STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

January 28, 2013

The Honorable Peter Hammen
Chair, House Health and Government Operations Committee
House Office Building, Room 241
Annapolis, MD 21401

Dear Chair Hammen:

Attached is a report from the Midwives Workgroup, convened by the Maryland Department of Health and Mental Hygiene (the Department) per your 2012 request regarding HB 1056.

You will note that the report did not find consensus, but rather provides a wide a range of options. This is because there are very diverse views on how best to address the increased demand for licensed, safe home birth services in Maryland.

It was reported that while there are 214 certified nurse midwives licensed to practice in Maryland, fewer than half actually practice full-scope midwifery, and only four currently attend home births. As a result, the Department recommends further exploration of the barriers to training and practice for certified nurse-midwives in Maryland, which are detailed in the enclosed report. The Department's position is that this approach will best balance access to a home birth with infant and maternal safety. The Department remains in support of the joint statement on Planned Home Births released last year that was endorsed by the Maryland Board of Nursing as well as by the Maryland Association of County Health Officers. The joint statement is also enclosed.

If you would like to discuss these matters further, please feel free to contact me at 410-767-6525 or laura.herrera@maryland.gov.

Sincerely,

Laura Herrera, M.D., M.P.H.
Deputy Secretary for Public Health

Enclosure

Midwives Workgroup
Report to the Maryland House Health and Government Operations Committee and the Maryland Senate Education, Health, and Environmental Affairs Committee

January 2013

Introduction

Creation of Workgroup

During the 2012 legislative session, HB 1056 entitled "Health Occupations – Licensed Midwives" was introduced. The bill hearing generated a great deal of public interest. The Department of Health and Mental Hygiene (DHMH) did not support that measure but supported the concept of a workgroup to examine the apparent increase in demand for licensed, safe home birth services. HB 1056 did not ultimately pass, however, Delegate Hammen, chair of the House Health and Government Operations Committee, requested that DHMH convene a workgroup on this topic. Therefore, DHMH formed the Midwives Workgroup comprised of interested health care providers and stakeholders.

Charge of Workgroup

The Workgroup was given four charges to address:

1. Analyze the shortage of certified nurse-midwives (CNMs) in Maryland, including barriers in training nurse-midwives and barriers in nurse-midwifery practice in hospitals and non-hospital settings;

2. Evaluate consumer concerns and motivations surrounding the birthing process, including the choice to pursue a home birth or birth center birth, and concerns related to hospital births;

3. Conduct a review of current legislation and regulations in other states concerning the licensing, educational requirements, and scope of practice of certified professional midwives; and

4. Review available evidence regarding the safety and outcome of births attended by certified professional midwives, certified nurse-midwives, and obstetricians, as well as the safety of home births and birth center births compared to hospital births.

Several issues came up during discussions that were not specifically mentioned in the Workgroup's charges but are relevant to them. They are noted in this report and include: Medicaid reimbursement, vicarious liability, professional liability insurance, and Board of Nursing (BON) composition, composition of committees within the BON (CNM peer review and joint review committees), and processing of complaints against certified nurse-midwives.

Workgroup Membership

The Midwives Workgroup was composed of 13 members who represented a broad array of stakeholder groups. Members were drawn from the Maryland General Assembly, professional associations and organizations, accreditation bodies, trade organizations, academic institutions, hospitals, and consumer advocacy groups. Multiple types of providers were represented in the group, including Certified Professional Midwives (CPMs), Certified Nurse-Midwives (CNMs), nurses, and physicians.

Midwives Workgroup Roster
Bonnie S. Birkel, CRNP, MPH – *Chair*, Maryland Department of Health and Mental Hygiene
Mairi Breen Rothman, CNM – American College of Nurse-Midwives
Ida Darragh, CPM – North American Registry of Midwives
Susan Jean Dulkerian, MD – American Academy of Pediatrics, Maryland Chapter
Jenifer O. Fahey, CNM, MPH – University of Maryland Medical Center
Karen Fennell, MS, RN – American Association of Birth Centers
Jeremy Galvan, NREMT-P – Maryland Families for Safe Birth
The Honorable Ariana Kelly – Maryland House of Delegates
Janice Lazear, DNP, CRNP, CDE – University of Maryland School of Nursing
The Honorable Karen Montgomery – Maryland State Senate
Joseph Morris, MD – Maryland Hospital Association
MaryLou Watson, RN, MS – Maryland Board of Nursing
Melissa M. Yates, MD – American College of Obstetricians and Gynecologists, Maryland Section
Maura Dwyer, DrPH, MPH – *Staff*, Maryland Department of Health and Mental Hygiene

Workgroup Meetings and Materials

The Workgroup held four public meetings over the course of the summer and fall of 2012 (July 12, August 23, September 20, and October 25).

All Workgroup meeting agendas, minutes, materials and available data can be accessed at: http://dhmh.maryland.gov/midwives/SitePages/Home.aspx.

Data regarding midwifery services in Maryland are limited. Data that were requested but unavailable include: unmet need for midwifery practice; outcomes among midwife- and physician-attended births, adjusting for risk; outcomes among home, birth center and hospital births, adjusted for risk; and obstetric shortage areas in Maryland.

A period for public comment was allowed at meetings. Public comment could also be submitted via the Workgroup web site. Public comments are summarized in this report under charges #2 and #4.

Overview of Report and Options for Action

This report provides background information on the charges examined by the Workgroup, provides a summary of key discussion points for each of the four Workgroup charges, and presents ***all*** Options for Action suggested by Workgroup members related to each charge.

