



**Arizona Department of Health Services
Midwifery Scope of Practice
Advisory Committee
Meeting Minutes**



**Division of Public Health Services – Licensing
Office of Special Licensing**

150 N. 18th Avenue
4th Floor, Suite 460
Phoenix, AZ 85007
(602)364-2079

Jan Brewer, Governor

Will Humble, MPH, Director

Cara Christ, MD, MPH, Assistant Director

Røhno Geppert, MPA, Office Chief

Date & Time of Meeting: Wednesday April 3, 2013 from 4:00 pm to 5:55 pm

Location of Meeting: ADHS State Laboratory Conference Room
250 N. 17th Avenue
Phoenix, AZ 85007

Advisory Committee In-Person Attendees:

Wendi Cleckner, LM, CPM – Midwife
Allyson Fernstrom, MSW – Public Member
Mary Langlois, LM, CPM – Midwife
Maria Manriquez, MD – OB/GYN Physician
Jeffrey Northup, DO – OB/GYN Physician
Janice L. Bovee, CNM, MSN – Nurse Midwife

Advisory Committee Telephonic Attendees:

None

Advisory Committee Member Absentees:

Julie R. Gunnigle, JD – Public Member
Susan Hadley, MD – Family Practice Physician

ADHS Attendees:

Will Humble, MPH – Director
Cara Christ, MD, MPH – Assistant Director
Tom Salow, JD – Acting Deputy Assistant Director
Røhno Geppert, MPA – Licensing Office Chief
Don Gibson, MPA – Licensing Team Lead
Patricia Glass, RN – Licensing Surveyor
Patricia Cordova – Rules Analyst



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Agenda Item A: Call To Order

Director Humble called the meeting to order at 4:00 pm and confirmed the presence of a quorum of members as noted above.

Agenda Item B: Minutes Review/Approval of Feb. 11, 2013

Director Humble called for a motion to accept the minutes from the previous meeting. Committee Member Bovee made a motion to accept the minutes as submitted. Committee Member Langlois seconded the motion. Director Humble called for a vote. All members present voted in the affirmative so the motion carried unanimously.

Director Humble mentioned that the draft rules that will be discussed in agenda item “D” are posted for public comment over the next 30 days and asked people to submit their comments in writing.

Agenda Item C: Discussion of U of A Literature Review

Assistant Director Christ open by predicating her presentation on the policy held by the Department to make decisions based-upon evidence and then moved on to present the findings from “Outcome of Home vs. Hospital Births by Midwives: A systematic review and Meta-analysis” by the University of Arizona/Division of Health Promotion Sciences in the Mel & Enid Zuckerman College of Public Health.

BACKGROUND:

Studies conducted in the US and other high income countries show that an increasing number of women elect homebirth.

- Reasons:
 - Considered safe by consumers
 - Often involves fewer medical interventions
 - Performed in the comfort of their own homes

Objective: To critically assess and summarize evidence on outcome of home versus hospital births attended by midwives.

Methodology:

- U of A performed a very extensive search of the literature
- 3-4 people searched multiple databases (to February, 2013)
- Unpublished data from the grey literature through Google and Google Scholar searches
- References in articles were hand searched to find additional resources
- Each identified article was assessed independently by 5 reviewers



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- Reviewers came together to decide which articles were relevant
- Analysis done by PhD statistician

Types of studies

- Case-control studies
- Randomized controlled studies
- Cohort studies
- Time-series studies

Had to look at outcome of births attended by midwives in hospital/health facilities or in homes.

Nine studies were included in the meta-analysis of child health outcome of births attended by midwives in homes or in hospitals.

Analyzed 7 outcomes of child health:

- Neonatal deaths
- Prenatal deaths
- Apgar<7 at 5 min
- Intrapartum deaths
- Low birth weight < 2500g
- Birth seizures
- Meconium aspiration

RESULTS: MATERNAL HEALTH

- Eight studies qualified for inclusion in the meta-analysis of the impact of setting (home or hospital) of births attended by midwives.
- 13 outcomes were analyzed:
 - Spontaneous delivery
 - Vacuum extraction
 - Assistant delivery
 - Caesarean delivery
 - Forceps
 - Episiotomy
 - Lacerations/Perineal tear (3-4 degree)
 - Lacerations/Perineal tear (intact)
 - Cervical tear
 - Postpartum hemorrhage (>500 mls)
 - Retained placenta
 - Blood transfusion



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- Prolapsed cord
- Homebirths were more likely to result in a spontaneous birth with an intact perineum.
- There were fewer surgical interventions among women who elected to deliver with a midwife in the home.
- Hospital births by midwives were associated with increased risk of assisted delivery, caesarean sections, forceps, episiotomy, lacerations/perineal tear (3-4 degrees).
- Decreased risk of postpartum hemorrhage >500mL and having a retained placenta among midwife attended homebirths.

