Official Title: Hospital Waterbirth: A pilot randomized control study

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I. BACKGROUND AND SIGNIFICANCE

Waterbirth is a method of pain control during childbirth that has been growing in popularity since the 1970s.[1,2,3,4] The safety of first stage water immersion is well established and is considered an effective method of pain control.[3-5] Waterbirth advocates claim that it is a low-intervention, physiologic means of pain control for laboring women.[3] The American College of Nurse-Midwives (ACNM) position statement supports the safety of waterbirths attended by qualified maternity providers, yet the 2016 statement by American College of Obstetricians and Gynecologists (ACOG) and endorsed by the American Academy of Pediatrics (AAP) recommended that all waterbirths in the United States be conducted in the context of a clinical trial.[6,7]

In 2019, ACOG updated Committee Opinion Number 766, *Approaches to Limit Interventions During Labor and Birth*, recommending that clinicians be familiar with approaches to limit unnecessary interventions in labor and birth for low-risk women.[8] While not addressed in the committee opinion, waterbirth may be a less interventive option for pain control compared to standard interventions (e.g. IV narcotics, epidural anesthesia). A literature search was conducted using OVID Medline, CINAHL, PsycInfo, Alt Health watch, Scopus, Embase, Google Scholar, and reference lists of each article. Current literature associates waterbirth with high levels of maternal satisfaction and increased perception of control.[1,2,9] It is also associated with a shorter duration of labor.[3, 18] Waterbirth is also associated with increased cases of intact perineum, low likelihood of episiotomy, increased buoyancy, mobility, and maternal upright position, as well as decreased blood pressure.[1,3,4,10,11,12,13,18] Only five randomized control trials have been conducted and published.[15-17,19,20] In the recently updated Cochrane Database of Systematic Reviews Immersion in Water During Labor and Birth, four RCTs of water immersion for both first and second stage labor were included[15-17,19] and two studies were of immersion in the second stage of labor only.[4,19,20] The trials were conducted in Iran, China, the United Kingdom, and South Africa; and of these, only three are available in English.[4,31] Results from the trials are available in a secondary source.[31,39] There have been no RCTs of waterbirth conducted in the United States (USA) and to our knowledge, there are no ongoing trials of waterbirth.

Large retrospective, prospective, and observational trials have also been conducted, mostly outside of the United States.[21-26] These studies report measurable clinical markers: ***maternal markers*** include rate of spontaneous vaginal birth (SVD), rate of cesarean section, length of labor, blood loss, use of pharmacological or anesthetic analgesia, and perineal lacerations; ***neonatal markers*** include Apgar score, admission to neonatal intensive care (NICU), respiratory distress, and rate of infection.[21-26] The most controversial aspect of waterbirth is the unknown risks and/or benefits to the neonate. Several studies and meta-analyses have focused entirely on neonatal outcomes. One systematic review and meta-analysis included only data from hospital births and found no increased risk to the neonate; however, there is significant heterogeneity among the included studies.[26-31]

Despite the current body of literature, there are many limitations to use of the above studies in the United States. The authors of the Cochrane review note that studies are not comparable and there were wide protocol and data collection variations.[4] Moreover, the studies come from a wide

variety of countries and health systems, which limits their generalizability and applicability in the United States. Researchers estimate that approximately 6-15% of US hospitals offer waterbirth.[33]

Per ACOG Committee Opinion Number 766, obstetric providers should be familiar with and consider using measures to decrease labor interventions, waterbirth may be one such option with the additional benefit of increasing maternal satisfaction. The 2014 ACNM statement on waterbirth supports waterbirth as an option for low-risk women because it "provides comfort, supports relaxation, and is a safe and effective non-pharmacologic pain relief strategy that promotes physiologic childbirth".[7] The Cochrane database recommends that waterbirth trials be conducted in midwife-led settings.[4] While our hospital has a multiple types of maternity care providers, we also house the largest group of Certified Nurse Midwives in Wisconsin, making our site ideal for this trail. Moreover, given hospital location, we will offer study participation to a diverse group of low-risk, healthy women with a term pregnancy planning to give birth in the hospital setting. Therefore, we aim to pilot the first randomized control trail for waterbirths in the United States, in order to (1) assess the feasibility of conducting a larger, multi-site trail, (2) explore or test differences in maternal/neonatal outcomes, and (3) explore or test differences in patient satisfaction.

II. SPECIFIC AIMS

The proposed pilot randomized control trial will be approached as a feasibility study to explore or test (if sample size permits) our hypotheses. Additional sample size analyses have been conducted since this study was first submitted as we continue to explore the feasibility of this study in hopes of answering our primary outcome.

Primary outcome: Women in the waterbirth group will use less IV narcotic and epidural anesthesia than women in the land birth group.

We further seek to address the following additional specific aims:

Specific Aim 1: Evaluate waterbirth outcomes in adult low-risk laboring women randomized to waterbirth in comparison to women randomized to birth on land.

> **Hypothesis 1a.** Women in the waterbirth cohort will have shorter labor duration than women in the land cohort.
> **Hypothesis 1b.** Women in the waterbirth cohort will be more likely to initiate breastfeeding before discharge.

Specific Aim 2: Evaluate the safety of waterbirth in adult low-risk laboring women randomized to waterbirth in comparison to women randomized to birth on land.