The Options for Action presented with each charge in this report ***do not reflect consensus*** but instead represent the full range of options presented by Workgroup members, some of the options are mutually exclusive. The Workgroup was not able to reach consensus on many of the issues examined.

The Options for Action do not necessarily represent the views of DHMH, nor do they necessarily represent the views of DHMH's health occupations boards.

Background on Midwives, Home Births, and Birth Centers

Midwives

According to the American College of Nurse-Midwives (ACNM), midwives are "primary health care providers to women throughout the lifespan… Midwives perform physical exams, prescribe medications including contraceptive methods, order laboratory tests as needed, provide prenatal care, gynecological care, labor and birth care, as well as health education and counseling to women of all ages" (http://www.midwife.org/About). This definition applies to certified nurse-midwives CNMs and certified midwives (CMs), as ACNM is the professional association that represents CNMs and CMs.

According to the North American Registry of Midwives (NARM), a Certified Professional Midwife (CPM) is a knowledgeable, skilled and professional independent midwifery practitioner who has met the standards for certification set by NARM and is qualified to provide the Midwives Model of Care and is the only midwifery credential that requires knowledge about and experience in out-of-hospital settings (http://narm.org/). In partnership with their clients, CPMs carefully monitor the progress of the pregnancy, labor, birth and postpartum period and recommend appropriate management if complications arise, collaborating with other health care providers when necessary. The CPM scope of practice is limited to the childbearing year and out-of-hospital births. According to the American Association of Birth Centers, one-half of the 179 birth centers in the United States are CPM-owned.

Currently, only CNMs are licensed to practice in the State of Maryland, and licensure in Maryland allows for the full CNM scope of practice. There are, however, three national credentials in the United States for midwifery:

- Certified Professional Midwife (CPM) - non-nurses credentialed through the North American Registry of Midwives (NARM); high school education is the minimum requirement and competencies are verified in clinical settings (including required attendance of home births); have completed a formal program of study either through a

midwifery school accredited by MEAC (Midwifery Education Accreditation Council) or through the NARM Portfolio Evaluation Process (PEP), which includes a three to five year clinical internship and the attendance of a minimum of 20 births as a midwife assistant, followed by 75 prenatal exams, 20 births as the primary attendant, 20 newborn exams, and 40 postpartum exams. CPMs must also pass the eight hour national certifying exam and skill assessment administered by NARM;

- Certified Midwife (CM) - a non-nurse midwife who holds a master's degree from a midwifery education program accredited by the Accreditation Council on Midwifery Education (ACME) in addition to a Bachelor's degree in any subject, with completion of specific science courses, and has passed a national certifying exam administered by the American Midwifery Certification Board (AMCB); and

- Certified Nurse-Midwife (CNM) - a practitioner with a degree in nursing who has completed a master's level midwifery education program accredited through ACME, and passed a national certifying exam administered by AMCB.

According to data provided by the Maryland Vital Statistics Administration, Maryland experienced a statistically significant decrease in CNM or "other midwife" (both categories are listed on the Maryland Birth Certificate) births of 12% between 1998 and 2010, from 5,954 births (representing 8.3% of all births) to 5,379 (representing 7.3% of all births) (Table 1). The Maryland Board of Nursing (BON) reports that there are 214 CNMs licensed to practice in Maryland. However, it is estimated that fewer than half of these CNMs are actually practicing full-scope midwifery (independently providing antepartum, intrapartum, postpartum, or gynecologic or primary care for women). Many CNMs in Maryland are working solely in outpatient gynecology offices, in local health departments (LHDs), in family planning clinics, teaching, in administration, research, or as "physician extenders" by performing prenatal care in a physician-owned practice where they are not allowed to attend deliveries. Many CNMs in the State are not working in any health-related field. Only two or three practices in Maryland are owned and operated by CNMs. According to Maryland Families for Safe Birth, only four CNMs based in Maryland practices currently attend home births. It is not surprising, therefore, that of the births attended by CNMs in Maryland, 97% take place in the hospital. There are no data on the number of CPMs and CMs in Maryland as they are not licensed to practice in the State.

Table 1.

Certified Nurse-Midwife (CNM)/Midwife[1] Attended Births in Maryland, 1998, 2010

Jurisdiction	# of CNM/Midwife Attended Births 1998	2010	%* of Total Births 1998	2010	Rate Percent Change** (1998-2010) % Change	Stat Sig
ALLEGANY	6	0	0.8			
ANNE ARUNDEL	477	525	7.2	7.4	2.7	
BALTIMORE COUNTY	523	721	5.8	7.3	26.6	***
CALVERT	12	13	1.3	1.4	12.8	
CAROLINE	44	35	13.1	8.1	-38.1	***
CARROLL	89	68	4.6	4.2	-8.6	
CECIL	37	55	3.4	4.6	37.2	
CHARLES	46	27	2.7	1.5	-45.0	***
DORCHESTER	31	25	10.4	6.6	-36.9	
FREDERICK	853	70	31.2	2.5	-92.1	***
GARRETT	6	11	1.7	4.0	136.1	
HARFORD	238	216	7.7	8.0	3.3	
HOWARD	518	476	15.4	14.1	-8.5	
KENT	66	4	36.5			
MONTGOMERY	514	344	4.2	2.6	-38.2	***
PRINCE GEORGE'S	769	802	6.3	6.6	3.8	
QUEEN ANNE'S	52	21	10.9	4.3	-60.4	***
SAINT MARY'S	49	13	4.0	0.9	-77.6	***
SOMERSET	19	0	7.7			
TALBOT	43	23	13.4	6.4	-51.8	***
WASHINGTON	609	762	38.6	43.1	11.7	***
WICOMICO	87	11	8.4	0.9	-89.5	***
WORCESTER	60	1	12.3			
BALTIMORE CITY	806	1156	8.4	12.9	54.3	***
MARYLAND	**5954**	**5379**	**8.3**	**7.3**	**-12.1**	***

