality rates and achieving favorable home birth outcomes. These factors include the appropriate selection of candidates for home birth; the availability of a certified nurse–midwife, certified midwife or midwife whose education and licensure meet International Confederation of Midwives' Global Standards for Midwifery Education, or physician practicing obstetrics within an integrated and regulated health system; ready access to consultation; and access to safe and timely transport to nearby hospitals.
- The Committee on Obstetric Practice considers fetal malpresentation, multiple gestation, or prior cesarean delivery to be an absolute contraindication to planned home birth.

In the United States, approximately 35,000 births (0.9%) per year occur in the home (1). Approximately one fourth of these births are unplanned or unattended (2). Among women who originally intend to give birth in a hospital or those who make no provisions for professional care during childbirth, home births are associated with high rates of perinatal and neonatal mortality (3). The relative risk versus benefit of a planned home birth, however, remains the subject of debate.

High-quality evidence that can inform this debate is limited. To date, there have been no adequate randomized clinical trials of planned home birth (4). In developed

countries where home birth is more common than in the United States, attempts to conduct such studies have been unsuccessful, largely because pregnant women have been reluctant to participate in clinical trials that involve randomization to home or hospital birth (5, 6). Consequently, most information on planned home births comes from observational studies. Observational studies of planned home birth often are limited by methodological problems, including small sample sizes (7–10); lack of an appropriate control group (11–15); reliance on birth certificate data with inherent ascertainment problems (2, 16–18); reliance on voluntary submission of data or self-reporting (7, 12, 14, 15, 19); limited ability to distinguish accurately between planned and unplanned home births (16, 20); variation in the skill, training, and certification of the birth attendant (14–16, 21); and an inability to account for and accurately attribute adverse outcomes associated with antepartum or intrapartum transfers (8, 16, 22). Some recent observational studies overcome many of these limitations, describing planned home births within tightly regulated and integrated health care systems, attended by highly trained licensed midwives with ready access to consultation and safe, timely transport to nearby hospitals (7, 8, 10, 11, 16, 19, 23–28). However, these data may not be generalizable to many birth settings in the United States where such integrated services are lacking. For the same reasons, clinical guidelines for the intrapartum care of women in the United States that are based on these results and are supportive of planned home birth for low-risk term pregnancies also may not currently be generalizable (29). Furthermore, no studies are of sufficient size to compare maternal mortality between planned home and hospital birth and few, when considered alone, are large enough to compare perinatal and neonatal mortality rates. Despite these limitations, when viewed collectively, recent reports clarify a number of important issues regarding the maternal and newborn outcomes of planned home birth when compared with planned hospital births.

Women planning a home birth may do so for a number of reasons, often out of a desire to avoid medical interventions and the hospital atmosphere (30). Recent studies have found that when compared with planned hospital births, planned home births are associated with fewer maternal interventions, including labor induction or augmentation, regional analgesia, electronic fetal heart rate monitoring, episiotomy, operative vaginal delivery, and cesarean delivery (Table 1). Planned home births also are associated with fewer vaginal, perineal, and third-degree or fourth-degree lacerations and less maternal infectious morbidity (18, 27, 31, 32). These observations may reflect fewer obstetric risk factors among women planning home births compared with those planning hospital births. Parous women comprise a larger proportion of those planning out-of-hospital births (27, 32). Compared with nulliparous women, parous women collectively experience significantly lower rates of obstetric intervention, maternal morbidity, and neonatal morbidity and mortality, regardless of birth location. Those planning home births also are more likely to deliver in that setting than nulliparous women (15, 27, 33). For these reasons, recommendations regarding the intrapartum care of healthy nulliparous and parous women may differ outside of the United States (29). Also, proportionately more home births are attended by midwives than planned hospital births, and randomized trials show that midwife-led care is associated with fewer intrapartum interventions (34).