> **Hypothesis 2a.** Women in the waterbirth cohort will not experience more adverse outcomes (e.g., postpartum hemorrhage, third- or fourth-degree perineal lacerations, etc.) than women in the control group.

Specific Aim 3: Evaluate satisfaction with waterbirth in adult low-risk laboring women randomized to waterbirth in comparison to women randomized to birth on land.

> **Hypothesis 3.** Women in the waterbirth cohort will experience greater satisfaction scores on the revised United States Birth Satisfaction Scale-Revised (US-BSS-R),[34,36,37] than women in the land cohort.

Specific Aim 4: Evaluate the safety of waterbirth for term low-risk neonates in comparison to land birth term low-risk neonates.

> **Hypothesis 4a.** Infants in the waterbirth group will not experience more adverse outcomes (e.g., NICU admission, APGAR scores <7, umbilical cord injury, etc.) than infants born to women in the land cohort.
> **Hypothesis 4b.** Infants in the waterbirth group will experience fewer instrumental (e.g., forceps, vacuum, etc.) or cesarean deliveries.
> **Hypothesis 4c.** Infants born to women in the waterbirth cohort will have immediate skin-to-skin contact.

III. STUDY POPULATION

The study participants will be healthy, low-risk, adult women seeking prenatal care with the Aurora UW faculty midwives and obstetricians at Aurora Sinai Medical Center. This will be a convenience sample of patients who voluntarily present for routine prenatal care, agree to study participation, and are randomized to either waterbirth or conventional land birth. As further research is needed to truly determine our desired sample size for testing our proposed hypothesizes, our study aims to determine the feasibility of exploring or testing these hypotheses. This may allow us to make estimations for sample size to plan a larger, randomized controlled study in the future, or to contribute to meta-analyses of waterbirth.

Inclusion criteria based on *A model practice template for hydrotherapy in labor and birth (2016)*[35]*:*

1. ***Prenatal*** low-risk, healthy, adult women (≥18 years of age), including:
    a. Able to speak and understand English
    b. Women with a singleton gestation
    c. Able to ambulate with no mobility restrictions (i.e., no difficulty getting from seated to standing)
    d. Less than class III obesity (BMI <40 kg/m^2) at initiation of prenatal care
    e. No active infections such as HIV, Hepatitis B, Hepatitis C, HSV outbreak (on prophylaxis acceptable),
        i. GBS positive is acceptable
    f. No pre-existing medical conditions such as: heart disease, uncontrolled asthma, diabetes, chronic hypertension, or other condition that requires continuous observation and/or activity restrictions
    g. No high-risk pregnancy conditions: including preeclampsia, gestational hypertension, preterm gestation, multiple gestation, substance abuse, placental abruption or other unexplained vaginal bleeding, previous cesarean section,

suspected fetal macrosomia (>4500 gm) or intrauterine growth restrictions (<10th percentile), or other condition that requires continuous observation and/or activity restrictions per provider discretion; ultimately patient participation is dependent on provider recommendation

2. ***Labor*** inclusion criteria:
    h. Greater than 37 weeks and less than 42 completed weeks gestation in vertex presentation
    i. Not hypertensive or febrile (two blood pressures 140/90 four hours apart; two fevers of over 100.4 one hour apart)
    j. Category 1 fetal heart tones (obtained on a 20-minute admission external fetal monitor strip)
    k. Amniotic sac may be intact or ruptured. If ruptured, amniotic fluid must be clear.

Women will be **excluded** from the study if they do not meet the above inclusion criteria, or they will be further **excluded** under the following circumstances:

1. Known need for cesarean section
2. Participant may be excluded from the study at any time at the discretion of the birth attendant (reason for study exclusion will be documented but will remain in the study group previously selected based on intention to treat).

Women will be notified of exclusion by their provider, who will also notify appropriate study team members including coordinators. Documentation of exclusion will be done in Epic through a dot.phrase (.waterbirthexclusion; Appendix A).

IV. STUDY DESIGN

This study is a pilot randomized control trial that aims to assess feasibility and explore or test (if possible) outcomes of waterbirth to that of conventional land birth for low-risk healthy women and neonates in a hospital setting in Milwaukee, WI. Low-risk healthy adult women will be enrolled from January 2022 through December 2025. The study could be introduced to potentially eligible women in their second trimester. Patient recruitment materials will also be placed in the waiting room and exam rooms. Patient recruitment materials will be created upon receipt of the birthing tub (October 2021) and will be approved by the IRB prior to use. We have attached the recruitment poster for approval.

We plan to enroll women using a random allocation rule in the ratio 2:1, with two women randomized to the waterbirth group for everyone one woman randomized to the land birth group. Women will be randomized in the Midwifery and Wellness Clinic, Exclusively for Women, and the Women's Health Clinic at Aurora Sinai Medical Center at the beginning of the third trimester (25 weeks 0 days to 34 weeks 0 days gestation) upon consent by the research coordinator, faculty physician(s), or midwives listed on this study. Consent will be documented with a dot.phrase (.waterbirthconsent2; Appendix A). Patients will be presented with a sealed envelope which will contain a slip of paper identifying the patient's random assignment to either the waterbirth or land birth (again with a 2:1 randomization allocation). Currently, randomization is completed through REDcap.