Data Source: MD DHMH, Vital Statistics Administration *Percentages based on <5 events are not displayed

** Percent change is based on the exact rates and not the rounded rates presented here. *** Percentages for 1998 and 2010 differ significantly (p<0.05)

[1] Note, the Maryland birth certificate contains both categories, 'CNM' and 'Other Midwife.' Maryland Vital Statistics Administration is not able to discern if other midwives are practicing in Maryland or if CNMs are sometimes misclassified as 'Other Midwife' on the birth certificate.

Home Birth

Home birth was an ongoing focus of Workgroup discussion at all four meetings. Workgroup members reported increasing demand in Maryland for non-hospital birth services but an insufficient number of CNMs who perform home births in Maryland to meet this demand. The safety of home births was discussed extensively in Workgroup meetings. A detailed summary of these discussions can be found under Charge 4 of this report.

The percentage of US births occurring at home increased between 2004 and 2009 by 29%, from 0.56% of all births to 0.72%, following a gradual decline between 1990 and 2004 (MacDorman, Mathews and Declercq 2012). According to the Maryland Vital Statistics Administration, the percentage of Maryland births occurring at home increased by 23% between 2009 and 2011, from 387 home births in 2009 (representing 0.52% of all births), to 414 in 2010 (representing 0.56% of all births), to 465 in 2011 (representing 0.64% of all births). Home births still represent less than 1% of all births in the State. Maryland's home birth rate does not exceed the national rate.

Since many members of the Workgroup had not had direct experience with home birth or birth center births, a CNM who attends home births provided some information regarding the specifics of the home as a setting for births, and about the care provided by CNMs during home birth. According to the ACNM representative, planned home birth services involve all of the equipment and supplies available at a birth center. These include: intravenous (IV) line set-up and fluids, oxygen, medications including pitocin and antibiotics, resuscitation equipment, sutures and local anesthetic, various needles and syringes, urinary catheters, amnihooks, sterile instruments, baby scale, and more. CNMs monitor the mother's vital signs, cervical dilation, contraction patterns, nutrition, energy, and monitor the baby's heart rate according to ACOG Guidelines for Intermittent Auscultation, or more frequently. The baby is kept warm by skin-to-skin contact on the mother for 1-2 hours following delivery. CNMs leave only when the mother can eat, drink, nurse, empty her bladder and shower unassisted, and the baby has been thoroughly examined and has nursed. In a typical CNM home birth practice, the baby is examined again by the CNM the day after delivery, by the pediatric provider the next day, and the CNM on the third day. The mother is seen by the CNM on postpartum days one and three, and again at two weeks and six weeks postpartum. The NARM representative reported that CPMs attend home births in the same manner.

Birth Centers

The American Association of Birth Centers (AABC) defines a birth center as "a homelike facility existing within a health care system with a program of care designed in the wellness model of pregnancy and birth . . .Birth centers provide family-centered care for healthy women before, during and after normal pregnancy, labor and birth." According to the Maryland Vital Statistics Administration, the percentage of Maryland births occurring at birth centers increased by 15% between 2009 and 2011, from 254 center births in 2009 to 292 in 2011. According to the AABC, five birth centers have closed in Maryland since 1998. Two freestanding birth centers remain in Maryland, both are located in Anne Arundel County. One is owned by Anne

Arundel Medical Center, where its CNMs have privileges. The other, privately owned, is located near a hospital and is operated by CNMs. Workgroup members reported that many of the birth centers that closed did so because of the difficulty finding or maintaining an agreement with a collaborating physician and financial solvency due to low volumes. The prohibitive cost of professional liability insurance was cited as another reason Maryland birth centers closed.

According to the Guidelines for Perinatal Care, Seventh Edition (2012) published jointly by ACOG and AAP, "*A hospital, birthing center within a hospital complex, or a freestanding birthing center that meets the standards of the Accreditation Association for Ambulatory Health Care, The Joint Commission, or the American Association of Birth Centers provides the safest setting for labor, delivery, and the postpartum period*."

The demographic characteristics of women in Maryland who give birth at home and in birth centers are significantly different than women who give birth in hospitals. In 2010-2011, 78% of home births and 79% of birth center births were among white women, compared to 45% among all hospital births. During that same time period, 67% of home birth mothers and 55% of birth center birth mothers were over age 30 years compared to 45.7% of all hospital births. In terms of education, 89% of home births and 91% of birth center births were to mothers with more than a 12^{th} grade education, compared to 63% of all hospital births.

Charge 1: Analyze the shortage of CNMs in Maryland, including barriers in training CNMs and barriers in nurse-midwifery practice in hospitals and in non-hospital settings.