Strict criteria are necessary to guide selection of appropriate candidates for planned home birth. In the United States, for example, where selection criteria may not be applied broadly, intrapartum (1.3 in 1,000) and neonatal (0.76 in 1,000) deaths among low-risk women planning home birth are more common than expected when compared with rates for low-risk women planning hospital delivery (0.4 in 1,000 and 0.17 in 1,000, respectively), consistent with the findings of an earlier meta-analysis (15, 31, 33). Additional evidence from the United States shows that planned home birth of a breech-presenting fetus is associated with an intrapartum mortality rate of 13.5 in 1,000 and neonatal mortality rate of 9.2 in 1,000 (15). United States data limited to

Table 1. Maternal Events Associated With U.S. Planned Out-of-Hospital Births Versus Hospital Births ⇦

Event	Planned Out-of-Hospital Birth (Events per 1,000 births)	Planned Hospital Birth (Events per 1,000 births)	Adjusted Odds Ratio	95% CI
Labor induction	48	304	0.11	0.09–0.12
Labor augmentation	75	263	0.21	0.19–0.24
Operative vaginal delivery	10	35	0.24	0.17–0.34
Cesarean delivery	53	247	0.18	0.16–0.22
Blood transfusion/hemorrhage	6	4	1.91	1.25–2.93
Severe perineal lacerations	9	13	0.69	0.49–0.98

Abbreviation: CI, confidence interval.

Data from Snowden JM, Tilden EL, Snyder J, Quigley B, Caughey AB, Cheng YW. Planned out-of-hospital birth and birth outcomes. N Engl J Med 2015;373:2642–53.

singleton-term pregnancies demonstrate a higher risk of 5-minute Apgar scores less than 7, less than 4, and 0; perinatal death; and neonatal seizures with planned home birth, although the absolute risks remain low (Table 2) (17, 18, 32).

Although patients with one prior cesarean delivery were considered candidates for home birth in two Canadian studies, details of the outcomes specific to patients attempting home vaginal birth after cesarean delivery were not provided (24, 25). In England, women planning a home trial of labor after cesarean delivery (TOLAC) exhibited fewer obstetric risk factors, were more likely to deliver vaginally, and experienced similar maternal and perinatal outcomes compared with those planning an in-hospital TOLAC (35). In contrast, a recent U.S. study showed that planned home TOLAC was associated with an intrapartum fetal death rate of 2.9 in 1,000, which is higher than the reported rate of 0.13 in 1,000 for planned hospital TOLAC (36, 37). This observation is of particular concern in light of the increasing number of home vaginal births after cesarean delivery (38). Because of the risks associated with TOLAC, and specifically considering that uterine rupture and other complications may be unpredictable, the College recommends that TOLAC be undertaken in facilities with trained staff and the ability to begin an emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.

The decision to offer and pursue TOLAC in a setting in which the option of immediate cesarean delivery is more limited should be considered carefully by patients and their health care providers. In such situations, the best alternative may be to refer patients to facilities with available resources. Health care providers and insurers should do all they can to facilitate transfer of care or comanagement in support of a desired TOLAC, and such plans should be initiated early in the course of antenatal care (39).

Recent cohort studies reporting comparable perinatal mortality rates among planned home and hospital births describe the use of strict selection criteria for appropriate candidates (23–25). These criteria include the absence of any preexisting maternal disease, the absence of significant disease arising during the pregnancy, a singleton fetus, a cephalic presentation, gestational age greater than 36–37 completed weeks and less than 41–42 completed weeks of pregnancy, labor that is spontaneous or induced as an outpatient, and that the patient has not been transferred from another referring hospital. In the absence of such criteria, planned home birth is clearly associated with a higher risk of perinatal death (15, 26, 40). The Committee on Obstetric Practice considers fetal malpresentation, multiple gestation, or prior cesarean delivery to be an absolute contraindication to planned home birth.

Another factor influencing the safety of planned home birth is the availability of safe and timely intrapartum transfer of the laboring patient. The reported risk of needing an intrapartum transport to a hospital is 23–37% for nulliparous women and 4–9% for multiparous women. Most of these intrapartum transports are

Table 2. Adverse Perinatal Events Associated With U.S. Planned Home Births Versus Hospital Births ⇦

Event	Planned Home Birth (Events per 1,000 Births)	Hospital Birth (Events per 1,000 Births)	Odds Ratio	95% CI
5-minute Apgar score				
<7	24.2*	11.7*	2.42*	2.13–2.74*
	23†§	18†	1.31†	1.04–1.66†
<4	3.7*	2.43*	1.87*	1.36–2.58*
	6†§	4†	1.56†	0.98–2.47*
0	1.63‡	0.16†	10.55‡	8.62–12.93‡
Neonatal seizures (or serious neurologic dysfunction‡)	0.58*	0.22*	3.08*	1.44–6.58*
	0.86‡	0.22†	3.80†	2.80–5.16†
	1.3†§	0.4†	3.60†	1.36–9.50†
Perinatal mortality (fetal death and neonatal mortality)	3.9†§	1.8†	2.43†	1.37–4.30†

Abbreviation: CI, confidence interval.