We initially aimed to enroll 120 patients in the study, 80 enrolled within the waterbirth group and 40 in the land group. We recognize that some women will risk-out or opt-out because of the unpredictability of labor and birth. Additionally, we aim to approach most patients eligible for waterbirth with the understanding that some women will not want to participate in a research study. We have recalculated our sample sized based on the current enrollment attrition rate of 39.4% (rate in which patients risk out of the study). With a 2:1 allocation ratio, approximately 120 subjects were initially earmarked to be recruited into the study given 74 would be needed in the waterbirth and 37 would be needed in the land birth group to detect a 40% reduction in epidural use. Following the recommendations of Sakpal[41], we used the attrition rate (rate in which patients risk out of the study) to calculate adjusted sample sizes as 124 in the waterbirth group and 62 in the land birth group for a total of 186.

Participants who are ineligible for waterbirth will be excluded from both the land or water groups, and no further data will be collected. Please note that given the variable nature of birth, once a woman is randomized and enrolled to either group and meets ongoing eligibility criteria, an intention to treat model will be used for analysis following the birth.

Study participation will be offered to women seeking routine prenatal care in the Midwifery and Wellness Clinic, Exclusively for Women, and the Women's Health Clinic at Aurora Sinai Medical Center at the beginning of the third trimester (25 weeks 0 days to 34 weeks 0 days gestation). Eligible patients will be consented by a research study coordinator (risks and benefits will be done by an Aurora UW Medical Group midwifery or obstetric provider [CNM or physician] listed on this protocol) following the patient's prenatal visit. Note, in rare cases midwifery or obstetric providers listed on this protocol may conduct full consent. Following voluntary consent, all study participants will be randomized (see above for randomization).

Data collection will be completed as described below and will be obtained from Epic and the AUWMG midwifery database. A validated questionnaire *The US Birth Satisfaction Scale Revised* (US-BSS-R)[34,36,37] will be used to evaluate maternal satisfaction and will be obtained within the first three days postpartum by either a study coordinator or midwife provider via an iPad. In some cases, the US-BSS-R will by collected by phone. We have obtained permission from the authors to use the validated scale US-BSS-R. The US-BSS-R is the recommended birth satisfaction measure by the International Consortium for Health Outcomes Measurement (ICHOM). Questions (below) are measured on 5-point Likert scale [strongly agree-strongly disagree] and a full copy of the scale was obtained from the authors and is available upon request:

1. I came through childbirth virtually unharmed.
2. I thought my labor was excessively long.
3. The delivery room staff encouraged me to make decisions about how I wanted my birth to progress.
4. I felt very anxious during my labor and birth.
5. I felt well supported by staff during my labor and birth.
6. The staff communicated well with me during labor.
7. I found giving birth a distressing experience.
8. I felt out of control during my birth experience.

9. I was not distressed at all during labor.
10. The delivery room was clean and hygienic

Routine management of the tub will be done in compliance with Infection Control and facility services. Water temperature will be maintained at less than or equal to 100 degrees Fahrenheit and will be monitored and recorded hourly through both a paper copy that will go the mid-wife call room (or study binder), as well as through an EPIC smart phrase .waterbirthlaborprogressnote (Appendix A and Appendix B). The Water Tub Protocol (Appendix C) has been created following receipt of the tub.

Waterbirths are an alternative method of pain control and are not standard of care. Therefore, only patients who voluntarily agree to participate in this study will be able to undergo waterbirth. We will collect regularly recorded measures, in addition to patient satisfaction surveys for all participants. The US-BSS-R questionnaire is the only deviations from standard care for patients in the conventional land birth group.

V. WATERBIRTH PROTOCOL

This protocol is taken directly from the American College of Nurse-Midwive's 'A Model Practice Template for Hydrotherapy in Labor and Birth' (2016)[35]

A. Management of labor in water

1. Before immersion, ensure that the woman is a candidate for warm water immersion based on inclusion and exclusion criteria
    a.) The tub should be filled using ordinary tap water without additives (e.g., salt, essential oils, sanitizers).
    b.) The water temperature should be assessed and documented hourly by nursing.
    c.) During the first stage of labor in water, the water temperature should never exceed 37.7°C (100°F) and may be adjusted to cooler temperatures per the woman's preference.
2. The woman in labor may enter or leave the water at any point with assistance.
    a) The woman should be instructed to use proper body mechanics when entering and exiting the tub and do so only with staff or a support person in attendance.
    b) If complications or changes occur in the maternal or fetal condition that require further assessment or treatment outside of the tub, share this information with the family and assist the woman out of the tub.
3. Positioning for comfort in the tub is dependent on the preferences of the woman and the judgment of the provider in consultation with the woman.
4. Provide hydration in the form of oral liquids or intravenous (IV) fluids as indicated. All IV or saline lock sites should be covered with an occlusive, water-resistant dressing while the woman is in the tub.
5. The well-being of the woman and fetus are assessed and managed in accordance with practice protocols for *any other woman* during labor, including monitoring maternal vital signs, assessing the fetal heart rate and initiating intrauterine resuscitation strategies when indicated (e.g., maternal position changes and IV fluid bolus for fetal heart rate changes or Category II fetal heart rate).

a.) A waterproof Doppler or waterproof electronic fetal monitoring equipment should be used to assess the fetal heart rate.
b.) Waterproof electronic fetal monitoring equipment may be used to verify or clarify if an indeterminate fetal heart rate pattern is present, and this can guide management.
c.) Management of indeterminate fetal heart rate patterns depend on multiple factors. Intrapartum resuscitation techniques such as position change, hydration, and correction of hypotension or tachysystole are instituted as necessary.