Barriers to Midwifery Training

Workgroup members reported a number of barriers related to midwifery training in Maryland. Currently, the only nurse-midwifery training program available in the State is the Johns Hopkins University School of Nursing's CNM program, where students can earn a Master of Science in Nursing from Hopkins and a Certificate in Midwifery from Shenandoah University in Virginia (which makes this component of training a distance program). The program began admitting students in 2008 and has graduated 20 CNMs to date. With recent interest, the program has doubled the number of applications for the most recent admission cycle. The University of Maryland School of Nursing's CNM program closed in 2009 due to the significant costs of liability insurance, declining enrollment at that time, and difficulty in finding preceptor sites for student training (reasons cited include the fact that CNM preceptors are not paid as preceptors for medical students are and precepting affects productivity). Further, some Workgroup members reported that graduates from this program had difficulty finding jobs in Maryland practicing full-scope midwifery, as was previously described. Maryland students interested in midwifery training can access distance-learning programs, such as Frontier Nursing University, the University of Cincinnati, and Philadelphia University.

Proposed Options for Action (offered by Workgroup members on behalf of the organizations they represent; Workgroup did not reach consensus on the Options listed).

- Require hospitals that have obstetrical units and that receive Medicaid reimbursements to establish clinical practice sites for CNM students.
- Require all hospitals that have CNMs practicing there to allow CNMs to accept students to train with them.
- Establish a State scholarship and loan forgiveness program for midwives who work in shortage areas after graduation from midwifery school.
- Explore potential options for opening an in-State nurse-midwifery education program.
- Provide in-state tuition for students attending distance midwifery programs.
- Assure that students attending midwifery programs via distance learning obtain clinical placements in Maryland hospitals.

Barriers to Midwifery Practice

Oversight and Regulation

As of June 2010, midwives in Maryland are no longer required to have a physician sign a collaborative agreement to provide clinical support to CNM-attended births, but instead must give the BON a copy of a collaborative plan that lists a physician to whom they would transfer a patient in case of emergency. Workgroup members reported that this still presents a significant challenge. The CNM representative to the Workgroup reported that there is a perception that many OB/GYNs are unwilling to collaborate with CNMs, for both home and birth center births. Workgroup members cited three primary barriers to collaboration: (1) physicians do not get paid to collaborate without a formal referral; (2) they fear vicarious liability, i.e. that they will be sued for issues arising from management decisions made by the CNM; and (3) there are no clinical practice guidelines for receiving transferred patients. Some Workgroup members expressed the goal of an integrated health care system, where CNMs are recognized as independent practitioners, with admitting and discharge privileges in hospitals, and access to other health care providers for consultation or transfer of care, if necessary.

Some Workgroup members cited factors associated with the Maryland Board of Nursing (BON) policies and procedures, which is mandated to regulate the practice of CNM, as barriers to midwifery practice in Maryland. Reported barriers include: incomplete data regarding the number of CNMs practicing full-scope midwifery in the State; the length of time it takes to become licensed; the lack of CNM representation on the BON; BON's practice of immediately suspending the license of CNMs who have received a complaint; a peer review process following complaints that does not include CNMs; and lengthy investigations following complaints. The

BON stated that their first responsibility is always to protect the public and that the process for investigating allegations can take up to two years. They reported that in the past, there had been a backlog of cases to be reviewed, but that the backlog has been eliminated under new leadership. The BON representative on the Workgroup refuted the statement that there is a lack of CNM presence on the BON and explained that as a representational Board, there is indeed access to an advanced practice nurse and additional access to a subcommittee of CNMs as needed.

Certificate of Need (CON) requirements were also reported by some Workgroup members as a barrier to freestanding birth centers. Some members believe that currently, these requirements do not allow birth centers to be located near a hospital as it would be deemed to be a competitor of the hospital. The Workgroup did not review the CON requirements during its deliberations. The Maryland Health Care Commission reports that freestanding birth centers are not regulated under State CON laws.

<u>Proposed Options for Action</u>

- Eliminate the Board of Nursing regulation requiring submission of a Collaborative Plan form between physician and midwife or any other barrier to independent practice (as of June 2010, CNMs in Maryland are no longer required by Board of Nursing to have a physician sign a Collaborative Agreement to provide clinical support to CNM-attended births).

- In place of a Collaborative Plan, adopt a regulation such as the District of Columbia's, which simply requires the CNM to provide proof of her/his education, certification, and attestation of intention to practice according to ACNM's Standards for the Practice of Midwifery (which require every CNM to have Clinical Practice Guidelines that include plans for consultation, collaboration, and referral).

- Establish an independent midwifery board for licensure, regulation, and oversight of midwives. In the interim, adjust the current complaint process so that CNM cases are investigated by CNMs who are experienced in the practice setting of the midwife receiving the complaint.

- Establish a study group consisting of CNMs and CPMs to develop a plan and timeline for establishing a Board of Midwifery.

- Regulate all midwives under the Board of Nursing with CNMs.

- Reform the Board of Nursing's complaint process to promote transparency of investigative and disciplinary processes, especially regarding the suspension of licenses while cases are heard.

- Require that a nurse-midwife serve on Board of Nursing committee that reviews complaints against CNMs.

- Reform the licensure process to expedite the length of time it takes to obtain a license to practice midwifery.

- Assure any regulatory framework includes significant training, certification, and recertification processes for midwives.

- Conduct an independent audit of CNM licensees regarding current setting and scope of practice, to correctly inventory how many CNMs are practicing full-scope midwifery and in what settings.

- Investigate using the licensing process to continue to increase the visibility of the profession among the public and other providers because the State does not have adequate data to evaluate the shortage or unmet need for nurse-midwives or certified midwives.