RESULTS: CHILD HEALTH

- The risk of neonatal death increased among homebirths (OR=3.11, 95% CI: 2.49-3.89).
- Otherwise, there were no significant differences in infant health outcomes between home and hospital births attended by midwives.

GENERAL RESULTS

- The findings of this meta-analysis have implications primarily for women with generally low-risk pregnancies and the midwives who may be their primary perinatal care providers, because low-risk women account for most of the sample analyzed.
- Findings suggest that homebirths attended by midwives may be equally safe if not safer for women with low-risk pregnancies.
- Homebirths should only be recommended to women who are classified as low-risk, as this data demonstrates an increased risk of neonatal mortality among homebirths.
 - Access to emergency services, prior consultation, and having a contingency plan with a nearby medical facility with appropriate obstetrical equipment is encouraged, in the case that a medical emergency occurs.

LIMITATIONS OF THE STUDY

- Studies reviewed here tended to exclude high-risk pregnancies.
 - Tendency for women with high-risk pregnancies to be referred to or to opt for obstetrical care.
 - Lack of data and evidence on the safety and efficacy of homebirths for high-risk pregnancies.
- Studies were included from several different countries.
 - Education and regulation of midwives may differ from that in the United States.
- Lack of data on vaginal births after cesarean (VBAC), multiple births, and breech births.



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- Not included in the analysis due to the fact that these are high-risk pregnancy conditions and are not typical of women elected for homebirths in attendance by midwives.
- Exclusion of patients who were transferred from home during labor/delivery.
- May have excluded some of the maternal outcomes.

Committee member Manriquez commented about the invalidity of the study results because of the lack of inclusion of outcomes from cases that were transferred from a midwife to a medical provider.

Assistant Director Christ indicated she would ask the researchers to review that element.

CONCLUSIONS

- This review of the literature, as it pertains to births that occur in the home versus a hospital, provides evidence that midwives are effective in assisting with low risk home and hospital deliveries.
 - While there appears to be some increased risk for infants among births that occur in the home, there also appears to be fewer surgical interventions among women delivering with a midwife in the home and decreased assisted deliveries, c-sections, use of forceps, episiotomy, lacerations, and perineal tears.

Assistant Director Christ reiterated the Department’s intentions to inquire about the aforementioned validity issue.

Director Humble reminded the Committee members about the limitations with finding statistical power within available research to draw conclusions about the factors that drive the decision-making processes specific to the scope of practice issues under consideration. With that, Director Humble opened the committee floor to discussion of the implications of the study’s findings and conclusions:

Committee member Langlois commented that the neonatal death rate of the studies did not account for birth anomalies or the details of how or why those deaths occurred; as well as other factors contributing to such deaths in which the studies were of midwifery practices outside the U.S. in which the emergency medical systems may be lacking, or that the hospital to which a case was brought did not have an obstetrician on duty that day, etc.

Committee member Bovee commented that the biggest factor with respect to the research is that it is not indicative or reflective of Arizona outcomes; and especially given the limitations of the



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findings due to variations of midwifery practitioners (CNMs, LMs, CPMs, etc.), midwifery training and education, and other such variables.

Committee member Cleckner added that because the research does not present information about VBACs, multiple gestations, and breech presentations, she questioned the validity of reviewing the information as it does not inform the discussion and mission of this Advisory Committee.

To which Committee member Bovee responded by adding that she believes home births involving cases of VBACs, multiple gestations, and breech presentations are occurring in Arizona and expressed the desire to know about those outcomes.

Director Humble concurred with the sentiments about the lack of data available on Arizona home births and refocused the discussion on using evidenced-based decision-making using the research that is more globally available. He also reminded the Committee that the decision-making is informed by the available research but that such research is not where the decision-making begins or ends.

Committee member Manriquez mentioned that although there is no significant information available about midwife-attended birth outcomes in Arizona, there is information available from other states in which there is such data and named the state of Oregon specifically.

Committee member Cleckner asked for clarification of information contained on page 13, figure number 2 noting that the average death rate improves if one were to remove the deaths that occurred in cases attended by midwives in a hospital setting.

Director Humble indicated that the element would be revisited with the researches when the other limitations are follow-up on accordingly.

Committee member Manriquez presented some baseline Oregon data (Intrapartum and neonatal death rates) from that state's birth records noting that outcomes were better for births in a hospital setting compared to outcomes of births attended by "Direct Entry Midwives"

To which Committee member Fernstrom responded by adding the Oregon outcome data includes data from both licensed and unlicensed midwives that therefore the data does not compare outcomes of births attended by qualified and licensed midwives.