B. Management of the second stage of labor

1. The woman may choose any position in the tub or pushing during the second stage of labor that feels comfortable and that is deemed safe by the attending provider or registered nurse. The health care professional may request adjustments to the position to facilitate observation of progress and/or to maintain assessment of maternal and fetal wellbeing. Additionally, the health care professional will document that they are comfortable proceeding with the subject in the study once in the second stage of labor through a dot.phrase (.waterbirthsecondstage Appendix A).
2. Water temperature
    a.) During the second stage of labor, the water temperature should never exceed 37.7°C (100°F) and may be adjusted based on the woman's preference within a narrow range of 36.1°C to 37.7°C (97.0°F to 100°F).
3. Maternal and fetal well-being should be assessed and documented as they would be for a conventional (land) birth
4. Fetal heart rate and contraction pattern are assessed in accordance with standard of care recommendations, generally every 5 to 15 minutes (in accordance with AWHONN/ACOG guidelines[38]).
5. Supporting birth of the neonate
    a.) The woman should be supported in the use of spontaneous, physiologic pushing.
    b.) The health care provider may use a hands-off or hands-poised position to facilitate birth by controlled, spontaneous, pushing efforts; a hands-on method of birth management may be employed when indicated.
    c.) It may not be necessary to feel for the presence of a nuchal cord if the birth of the body quickly follows the head. Loose nuchal cords and other entanglements can be resolved as the neonate is born underwater before the first breath
    d.) The time of birth will be noted when the neonate's entire body is outside of the woman.
    e.) The neonate must be born completely underwater without exposure to air until the face is brought gently and directly to the surface. The neonate's head **must not** be re-submerged under water after it has been brought to the surface.
    f.) If a woman raises herself out of the water and exposes the head of the fetus to air, she should be assisted/supported to remain out of the water to avoid the potential risk of the neonate gasping underwater with re-submersion.
    g.) After birth, assist in bringing the neonate directly and gently to the surface (within 5–10 seconds) to minimize tension on the umbilical cord and to reduce the possibility of avulsion. Cord clamps should be readily available.
    h.) Maintain warmth of the neonate through skin-to-skin contact with the woman

and submersion of the neonate's lower extremities, abdomen, and chest. Dry the neonate's exposed head to reduce heat loss.

i.) Apgar scores should be obtained at one and 5 minutes after birth per routine standards.

j.) In the presence of stable newborn status and transition to extrauterine life, care of the cord can follow best practices to support delayed cord clamping.

k.) If neonatal resuscitation measures are indicated and this is not possible without cutting the cord the cord should be clamped and cut, and the neonate removed from the water immediately and brought to the infant warmer.

C. Management of the third stage of labor

1. Although the third stage of labor may occur in or out of the tub depending on the status of the woman and neonate, provider skill and comfort, and duration of third stage, for the purpose of this study ***the third stage will be managed outside of the water.*** In rare cases, this may not be possible and the reason will be documented.

a.) The woman will be assisted out of the water and to the bed. Her infant may remain skin to skin or may be handed to a staff member while she moves to the bed. The infant will be placed skin-to-skin when she is in the bed.

b.) Quantified blood loss (QBL) will begin after the birth of the placenta, per routine unit standards.

c.) Inspection of the perineum and vagina for lacerations will occur in the bed per routine unit standards

D. Evaluation and care of the neonate

a.) The neonatal resuscitation (NRP) guidelines of the American Heart Association should be utilized to assess the neonate and Apgar scores should be obtained at one and 5 minutes after birth per routine. If neonatal resuscitation measures are indicated and this is not possible without cutting the cord, the cord should be clamped and cut, and the neonate removed from the water immediately.

b.) Make certain the neonate remains close to the woman (skin-to-skin) and partially submerged to help maintain body temperature. Dry the neonate's exposed head to reduce heat loss.

c.) If neonatal tachycardia (heart rate greater than 160 bpm), bradycardia (heart rate less than 100bpm), hyperthermia (temperature greater than 38°C [100.4°F]), hypothermia (temperature less than 36°C [97.0°F]), tachypnea (respirations greater than 60 per min), grunting, or retracting is noted, the neonate should be moved to the infant warmer for further assessment, per routine unit standards.

E. Complications

1. As when caring for any woman in labor, the health care professional is responsible for using clinical judgment to respond appropriately when complications arise. If deviations from normal during immersion are observed, the woman should be asked to exit the tub and assisted out of the water for further assessment as necessary to perform standard care assessments and interventions.