- Require hospitals to grant admitting privileges for CNMs (modeled after the District of Columbia law).

- Require/encourage hospitals providing maternity services to recognize and offer the Midwifery Model of Care.

- Expand access to services and community models of care that include CNMs and freestanding birth centers, which have been shown to improve quality and outcomes of maternity care for vulnerable populations.

- Remove barriers to out-of-hospital practice for CNMs, and license certified professional midwives (CPMs) to provide those services.

- Exempt independent birth centers from Certificate of Need requirements.

Obstetric Practice Environment

Several members cited liability insurance as an impediment to practicing midwifery in the State. The costs of liability insurance are significant in Maryland and have reportedly driven many providers out of the field. Further, workgroup members reported that CNM liability insurance costs are not low enough to compensate for the lower revenue CNMs generate due to the fact that their scope of practice does not include higher grossing procedures such as surgery. Finally, workgroup members reported that when a physician is named in a case, his/her insurance premiums will likely increase. Workgroup members reported that this has forced many of the OB/GYN physicians who collaborated with CNMs in the past to stop collaborating and/or stop practicing obstetrics entirely.

<u>Proposed Options for Action</u>

- Reconsider professional liability insurance reform in Maryland to reduce barriers to practice for all OB providers.

- Adopt "vicarious liability language" to protect physicians and receiving hospitals from liability for care provided to a woman and her child who selects an out-of-hospital birth.

- Remove any vestiges of "vicarious liability" by ensuring that statutory and regulatory measures clarify the role of CNMs as independent providers responsible and liable for their own management decisions.

- Consider a requirement for all OB providers to maintain reasonable malpractice insurance coverage; or require OB providers to disclose lack of malpractice coverage to consumers.

- Promote collaborative care models that incorporate appropriately skilled, lower cost clinicians.

- Promote the hiring of nurse-midwives into practices, hospitals, and health centers such as FQHCs particularly in underserved areas of Maryland.

Charge 2: Evaluate consumer concerns and motivations surrounding the birthing process, including the choice to pursue a home birth or birth center birth and concerns related to hospital births.

Limited access to licensed home birth midwives was reported to be a primary concern among some consumers in Maryland. Consumers who provided public input at meetings stated that many Maryland women who are interested in having a home birth are "forced underground" to deliver at home, unattended, without prenatal or postpartum care because they cannot find a home birth attendant. Other consumers reportedly delivered with a CPM (not licensed to practice in Maryland) because they could not find a CNM to attend their birth, and petitioned for the licensure of CPMs as a means of upholding care standards of CPMs and improving access to safe and legal home birth and birth center services.

Consumers expressed that demand for home births is driven by interest in the midwifery model, which allows more time for education, provides for a more collaborative relationship between provider and patient, and produces excellent health outcomes. Many consumers also expressed a strong desire to avoid a surgical delivery and to have more flexibility regarding a number of medical interventions that more commonly occur in hospitals. Several consumers described their frustration with hospitals' perceived lack of support for a woman's right to labor as she desires, and problematic home birth transfers where patients feel degraded, care is disrupted, and outcomes are perceived as threatened. Consumers acknowledged that there are risks associated with birth and feel that determinations regarding delivery should be made between the mother and her practitioner, in all birth settings, with information about risks of each option conveyed through an informed consent process.

Lack of true access to vaginal birth after cesarean (VBAC) in Maryland hospitals was noted as a leading contributor to the increased interest in home birth. ACOG has issued a statement in support of VBAC, however both ACOG and the Maryland Hospital Association

recommend VBAC deliveries only in settings where an emergency C-section can be done. Many hospitals in the State do not allow women who have had a previous cesarean birth to try delivering vaginally because emergency services are not available 24/7. Further, the two CNMs on the Workgroup reported regularly receiving patients late in pregnancy who are seeking a VBAC delivery after being told their OB/GYNs would not support their desire to deliver by VBAC. In June 2008, the Commission for the Accreditation of Birth Centers (CABC) adopted a policy in support of VBAC deliveries for low risk women in accredited birth centers who have had one previous cesarean section (http://www.birthcenteraccreditation.org/2011/07/cabc-vbac-policy-adopted-june-2008/).

In March 2010 the National Institutes of Health (NIH) issued a consensus statement regarding VBAC delivery (Cunningham 2010) which noted:

"No strong comparative data are available to assess the relative impact of types of maternity care providers (obstetrician-gynecologists, family practice physicians, midwives) on patterns and utilization of trial of labor after controlling for selection bias and patient mix . . . Women give birth in a variety of settings in and out of hospitals, including tertiary care centers, community hospitals, freestanding birth centers, and at home. Most data on maternal and neonatal outcomes are collected in tertiary care settings, which means that there is little data that assesses these outcomes across numerous settings."

Attendance at Workgroup meetings by members of the public ranged from approximately 10 to 40 individuals who offered clear support for expansion of home birth services through the licensing of CPMs. Safety was cited as a primary reason for delivering at home where there is more flexibility regarding medical interventions, a greater likelihood of avoiding cesarean delivery, and the ability to attempt a VBAC delivery. However, safety was not defined in the workgroup. Consumers also expressed their belief that the public's health is served by allowing a mother to deliver with the provider and in the setting of her choice, and that more providers are needed to facilitate this choice and provide adequate oversight. Input was also submitted by one member of the public via the Midwives Workgroup web site, who expressed concern about the safety of out of hospital births and support for the Board of Nursing to provide continued oversight of midwifery practice in Maryland.