*Cheng YW, Snowden JM, King TL, Caughey AB. Selected perinatal outcomes associated with planned home births in the United States. Am J Obstet Gynecol 2013;209:325.e1–8.

†Snowden JM, Tilden EL, Snyder J, Quigley B, Caughey AB, Cheng YW. Planned out-of-hospital birth and birth outcomes. N Engl J Med 2015;373:2642–53.

‡Grunebaum A, McCullough LB, Sapra KJ, Brent RL, Levene MI, Arabin B, et al. Apgar score of 0 at 5 minutes and neonatal seizures or serious neurologic dysfunction in relation to birth setting. Am J Obstet Gynecol 2013;209:323.e1–6.

§Includes planned birth center and home births.

for lack of progress in labor, nonreassuring fetal status, need for pain relief, hypertension, bleeding, and fetal malposition (27, 41, 42). The relatively low perinatal and newborn mortality rates reported for planned home births from Ontario, British Columbia, and the Netherlands were from highly integrated health care systems with established criteria and provisions for emergency intrapartum transport (23–25). Cohort studies conducted in areas without such integrated systems and those where the receiving hospital may be remote, with the potential for delayed or prolonged intrapartum transport, generally report higher rates of intrapartum and neonatal death (6, 9, 11, 15, 22). Even in regions with integrated care systems, increasing distance from the hospital is associated with longer transfer times and the potential for increased adverse outcomes. However, no specific thresholds for time or distance have been identified (43, 44). The College believes that the availability of timely transfer and an existing arrangement with a hospital for such transfers is a requirement for consideration of a home birth. When antepartum, intrapartum, or postpartum transfer of a woman from home to a hospital occurs, the receiving health care provider should maintain a nonjudgmental demeanor with regard to the woman and those individuals accompanying her to the hospital.

A characteristic common to those cohort studies reporting comparable rates of perinatal mortality is the provision of care by uniformly highly educated and trained certified midwives who are well integrated into the health care system (23–25, 27). In the United States, certified nurse–midwives and certified midwives are certified by the American Midwifery Certification Board. This certification depends on the completion of an accredited educational program and meeting standards set by the American Midwifery Certification Board. In comparison with planned out-of-hospital births attended by American Midwifery Certification Board-certified midwives, planned out-of-hospital births by midwives who do not hold this certification have higher perinatal morbidity and mortality rates (18). At this time, for quality and safety reasons, the College specifically supports the provision of care by midwives who are certified by the American Midwifery Certification Board (or its predecessor organizations) or whose education and licensure meet the International Confederation of Midwives Global Standards for Midwifery Education. The College does not support provision of care by midwives who do not meet these standards.

Although the College believes that hospitals and accredited birth centers are the safest settings for birth, each woman has the right to make a medically informed decision about delivery (45). Importantly, women should be informed that several factors are critical to reducing perinatal mortality rates and achieving favorable home birth outcomes. These factors include the appropriate selection of candidates for home birth; the availability of a certified nurse–midwife, certified midwife or midwife whose education and licensure meet International Confederation of Midwives' Global Standards for Midwifery Education, or physician practicing obstetrics within an integrated and regulated health system; ready access to consultation; and access to safe and timely transport to nearby hospitals.

For More Information

The American College of Obstetricians and Gynecologists has identified additional resources on topics related to this document that may be helpful for ob-gyns, other health care providers, and patients. You may view these resources at www.acog.org/More-Info/PlannedHomeBirth.

These resources are for information only and are not meant to be comprehensive. Referral to these resources does not imply the American College of Obstetricians and Gynecologists' endorsement of the organization, the organization's website, or the content of the resource. The resources may change without notice.