A. *Tight nuchal cord*: If a tight nuchal cord cannot be reduced, and the somersault maneuver is ineffective, the woman should be assisted to stand above the water so

the cord can be clamped and cut to facilitate birth out of the water. **Under no circumstances should a nuchal cord be clamped and cut under water.** The woman should remain standing to give birth to the rest of the body and to avoid submersion of the neonate's head after birth. The tub will be drained.
B. *Shoulder dystocia:* If a shoulder dystocia occurs in the tub and cannot be resolved with position change, assist the woman out of the tub to complete the birth. Once the neonate's head is exposed to air, it should not be re-submerged.
C. *Excessive bleeding:* The presence of excessive bleeding into the water should prompt the immediate evaluation of the source. According to Waterbirth International, the water should never be dark enough that the woman is not visible through the water. In the case of excessive bleeding, assist the woman out of the tub for further evaluation. Initiate quantification of blood loss to more accurately assess blood loss volume. Excessive bleeding or blood loss will be determined based on the color of the water in the tub. Obstetricians, midwives, and nursing staff will be taught to evaluate the amount of bleeding prior to the start of the study. There should be minimal bleeding prior to the birth of the baby, and more than minimal bleeding in the first stage of labor should prompt the team to assist the woman out of the water.
D. *Umbilical cord avulsion:* If cord rupture is suspected, the cord should be immediately clamped at the umbilicus and cut. Cord clamps must be readily available. If cord rupture is confirmed, the newborn should be removed from the tub for assessment.
E. *Loss of consciousness*: Emergency procedures must be enacted immediately, and the woman should be removed from the tub quickly and safely. Assign one person to ensure the woman's head remains above the water surface at all times and activate the emergency response team to help lift the unconscious woman out of the tub and to initiate emergency evaluation and treatment.

VI. STANDARD LAND BIRTH PROTOCOL

Women randomized to the land birth group will be admitted to L&D as inpatients and will be cared for using routine standards of care, consistent with practice guidelines from ACNM/ACOG/AWHONN. Standard labor options (pain control, positioning, monitoring) will be offered to women in accordance with their particular labors and needs.

VII. STATISTICAL PLAN

The **primary outcome** we seek is a reduction of IV narcotic and epidural anesthesia use. We anticipate that this pilot project would be powered to detect a very clinically meaningful percentage point reduction in use of IV narcotic and epidural anesthesia. We carried out a power analysis using G*Power 3.1.9.6.[40] Using the Fleiss methodology to estimate power calculations with 80% power at the 0.05 level of significance, we estimate the following: to detect about 80%reduction in IV narcotic use from 24.5% down to 5.5%, estimated need would be 68 in the waterbirth group, 34 in the control group. To detect about 40% reduction in epidural use from 59% down to 34%, estimated need would be 74 in the waterbirth group, 37 in the control group. We have recalculated our sample sized based on the current enrollment attrition rate of 39.4%

(rate in which patients risk out of the study). With a 2:1 allocation ratio, approximately 120 subjects were initially earmarked to be recruited into the study given 74 would be needed in the waterbirth group and 37 would be needed in the land birth group to detect a 40% reduction in epidural use. Following the recommendations of Sakpal[41], we used the attrition rate (rate in which patients risk out of the study) to calculate adjusted sample sizes as 124 in the waterbirth group and 62 in the land birth group for a total of 186. We continue to approach most pregnant people eligible for waterbirth with the understanding that some will not want to participate in a research study. The results of this pilot should inform sample size required for a larger, definitive study that would be powered to detect smaller, still meaningful reductions in narcotic/epidural use.

We will compare baseline characteristics and pre-determined outcomes between patients who are randomized to either waterbirth or land birth. We will compute frequencies, means with 95% confidence intervals, and medians with interquartile ranges, as appropriate per variable type. Differences among the groups will be tested using the Pearson chi-squared test of independence (or Fisher's exact), Student's t-test, or Wilcoxon's rank sum test, respectively. Continuous variables will be assessed for normal distribution. Categorical variables will be assessed for collinearity. Potentially, we will use logistic regression for binary categorical outcomes (e.g., opioid use/anesthetist intervention, maternal tears, vaginal birth versus conversion to cesarean section, etc.) and linear regression for continuous outcomes (e.g., blood loss, time to skin-to-skin contact, etc.). Potentially, we will also perform ordered logistic regression on ordinal outcomes such as satisfaction level and APGAR. All underlying assumptions will be tested for each statistical method used. A one tailed p value lower than 0.05 will be considered statistically significant.

Please note, a data safety monitoring plan has been created for this study and is included in Appendix D. The first ten subjects that are enrolled for a waterbirth will be monitored and reviewed by the study PI, co-investigators, and Maternal Newborn Quality Committee for any rare adverse outcomes. For all subjects, the Principal Investigator and co-investigators will continue to review all adverse outcomes and will regularly monitor the data to identify trends throughout the study.

VII. DATA COLLECTION

» From January 2022 through December 2025 eligible women will be offered study participation during routine prenatal care at 25 weeks 0 days to 34 weeks 0 days gestation. The study could be introduced to potentially eligible women in their second trimester. Several data elements will be reviewed and collected from the delivery record in Epic and the AUWMG midwifery database. REDCap will be utilized for data collection and storage for this study. Data collection will be completed by those listed on this study. After the first year of data collection, we plan to conduct an interim analysis and present year one preliminary data at a scientific meeting (Advocate Aurora Scientific Day 2023).