<u>Proposed Options for Action</u>

Birthing Process

- Promote the midwifery, low-intervention model of maternity care as a priority for Maryland to improve quality and reductions in costs.

- Recognize and protect a woman's human right to choose her health care provider, procedures, and place of birth.

- Recognize and protect a woman's human right to refuse a surgical birth.

- Increase access to nurse-midwives in all birth settings including hospitals.

- Assure that consumers are provided education and information about the advantages and risks of home births versus hospital births.

- Require that providers and hospitals obtain informed consent using educational materials to provide objective information to consumers that includes a discussion of both risks and benefits of all procedures.

- Require informed consent for all women choosing home birth regarding the risks, limitations, and advantages of their care locations, care practices, and their maternity care provider.

- Assure access to vaginal birth after cesarean (VBAC) in all birth settings.

- Assure that women considering VBAC receive accurate and complete information regarding the risks and benefits of VBAC as well as the risks and benefits of elective repeat cesarean-section.

- Establish a formal structure for consumers, CNMs, CPMs, physicians, and hospital representatives to meet on a regular basis to determine ways to make home birth and hospital birth both safe and consumer-friendly options.

- Conduct an educational campaign for consumers and providers on safety and desirability of physiologic labor and birth including benefits of awaiting spontaneous birth.

Oversight and Regulation

- License CPMs under a board of midwifery to provide for adequate standards for home birth providers and to assure accountability for those providers.

- Establish a Consumer Advisory Panel on Midwifery and Birth at the Department level to include consumers who are not birth professionals.

- Require all birthing hospitals allow all qualified providers to have admitting privileges.

- Require all insurance carriers selling policies in Maryland to follow Maryland laws.

- Consider the creation of a Maternity Care Taskforce/Workforce with representatives from all disciplines who are involved in the care of women during pregnancy and childbirth that is charged with studying the quality of maternity care in the State and making recommendations on and assisting with the implementation of measures that ensure that the care provided to all women in the State is based on the highest quality of evidence, promotes excellence in outcomes, and reduces the costs related to unnecessary interventions.

Hospital Births

- Reduce initial cesarean rates by increasing access to midwives.

- Reduce hospital interventions by increasing access to midwives.

Out-of-hospital Births

- Require hospitals to have written clinical practice guidelines for accepting home birth and birth center birth transfers, including a point of contact available at all times and procedures for evaluation and follow-up of the transfer process.

- Require that all home births have a standardized transfer plan on both sides of the transfer relationship, for both emergent and non-emergent care, that facilitates continuity of midwifery care when possible.

- Require that all planned home births occur within a collaborative practice model that includes a maternity care team and integrated systems of care with established criteria and provision for emergency intrapartum transport.

Charge 3: Conduct a review of current legislation and regulations in other states concerning the licensing, educational requirements, and scope of practice of certified professional midwives.

The CPM credential, issued by NARM, is accredited by the National Commission for Certifying Agencies (NCCA), like the CNM credential. CPMs follow the practice standards of the National Association of Certified Professional Midwives (NACPM), which includes the development of collaborative relationships with other health care practitioners who can provide care outside the scope of midwifery practice when necessary. NACPM standards limit the CPM scope of practice to the primary maternity care of healthy women experiencing normal pregnancies. Practice settings for CPMs include homes, birth centers, and offices. Recertification is required every three years. Private insurance reimburses CPM services in some states; Medicaid reimburses CPM services in 10 states for home birth, and additional states reimburse through Medicaid if the birth occurs in a birth center.

CPM educational requirements include a high school diploma or GED (although most CPMs do attend some sort of formal education) and an apprenticeship training program, where the student must find a midwife preceptor who is nationally certified or state licensed, has practiced for at least three years, and attended at least 50 out-of-hospital births. The NCCA encourages their accredited certification programs to have an educational evaluation process so candidates' qualifications are evaluated for credentialing. The NARM apprenticeship requirement meets this recommendation. Clinical skill requirements must meet the core competencies developed by the Midwives Alliance of North America (MANA) and include management of prenatal, birth, and postpartum care for women and newborns. The CPM is the only NCCA-accredited midwifery credential that includes a requirement for out-of-hospital delivery experience.

The CPM is regulated in 26 states by licensure, certification, registration, voluntary licensure, or permit. All 26 states use the NARM exam for licensure, whether requiring the entire CPM credential or the exam in addition to a state evaluation process. There are two additional states that license direct entry midwives through the CM credential, which does not include the NARM exam. Licensure agencies vary by state and include departments of health, boards of medicine, and boards of midwifery.

Varied licensure requirements among states were cited as a barrier to safety and accountability by some Workgroup members. Nationally certified midwives operate within varied scopes of practice and levels of integration within regional health settings. Setting a common licensure could increase consumer awareness of different types of midwives and their scopes of practice.

The Workgroup, along with the Chair, identified 10 states that license CPMs, which could serve as models for Maryland: California, Delaware, Florida, Louisiana, New Jersey, New Mexico, Oregon, Texas, Virginia, and Washington. The laws and regulations vary significantly by state. Some states focus more on the duties of the regulatory board or council, while others give more weight to the scope of practice for midwives. Every state has requirements related to application and renewal fees, but these are not mentioned for the sake of brevity. Details are provided in Attachment 1: State Case Studies of Non-nurse Midwives.