References

1. MacDorman MF, Matthews TJ, Declercq E. Trends in out-of-hospital births in the United States, 1990-2012. NCHS Data Brief 2014;144:1–8. [PubMed] [Full Text] ⇦
2. Wax JR, Pinette MG, Cartin A, Blackstone J. Maternal and newborn morbidity by birth facility among selected United States 2006 low-risk births. Am J Obstet Gynecol 2010;202:152.e1–5. [PubMed] [Full Text] ⇦
3. Collaborative survey of perinatal loss in planned and unplanned home births. Northern Region Perinatal Mortality Survey Coordinating Group. BMJ 1996;313:1306–9. [PubMed] [Full Text] ⇦
4. Olsen O, Clausen JA. Planned hospital birth versus planned home birth. Cochrane Database of Systematic Reviews 2012, Issue 9. Art. No.: CD000352. DOI: 10.1002/14651858.CD000352.pub2. [PubMed] [Full Text] ⇦
5. Dowswell T, Thornton JG, Hewison J, Lilford RJ, Raisler J, Macfarlane A, et al. Should there be a trial of home versus hospital delivery in the United Kingdom? BMJ 1996;312:753–7. [PubMed] [Full Text] ⇦
6. Hendrix M, Van Horck M, Moreta D, Nieman F, Nieuwenhuijze M, Severens J, et al. Why women do not accept randomisation for place of birth: feasibility of a RCT in The Netherlands. BJOG 2009;116:537–42; discussion 542–4. [PubMed] [Full Text] ⇦
7. Wiegers TA, Keirse MJ, van der Zee J, Berghs GA. Outcome of planned home and planned hospital births in low risk pregnancies: prospective study in midwifery practices in The Netherlands. BMJ 1996;313:1309–13. [PubMed] [Full Text] ⇦
8. Ackermann-Liebrich U, Voegeli T, Gunter-Witt K, Kunz I, Zullig M, Schindler C, et al. Home versus hospital deliveries: follow up study of matched pairs for procedures and outcome. Zurich Study Team. BMJ 1996;313:1313–8. [PubMed] [Full Text] ⇦

9. Davies J, Hey E, Reid W, Young G. Prospective regional study of planned home births. Home Birth Study Steering Group. BMJ 1996;313:1302–6. [PubMed] [Full Text] ⇦

10. Janssen PA, Lee SK, Ryan EM, Etches DJ, Farquharson DF, Peacock D, et al. Outcomes of planned home births versus planned hospital births after regulation of midwifery in British Columbia. CMAJ 2002;166:315–23. [PubMed] [Full Text] ⇦

11. Woodcock HC, Read AW, Bower C, Stanley FJ, Moore DJ. A matched cohort study of planned home and hospital births in Western Australia 1981-1987 [published erratum appears in Midwifery 1995;11:99]. Midwifery 1994;10: 125–35. [PubMed] [Full Text]⇦

12. Anderson RE, Murphy PA. Outcomes of 11,788 planned home births attended by certified nurse-midwives. A retrospective descriptive study. J Nurse Midwifery 1995;40: 483–92. [PubMed] ⇦

13. Murphy PA, Fullerton J. Outcomes of intended home births in nurse-midwifery practice: a prospective descriptive study. Obstet Gynecol 1998;92:461–70. [PubMed] ⇦

14. Johnson KC, Daviss BA. Outcomes of planned home births with certified professional midwives: large prospective study in North America. BMJ 2005;330:1416. [PubMed] [Full Text] ⇦

15. Cheyney M, Bovbjerg M, Everson C, Gordon W, Hannibal D, Vedam S. Outcomes of care for 16,924 planned home births in the United States: the Midwives Alliance of North America Statistics Project, 2004 to 2009. J Midwifery Womens Health 2014;59:17–27. [PubMed] [Full Text] ⇦

16. Pang JW, Heffelfinger JD, Huang GJ, Benedetti TJ, Weiss NS. Outcomes of planned home births in Washington State: 1989-1996. Obstet Gynecol 2002;100:253–9. [PubMed] [*Obstetrics & Gynecology*] ⇦

17. Grunebaum A, McCullough LB, Sapra KJ, Brent RL, Levene MI, Arabin B, et al. Apgar score of 0 at 5 minutes and neonatal seizures or serious neurologic dysfunction in relation to birth setting. Am J Obstet Gynecol 2013;209: 323.e1–6. [PubMed] [Full Text]⇦

18. Cheng YW, Snowden JM, King TL, Caughey AB. Selected perinatal outcomes associated with planned home births in the United States. Am J Obstet Gynecol 2013;209:325.e1–8. [PubMed] [Full Text] ⇦