Variables to be collected at time of consent after coordinators have discussed participating in a randomized control trail:

- Do you wish to voluntarily participate in our randomized control trail that aims to evaluate maternal/neonatal outcomes associated with waterbirths, as well as your satisfaction with the birthing process? (0=No; 1=Yes)

Variables to be collected:

1. *Study related variables*
    a. Medical reason/s participant becomes ineligible for waterbirth
        i. Hep C positive (0=No; 1=Yes)
        ii. Gestational age <37 or >42
        iii. Non-vertex presentation (0=No; 1=Yes)
        iv. Hypertensive (0=No; 1=Yes)
        v. Febrile (0=No; 1=Yes)
        vi. Category 2 or 3 fetal heart tones (0=No; 1=Yes)
        vii. Amniotic sac is ruptured and fluid is not clear (0=No; 1=Yes)
        viii. Other: notes
    b. Maternal decision to withdraw participation (i.e. desire to leave the water): notes
2. *Maternal variables*
    a. REDCap Record ID
    b. Medical record number
    c. Date of birth
    d. BMI (kg/m^2) at initiation of prenatal care
        a. Height (inches) and weight (lbs) at initiation of prenatal care
    e. Race
    f. Ethnicity
    g. Education level
    h. Marital status
    i. Gravidity
    j. Paritya
    k. Date and time of admission
    l. Date and time of delivery
    m. Gestational age at time of delivery (WxDx)
    n. Maternal position for birth:
        a. upright (0=No; 1=Yes)
        b. squatting (0=No; 1=Yes)
        c. semi-sitting (0=No; 1=Yes)
        d. left tilt (0=No; 1=Yes)
        e. right tilt (0=No; 1=Yes)
        f. hands and knees (0=No; 1=Yes)
        g. standing (0=No; 1=Yes)
        h. other (0=No; 1=Yes)
            i. describe
    o. Quantified blood loss (QBL calculation begins after the delivery of the placenta using the blue bag; clots, linens, and lap sponges will be weighed. Unit protocol will be followed. Hemorrhage QBL ≥ 1,000 mL)
    p. Was patient switched from waterbirth to land birth?
        a. Why?

q. Was patient switched from any birth to cesarean or operative delivery?
    a. Why?
    b. Cesarean (0=No; 1=Yes)
    c. Instrumental delivery (0=No; 1=Yes)
        i. Forceps (0=No; 1=Yes)
        ii. Vacuum (0=No; 1=Yes)
r. Labor duration and time (by phase: first, second, third)
    a. Induction (0=No; 1=Yes)
    b. Spontaneous labor (0=No; 1=Yes)
s. Dilation at time of admission of birth
t. Medications used (analgesia and anesthesia) (0=No; 1=Yes)
    a. Epidural (0=No; 1=Yes)
        i. Epidural eligibility (0=No; 1=Yes)
    b. Spinal epidural (0=No; 1=Yes)
    c. IV narcotic medication (Nubain or Stadol) (0=No; 1=Yes)
u. Maternal complications (0=No; 1=Yes)
    a. Laceration (1^{st}, 2^{nd}, 3^{rd}, 4^{th} degree)
        i. Episiotomy (0=No; 1=Yes)
    b. Shoulder dystocia (0=No; 1=Yes)
v. Maternal satisfaction (US-BSS-R, modified)[34]
    a. Postpartum day survey was completed (0=PPD0; 1=PPD1; 2=PPD2; 3=PPD3)
w. Was breastfeeding initiated at any point prior to discharge? (0=No; 1=Yes)
x. Date and time of discharge
    a. Length of hospital stay

3. *Newborn variables*
    a. Date and time of skin-to-skin contact
        a. Time from birth to skin-to-skin contact
    b. One- and five-minute APGAR scores
    c. Were there any newborn complications at time of birth? (0=No; 1=Yes)
        a. If yes, newborn complications including:
            i. NICU admission (0=No; 1=Yes)
                1. If yes, NICU admission and discharge date for LOS
            ii. Infection (0=No; 1=Yes)
            iii. Injury (0=No; 1=Yes)
            iv. Cord injury (0=No; 1=Yes)
            v. Other (0=No; 1=Yes)
                1. What?
    d. If available, Cord Ph (arterial and venous)
    e. At approximately 4-8 weeks postpartum, coordinator follow-up regarding newborn status (at postpartum visit or via phone call, etc.)
        a. Were we able to touch base (0=No; 1=Yes)
        b. If yes, were there any neonatal complications since discharge? (0=No; 1=Yes)
        c. If any complications since discharge?
            i. Neonatal hospital admission (0=No; 1=Yes)
                1. If yes, follow-up comments
            ii. Neonatal infection postpartum (0=No; 1=Yes)

1. If yes, follow-up comments

iii. Other neonatal complications postpartum (0=No; 1=Yes)

1. If yes, follow-up comments

This research study plans to store and manage the entire dataset in an AAH version of REDCap.