Director Humble clarified that any Oregon data would be lacking as to validation because it includes both licensed and unlicensed midwifery practitioners, and has not gone through a scientific peer-reviewed process and with that, moved the meeting to the next agenda item.

Agenda Item D: Discussion of Draft Midwifery Rules

Acting Deputy Assistant Director Thomas Salow, JD, presented an overview of the draft rules:



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Administrative

- New reporting requirements and form
 - Electronic submission
 - Required when patient services terminated
 - Within 30 days of termination
- New administrative rules go into effect July 1, 2013

Committee member Langlois asked for clarification about the due date for on-going reporting to which Acting Deputy Assistant Director Salow noted that the expectation was for reporting to occur within 30 days of the last date of service to the client. Assistant Director Christ affirmed the requirement.

Committee member Cleckner asked for clarification about how the reporting rules apply to a shared practice in which several midwives work with the same client or how would the rules apply in the context of a practice in which a midwife works with a physician at a birth center. Director Humble asked that the question be posed in writing so it can be more carefully consider such dynamics and asked that the writer directly reference the rules in question (R9-16, etc.).

Informed Consent

- Informed consent provided by midwife
- Must be maintained in patient record
- Informed consent now combined:
 - General informed consent for all patients
 - Must discuss risk with higher risk conditions specific to the patient (VBAC, breech, multiples)
- General informed consent goes into effect July 1, 2013

Emergency Action Plan

- Completed and kept on file for every patient
- Midwife must attest that the delivery place is within 25 miles of the nearest hospital for specified conditions
- Must call ER charge nurse at hospital identified in emergency action plan for all patients
 - When patient goes into labor
 - When patient delivers or requires transport
- Emergency Action Plan goes into effect July 1, 2013



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Committee member Fernstrom expressed concern for the way the implementation of the action plans would transpire and wondered if a dialogue with hospitals might help inform the decision-making process, noting concern about fueling the discord between home-birth providers and hospitalists.

Committee member Bovee expressed concern about the requirement of communicating the plan to the emergency department charge nurse, which she believed would not be very fruitful.

Committee member Manriquez expressed concern about the informed consent form being minimalized and believed it was lacking the elements that would convey the scope and severity of risk factors pertinent to home births.

Director Humble reminded the Committee that the rules reflects that consent must occur on a form approved by the Department and that the goal is to create a form that reflects the data elements supported by the findings of the research and asked Committee members to submit their recommendations in written form. He further added that the form would also develop over time based upon data elements born out from the data set resulting from the new rulemaking moving forward in time.

Committee member Fernstrom recommended looking at other informed consent models currently employed by the Department.

Director Humber asked a clarifying question about the notification requirements contained in the rules dealing with emergency action plans and who was a more appropriate person if not the “ER Charge Nurse”, to which Committee member Northup stated it to be the Labor and Delivery Charge Nurse.

Committee member Fernstrom asked how that would be received by the hospital system.

Director Humble noted that the collaboration could be mandated within the hospital rule set which is currently being developed.

Committee member Manriquez noted the value-added of using the emergency action plan to change the culture into a collaborative one, to which Committee member Northup concurred.

Scope of practice

- Must be NARM certified to manage higher risk pregnancies
 - Only NARM certified will be able to expand their scope of practice
- Goes into effect July 1, 2014

Director Humble reminded the Committee that the rules for VBACs will be largely based upon the Practice Management Guideline for Managing VBACs (guideline #115 dated August 2010) and that the goals of the entire process is to improve upon the system of care for home-births.



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Committee member Fernstrom asked why the expansion would not take effect until July of 2014 (questioning the reason for the delayed implementation).

Director Humble noted that the date was not set in stone but the idea was to allow some training to occur for the licensees who will have the expanded scope (CPMs certified by the North American Registry of Midwives).

On-going Advisory Committee

- Committee established to
 - Review data from midwife reports
 - Examine evidenced based research
 - Recommend to the director changes in regulatory rules
- Consist of: 2 licensed midwives, 2 consumers, 1 licensed physician; 1 nurse midwife
- Advisory Committee goes into effect July 1, 2013

Agenda Item E: Next Steps & Timeline

Director Humble stated that the next meeting would be held in early May after which there would be another 30 day comment period before a final draft of the rules is submitted to the Secretary of State.

Agenda Item F: Closing Remarks

Director Humble thanks everyone for their diligent work on this Committee and expressed optimism for moving forward with the goals of the legislation leading to the formation of this Committee and the resulting subsequent rule-making.