19. Lindgren HE, Radestad IJ, Christensson K, Hildingsson IM. Outcome of planned home births compared to hospital births in Sweden between 1992 and 2004. A population-based register study. Acta Obstet Gynecol Scand 2008;87:751–9. [PubMed] [Full Text] ⇦

20. Mori R, Dougherty M, Whittle M. An estimation of intrapartum-related perinatal mortality rates for booked home births in England and Wales between 1994 and 2003 [published erratum appears in BJOG 2008;115:1590]. BJOG 2008;115:554–9. [PubMed] [Full Text] ⇦

21. Schramm WF, Barnes DE, Bakewell JM. Neonatal mortality in Missouri home births, 1978-84. Am J Public Health 1987;77:930–5. [PubMed] [Full Text] ⇦

22. Parratt J, Johnston J. Planned homebirths in Victoria, 1995-1998. Aust J Midwifery 2002;15:16–25. [PubMed] ⇦

23. de Jonge A, Geerts CC, van der Goes BY, Mol BW, Buitendijk SE, Nijhuis JG. Perinatal mortality and morbidity up to 28 days after birth among 743 070 low-risk planned home and hospital births: a cohort study based on three merged national perinatal databases. BJOG 2015;122:720–8. [PubMed] [Full Text] ⇦

24. Janssen PA, Saxell L, Page LA, Klein MC, Liston RM, Lee SK. Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician [published erratum appears in CMAJ 2009;181:617]. CMAJ 2009;181:377–83. [PubMed] [Full Text] ⇦

25. Hutton EK, Reitsma AH, Kaufman K. Outcomes associated with planned home and planned hospital births in low-risk women attended by midwives in Ontario, Canada, 2003-2006: a retrospective cohort study. Birth 2009;36:180–9. [PubMed] ⇦

26. Kennare RM, Keirse MJ, Tucker GR, Chan AC. Planned home and hospital births in South Australia, 1991-2006: differences in outcomes. Med J Aust 2010;192:76–80. [PubMed] [Full Text] ⇦

27. Brocklehurst P, Hardy P, Hollowell J, Linsell L, Macfarlane A, McCourt C, et al. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. Birthplace in England Collaborative Group. BMJ 2011;343:d7400. [PubMed] [Full Text] ⇦

28. Hutton EK, Cappelletti A, Reitsma AH, Simioni J, Horne J, McGregor C, et al. Outcomes associated with planned place of birth among women with low-risk pregnancies. CMAJ 2016;188:E80–90. [PubMed] [Full Text] ⇦

29. National Institute for Health and Care Excellence. Intrapartum care for healthy women and babies. Clinical Guideline 190. London: NICE; 2014. Available at: https://www.nice.org.uk/guidance/cg190. Retrieved April 20, 2016. ⇦

30. Neuhaus W, Piroth C, Kiencke P, Gohring UJ, Mallman P. A psychosocial analysis of women planning birth outside hospital. J Obstet Gynaecol 2002;22:143–9. [PubMed] ⇦

31. Wax JR, Lucas FL, Lamont M, Pinette MG, Cartin A, Blackstone J. Maternal and newborn outcomes in planned home birth vs planned hospital births: a metaanalysis. Am J Obstet Gynecol 2010;203:243.e1–8. [PubMed] [Full Text] ⇦

32. Snowden JM, Tilden EL, Snyder J, Quigley B, Caughey AB, Cheng YW. Planned out-of-hospital birth and birth outcomes. N Engl J Med 2015;373:2642–53. [PubMed] [Full Text] ⇦

33. Worley KC, McIntire DD, Leveno KJ. The prognosis for spontaneous labor in women with uncomplicated term pregnancies: implications for cesarean delivery on maternal request. Obstet Gynecol 2009;113:812–6. [PubMed] [*Obstetrics & Gynecology*] ⇦

34. Sandall J, Soltani H, Gates S, Shennan A, Devane D. Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database of Systematic Reviews 2015, Issue 9. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub4. [PubMed] [Full Text] ⇦

35. Rowe R, Li Y, Knight M, Brocklehurst P, Hollowell J. Maternal and perinatal outcomes in women planning vaginal birth after caesarean (VBAC) at home in England:

secondary analysis of the Birthplace national prospective cohort study. BJOG 2015; DOI: 10.1111/1471-0528.13546. [PubMed] [Full Text] ⇦