VIII. POTENTIAL RISKS AND BENEFITS

Potential risks associated with any vaginal delivery regardless of study participation:

- Maternal risks including infection and all risks associated with vaginal delivery including but not limited to hemorrhage, laceration, sepsis, and other rare maternal morbidity and mortality
- Neonatal risks associated with vaginal delivery including but not limited to infection, sepsis, water inhalation, umbilical cord avulsion, respiratory distress, low APGAR scores, NICU admission, and rare adverse neonatal morbidity and mortality including neonatal death

Potential benefits although unknown:

- Maternal benefits may include improved pain control, fewer obstetric lacerations, increased comfort during labor, increased mobility, and ease of delivery positioning due to increased buoyancy, improved relaxation, a more satisfying birth experience, increased perception of control, decreased cesarean delivery, and an additional option for pain control in a hospital setting in the Milwaukee area.
- Neonatal benefits may include less exposure to maternal pain medication/narcotic use, fewer interventions in labor, fewer instrumental and cesarean deliveries, immediate skin-to-skin contact with improved infant maternal bonding, and fewer NICU admissions.

Waterbirth is considered by ACOG/AAP to be an experimental procedure and, therefore, not all risks and benefits are known. It is considered a beneficial option for low-risk healthy women by the American College of Nurse Midwives and the Royal College of Obstetricians and Gynecologists/Royal College of Midwives. Providers who participate in the study will receive standardized training for waterbirth and will be in compliance with our internal Institutional Review Board research guidelines. Nursing staff will receive training by the study PI and co-investigators.

If our pilot study shows that waterbirth is a reasonable option for low-risk healthy women, we will seek to implement a larger, multi-center trial on the labor and delivery floor at Aurora Sinai Medical Center and at other Advocate Aurora hospitals. Additionally, we seek to publish and disseminate our findings so that other hospitals can adopt our protocols. Lastly, we also seek to model interdisciplinary collaboration between obstetrics, midwifery, and neonatology to offer this service.

IX. ROLES AND RESPONSIBILITIES

1. **Emily Malloy, PhD, CNM, APNP** (Principal investigator): Ms. Malloy is a faculty CNM at the Aurora Sinai Midwifery and Wellness Center and a PhD student at Marquette University, College of Nursing. She developed the original study concept and

will be the lead author and investigator in this study. She will (1) write the proposal and study protocol, (2) teach OB providers (OBs, family medicine, and CNMs) and nursing staff implementation of the study, (3) be the liaison between the study and AUWMG CNMs, (4) help interpret and write results, and (5) write the draft of the article and review, edit and submit abstracts, manuscripts, and presentations.

2. **Dr. Natasha Hernandez, MD** (Co-investigator): Dr. Hernandez is the medical director of the Midwifery and Wellness Clinic. She will assist with training CNMs and OBs to perform waterbirth. Dr. Hernandez will serve as an expert in obstetric care and will contribute to the study as a liaison between the study and obstetricians. She will (1) help edit and offer feedback on the proposal, (2) provide obstetric guidance to the study team, and (3) review the study protocol, proposal, abstracts, manuscripts and presentations.
3. **Jessica Kram, MPH** (Co-investigator): Ms. Kram will be an active investigator in this research study. She has significantly contributed to the development of the research proposal and will continue to function as the coordinator of research activities by (1) completing, submitting, and updating all necessary forms for IRB approval and continuing review, and (2) coordinating communications and meetings among team members and other relevant entities (e.g., Research Analytics, Cancer Registry). She will also significantly contribute to the preparation and submission of abstracts, presentations, and manuscripts following data analyses.
4. **MaryAnne Scherer, CNM, APNP** (Co-investigator): Ms. Scherer is the Lead CNM in the Midwifery and Wellness Clinic. She will assist CNMs with participant recruitment and inclusion, and training CNMs and OBs to perform waterbirth. She will serve as an expert in midwifery care and will contribute to the study as a liaison between the study and midwives. She will (1) help edit and offer feedback on the proposal, (2) provide obstetric guidance to the study team, and (3) review the study protocol, proposal, abstracts, manuscripts and presentations.
5. **James Adefisoye, MS** (Co-investigator, biostatistician): The biostatistician will conduct all statistical analyses and provide interpretation, summary, and dissemination of the results. Additionally, he/she will have an active role in writing, reviewing, editing, finalizing and submitting all abstracts, presentations, and manuscripts.
6. **Dr. Marie Forgie, DO** (Co-investigator): Dr. Forgie will serve as an expert in obstetric care and will contribute to the study as a liaison between the study and obstetricians. She will (1) help edit and offer feedback on the proposal, (2) provide obstetric guidance to the study team, and (3) review the study protocol, proposal, abstracts, manuscripts and presentations.
7. **Diana Kleber, RN** (Research Coordinators) – research coordinators will be involved in identifying eligible participants for the study and coordinating enrollment efforts. The coordinator will obtain consent and questionnaires, as well as oversee study materials and training of additional clinic key personnel in consenting and obtaining questionnaires.

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Appendix A.

Example/tentative dot.phrases for waterbirth study:

.waterbirthconsent2
Patient confirms adequate time to review informed consent document
The informed consent was reviewed page by page with the patient. The following were discussed and reviewed with the patient: purpose of study, investigational nature, procedure, follow-up, risks, benefits, alternative therapy, voluntary participation, right to refuse participation without consequences to continued care or access, confidentiality/privacy.
Patient verbalizes understanding and acknowledges all questions have been answered.

Outcome: Patient verbalizes willingness to participate and agrees to participate if all study eligibility criteria are met.