Table 2. Midwifery Laws and Regulations in 10 Case Study States

State and Year Enacted	*Regulatory Body*	*Title*	*State Oversight*	*Certification/ Exam*	*Education/ Pre-requisites*
California 1973	Midwifery Advisory Council; members appointed by the Medical Board	Licensed midwife	Medical Board	NARM exam	3 year post-secondary midwifery education program (84 semester units or 126 quarter units)
Delaware 1978	Division of Public Health	Direct-entry/ non-nurse midwife	Department of Health and Social Services	CPM from NARM or CM from ACNMCC	Complete accredited midwifery program
Florida 1995	Council of Licensed Midwives; 9 members appointed by the secretary	Licensed midwife	Department of Health	NARM exam	3 year approved training program with clinical, didactic, and practical preceptorship; at least 21 years old
Louisiana 1985	Louisiana Advisory Commission on Midwifery; 7 members appointed by the governor and confirmed by the senate	Licensed midwife/ apprentice midwife/ senior apprentice midwife	Board of Medical Examiners	NARM exam	Apprentice program; didactic and supervised clinical under MD, CRNM, or CM
New Jersey 2002	Board of Medical Examiners, Midwife Liaison Committee	Certified midwife or certified professional midwife	Professions and Occupations	NARM, ACC, or ACNM	Complete accredited midwife program
New Mexico 1978	Licensed Midwifery Advisory Board; 9 members and 1 ex-officio member appointed by the division	Licensed midwife (CPMs must be licensed)	Public Health Division of the Department of Health	NARM exam	New Mexico midwifery standards
Oregon 1993	State Board of Direct Entry Midwifery; 7 members appointed by the governor	Direct entry midwife	Health Licensing Agency	NARM	Didactic and clinical requirement
Texas 1983	Midwifery Board; 9 members appointed by the commissioner	Licensed midwife	Department of Health Services	NARM exam or any other approved by the Board	NARM-approved or MEAC-accredited program, didactic and clinical training or apprenticeship
Virginia 2005	Advisory Board of Midwifery; 5 members appointed by governor with senate approval (NARM document incorrectly stated it was a 10-member board)	Certified professional midwife	Department of Health Professions, Virginia Board of Medicine	NARM	No educational requirement
Washington 1991	Midwifery Advisory Committee; 7 members appointed by the secretary	Midwife	Department of Health	NARM exam and state exam	High school diploma, certificate or a diploma from midwifery program accredited by the secretary, min. 3 years of training

Proposed Options for Action

Licensing

- Establish licensure for CPMs, which will allow them to carry malpractice insurance and take responsibility for their practice.

- Adopt the CPM as the model for licensure of direct-entry midwives in Maryland.

- License and regulate all midwives under the Board of Nursing with CNMs.

- Establish Board of Midwifery or an Advisory Board within an existing board, composed mostly of licensed midwives and having the authority to set guidelines for practice and provide regulatory oversight of all licensed midwives.

- Further study licensure laws in the surrounding states before submitting legislation to the Maryland General Assembly.

Educational Requirements

- Require that the nationally accredited NARM certification be the educational requirement for CPM licensure in Maryland.

- Require a minimum level of education and training for all midwives according to standards set by the American Midwifery Certification Board.

- Adopt the ACNM position on education for all midwives, congruent with global standards laid out by the International Confederation of Midwives (ICM), which requires "[s]uccessful completion of a formal education program accredited by an agency recognized by the U.S. Department of Education**.** The requirement for formal education is one mechanism whereby the public can receive a significant measure of assurance that individual practitioners have been educated within a system where the quality of the faculty, relevance of class and clinical content, and the rights of the students to receive a quality education are evaluated on a regular basis by an outside agency which specializes in these types of assessments. The education program should consist of a standard curriculum taught by qualified faculty."

- License current CPMs while accredited educational programs are established and give a specific time frame for registration and completion of a formal, accredited, direct-entry midwifery educational program, in order to maintain licensure.

Scope of Practice

- License CPMs to practice in Maryland birth centers as well as for home births.

- Require a Board of Midwifery to regulate CPMs based on the NARM scope of practice.

- Limit the scope of practice for CPMs to prenatal care, home birth, and postpartum care of women with low-risk pregnancies. Newborn care should be assumed by a pediatric provider soon after birth.

- Limit the prescriptive authority of CPMs to medications only essential at the time of birth.

- Assure that CPMs are permitted to order laboratory and other needed prenatal tests for women with low-risk pregnancies.

- Establish in statute the specific medications and equipment permissible for use by midwives.

- Assure that any restrictions to the formulary do not limit a midwife's ability to provide the care they are licensed to provide.

- Require that a licensed home birth attendant have a process in place where consultation with hospital-based and privileged consultants can occur expeditiously in the prenatal, intrapartum, and postpartum periods to guarantee safe and expeditious transfer of care and transport to a hospital for optimal continuity of care.

Charge 4: Review available evidence regarding the safety and outcome of births attended by certified professional midwives, certified nurse-midwives, and obstetricians, as well as the safety of home births and birth center births compared to hospital births.

An annotated guide to home birth literature produced by ACNM (Vedam et al. 2012) was shared with the Workgroup, and Workgroup members were asked to cite published literature of peer-reviewed, high quality studies of births in non-hospital settings or births attended by CPMs. These studies and the ACNM annotated bibliography are cited in the References section of this report; the ACNM annotated bibliography is included as Attachment 2.