36. Cox KJ, Bovbjerg ML, Cheyney M, Leeman LM. Planned home VBAC in the United States, 2004-2009: outcomes, maternity care practices, and implications for shared decision making. Birth 2015;42:299–308. [PubMed] [Full Text] ⇦
37. Landon MB, Hauth JC, Leveno KJ, Spong CY, Leindecker S, Varner MW, et al. Maternal and perinatal outcomes associated with a trial of labor after prior cesarean delivery. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. N Engl J Med 2004;351:2581–9. [PubMed] [Full Text] ⇦
38. MacDorman MF, Declercq E, Mathews TJ, Stotland N. Trends and characteristics of home vaginal birth after cesarean delivery in the United States and selected States. Obstet Gynecol 2012;119:737–44. [PubMed] [*Obstetrics & Gynecology*] ⇦
39. Vaginal birth after previous cesarean delivery. ACOG Practice Bulletin No. 115. American College of Obstetricians and Gynecologists. Obstet Gynecol 2010;116:450–63. [PubMed] ⇦
40. Bastian H, Keirse MJ, Lancaster PA. Perinatal death associated with planned home birth in Australia: population based study. BMJ 1998;317:384–8. [PubMed] [Full Text] ⇦
41. Wax JR, Pinette MG, Cartin A. Home versus hospital birth—process and outcome. Obstet Gynecol Surv 2010; 65:132–40. [PubMed] ⇦
42. Blix E, Kumle M, Kjaergaard H, Oian P, Lindgren HE. Transfer to hospital in planned home births: a systematic review. BMC Pregnancy Childbirth 2014;14:179. [PubMed] [Full Text] ⇦
43. Paranjothy S, Watkins WJ, Rolfe K, Adappa R, Gong Y, Dunstan F, et al. Perinatal outcomes and travel time from home to hospital: Welsh data from 1995 to 2009. Acta Paediatr 2014;103:e522–7. [PubMed] ⇦
44. Rowe RE, Townend J, Brocklehurst P, Knight M, Macfarlane A, McCourt C, et al. Duration and urgency of transfer in births planned at home and in freestanding midwifery units in England: secondary analysis of the birthplace national prospective cohort study. BMC Pregnancy Childbirth 2013;13:224. [PubMed] [Full Text] ⇦
45. Informed consent. ACOG Committee Opinion No. 439. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009; 114:401–8. [PubMed] ⇦

ISSN 1074-861X

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

Planned home birth. Committee Opinion No. 697. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;129:e117–22.

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: 02/18/25 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Midwife Advisory Committee			
4) Meeting Date: 03/18/2025	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Licensed Midwives – Informed Consent Form – Discussion and Consideration.	
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? ☐ Yes ☒ No	9) Name of Case Advisor(s), if applicable:	
10) Describe the issue and action that should be addressed: Discussion and consideration of updates to DSPS form #2795 related to Informed Consent			
11) Authorization Whitney DeVoe — Signature of person making this request — Date: 02/18/25 Supervisor (Only required for post agenda deadline items) — Date Executive Director signature (Indicates approval for post agenda deadline items) — Date			
Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the Agenda Items folders. 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.			

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
Website: http://dsps.wi.gov

DIVISION OF PROFESSIONAL CREDENTIAL PROCESSING

LICENSED MIDWIVES – INFORMED CONSENT FORM

Last Name	First Name	MI	Former / Maiden Name(s)
Address (number street, city, state, zip code)			**Daytime Telephone Number**
			___ - ___ - ____

TRAINING: 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)	Dates To (month/year)
		__ / ____	__ / ____
		__ / ____	__ / ____
		__ / ____	__ / ____
		__ / ____	__ / ____
		__ / ____	__ / ____
		__ / ____	__ / ____
		__ / ____	__ / ____

CERTIFICATION: 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
		__ / __ / ____
		__ / __ / ____
		__ / __ / ____
		__ / __ / ____
		__ / __ / ____

MIDWIFE EXPERIENCE:

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:	

MALPRACTICE LIABILITY INSURANCE:

Do you have malpractice liability insurance coverage? ☐ Yes ☐ No List policy limits of coverage (if applicable):

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.)**

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

ACKNOWLEDGEMENT BY CLIENT: I acknowledge that I have received the oral and written disclosures required under Wis. Admin. Code § SPS 182.02.

Printed Name of Client	
Signature of Client (If unable to provide a digital signature print and sign form.)	**Date**
	☐☐ / ☐☐ / ☐☐☐☐