No study related procedures were performed prior to signing the study informed consent. A copy of the signed informed consent was given to the patient and a copy was placed in patient medical record chart.

Subject is enrolled

.waterbirthexclusion
This participant has been excluded from the waterbirth research study due to ***. The appropriate study coordinators and study team members have been notified.

.waterbirthlaborprogress [1776244]
This labor progress note includes standard of care labor assessments, in addition to documentation for hourly water temperatures.

.waterbirthsecondstage
The subject is now in the second stage of labor. I *** am comfortable proceeding with the subject on the waterbirth study who was randomized to the waterbirth.

Appendix B.

Waterbirth Hourly Tub Temperature

0700	1900
0800	2000
0900	2100
1000	2200
1100	2300
1200	0000
1300	0100
1400	0200
1500	0300
1600	0400
1700	0500
1800	0600

Appendix C.

Waterbirth Tub Protocol

Tub inflation
1. First inflate the bottom of the pool, starting with the floor valve, with the electric air pump. Use the appropriate size nipple.
2. Next, inflate the patient seat, using the valve on the seat with the electric air pump. Use the appropriate size nipple. These can be VERY full, like a football. Do not worry about overfilling this part!
3. Next inflate each wrung, starting with the bottom and moving up. You can make it VERY full.

Inflating the tub takes approximately 10-15 minutes

Tub Cleaning
1. Dispose of the individual liner and hose
2. Wipe out the tub with Sanitizing-wipes
3. Allow to the tub to COMPLETELY DRY

Tub Deflation
1. After tub is completely dry, use the electric air pump to deflate it.
2. Start with the top wrung and move down.
3. Deflate the patient seat
4. Deflate the floor
5. Fold tub and place back in the bag

Appendix D.

Monitoring Plan

Study Title: Hospital waterbirth: A pilot randomized control study
PI: Emily Malloy, PhD, CNM, APNP
IRB#: 20.176
ClinicalTrials.gov ID: NCT05175599
Date plan issued: 7/6/2020
Date plan updated: 4/14/2022

Introduction:

This monitoring plan includes reviews for both data integrity and subject safety. The study PI, co-investigators, Maternal Newborn Quality Committee and the Advocate Aurora Health Care Institutional Review Board will be involved in monitoring activities. These activities will be conducted in accordance to applicable regulations, ICH-GCP and institutional/IRB policies.

Data and safety monitoring activities and the roles of individuals involved are described below. The schedule and scope of each review is outlined as well.

This monitoring plan was prepared based on considerations such as purpose, design, complexity, size, and endpoints of the trial. Monitoring activities will be documented with a brief written report and on a subject monitoring log.

Monitoring plan:

PURPOSE
The purposes of trial monitoring are to verify that:
(a) The rights and well-being of human subjects are protected.
(b) The reported trial data are accurate, complete, and verifiable from source documents.
(c) The conduct of the trial follows the currently approved protocol/amendment(s) and applicable regulatory requirement(s).

ROLES/REVIEWS
PI and co-investigators: The Principle investigator and co-investigators will carefully assess and evaluate the first ten subjects and their infants following a completed waterbirth to monitor for any rare adverse outcomes that may or may not have been known prior to study start. As subjects may risk out and become ineligible for waterbirth prior to delivery, outcomes on the first ten subjects and their infants will be evaluated only for subjects who completed a waterbirth.

For all subjects, the Principal Investigator and co-investigators will continue to review all adverse outcomes and will regularly monitor the data to identify trends throughout the study.

The Principal Investigator and co-investigators will be responsible for reporting all adverse events to the IRB and for revising the protocol as needed to maintain safety. Primarily, the Principal Investigator and Manager of Translational Research for AUWMG (co-investigator) are responsible for the IRB submissions, ClinicalTrials.gov registration, safety reporting and other regulatory components of the study.

Maternal Newborn Quality Committee: The Maternal Newborn Quality Committee, an internal hospital committee at Aurora Sinai Medical Center, is involved in monitoring all maternal and neonatal adverse outcomes at the facility.

DESCRIPTION OF REVIEWS AND REPORTING

Schedule and scope of data integrity reviews (study team):

	Initial Review	**Continued Review**
Conducted by	PI, co-investigators, and Maternal Newborn Quality Committee	PI, co-investigators, and Maternal Newborn Quality Committee
When will review be conducted	After ten subjects and their infants in the waterbirth arm give birth in the water	Regularly throughout the study
What will be reviewed	100% of all data entered compared to source documents, any paper CRFs, etc.	100% of all data entered compared to source documents, any paper CRFs, etc.
Purpose of review	To monitor for any rare adverse outcomes that may or may not have been known prior to study start for waterbirth	To continue to regularly monitor for any rare adverse outcomes that may or may not have been known prior to study start for waterbirth
Reporting	A brief written report will be prepared by the Principal Investigator and study co-investigators that will be inclusive of feedback from the Maternal Newborn Quality Committee. This brief written report will be shared with the study team and the Advocate Aurora Health Care Institutional Review Board. Any adverse outcome(s) will be logged on a subject monitoring log.	Should the study team deem it necessary, an additional brief written report may be shared. Any adverse outcome(s) will be logged on a subject monitoring log.