Studies on the Safety of Out-of-hospital Births

According to the Guidelines for Perinatal Care, Seventh Edition (2012) published jointly by ACOG and AAP:

"Although the American College of Obstetricians and Gynecologists believes that hospitals and birthing centers are the safest setting for birth, it respects the right of a woman to make a medically informed decision about the delivery. 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 the absolute risk may be low, planned home birth is associated with a twofold to threefold increased risk of neonatal death when compared with planned hospital birth. Importantly, women should be informed that the appropriate selection of candidates for home birth; the availability of a certified nurse-midwife, certified midwife, or physician practicing within an integrated and regulated health system; ready access to

consultation; and assurance of safe and timely transport to nearby hospitals are critical to reducing perinatal mortality rates and achieving favorable home birth outcomes."

According to the ACNM Statement on Home Birth (2005):

"The safety of birth in any setting is of utmost priority and has been the focus of home birth research. Investigators have defined "planned home birth" as the care of selected pregnant women by qualified providers within a system that provides hospitalization when necessary.[6] Recently, well-designed controlled trials and descriptive studies have demonstrated that planned home births achieve excellent perinatal outcomes.[7-13] These high quality investigations of the safety of home birth indicate that optimal outcomes are associated with appropriate client selection, attendance by a qualified maternity care provider, and integrated systems that support collaborative care when a change of site is indicated. Home birth is also credited with the reduced use of medical interventions that are associated with perinatal morbidity. Unfortunately, some studies that have not differentiated between planned and unplanned home birth or attendance by qualified versus unqualified attendants, and/or have not used clearly defined appropriate inclusion criteria for analysis, have been used inappropriately to discredit all home birth."

Studies on birth center and home births attended by midwives have confirmed the safety of planned out-of-hospital birth for healthy women experiencing normal pregnancy and birth with midwives who have seamless access to and collaboration with qualified health care professionals and institutions within the health care system. Several high quality studies examined planned home birth compared to hospital births among low-obstetrical-risk women and found that mothers and neonates had similar or better outcomes at home (Vedam et al. 2012). Midwife-attended births also resulted in similar or better outcomes when compared to physician-attended births (Janssen et al. 2002, Janssen et al. 2009). However, it must be noted that these studies were primarily from Canada and Europe, not the United States. In these countries, as opposed to the U.S., midwives are fully integrated into the health care system. Further, methodological limitations among some home birth studies have been noted (Birthplace in England Collaborative Group 2011, Chang and Macones 2011, Janssen et al. 2009, Johnson and Daviss 2005).

A 2010 literature review (Wax et al.), published in the American Journal of Obstetrics and Gynecology found a twofold to threefold increased risk of neonatal death for planned home births versus hospital births for low-risk patients. Inconsistencies were noted in the Wax et al. (2010) study methodology and implementation (Gyte et al. 2010, Kirby and Frost 2011, Michal et al. 2011).

The ACNM representative to the Workgroup reported, from her experience, that the typical home birth practice experiences close to 95% normal vaginal deliveries; close to 100% breastfeeding rates; low rates of labor induction, episiotomy, epidural, and newborn infections; and very low rates of complications for mothers and newborns. The transport rate is low at 8 to 20%, with failure to progress cited as the primary reason for transport.

Several Workgroup members proposed that all women, regardless of birth setting, should go through a standardized process of risk assessment by their provider to establish appropriateness for birth in their chosen site and with their chosen provider. Selecting candidates for home birth on the basis of low-risk status will not protect patients from

unpredictable and potentially catastrophic outcomes, however, which highlights the need for midwives to be integrated into the health care system, enabling them to collaborate with qualified health professionals to minimize risk. Consultation or transfer plans that clearly delineate mechanisms for consultation, collaboration, and referral or transfer of care should be developed prior to birth (Smooth Transitions: Enhancing the Safety of Planned Out-of-Hospital Birth Transports).

CPM Studies

Only two studies assess outcomes among CPMs (Johnson and Daviss 2005, Chang and Macones 2011). Johnson and Daviss reported lower rates of medical intervention and similar intrapartum and neonatal mortality among planned home birth deliveries when compared to low-risk hospital births in the United States. This study has been criticized for using inappropriate comparison groups (Vedam et al. 2012). It is also worth noting that this study included midwives in Canada where there is no credential comparable to a CPM. Weaknesses in the design and interpretation of findings were cited regarding the Chang and Macones study, including an inability to determine if the non-CNM midwives in the study included CPMs (Vedam et al. 2012).

There is no national database of outcomes for CPMs. However, NARM cites as evidence of the safety of CPM-attended births the fact that no state that has a licensure program has ever closed a CPM practice as a result of poor outcomes or problems. Every state that licenses CPMs has given NARM positive feedback. The American Association of Birth Centers' Uniform Data Set (UDS) shows that CPMs outcomes are as good as those of CNMs, and that, overall, freestanding birth centers continue to have excellent outcomes. This study is pending publication, however, in January/February 2013.

Newborn Care

Both ACOG and AAP recommend that care for a neonate should be the same, independent of delivery site, and should follow the most current Guidelines for Perinatal Care (2012). The Workgroup representative from the Maryland Chapter of the AAP further stressed that the guidelines of the Neonatal Resuscitation Program (NRP) should be followed and that there should be one person present at the delivery whose sole responsibility is to care for the infant, and who can perform neonatal resuscitation, including intubation. There should also be appropriate neonatal equipment immediately available for all deliveries. Upon delivery, all providers should assess for risk factors for hypoglycemia, and screen if indicated; send in cord blood type and Coombs in all RH negative moms, as well as bilirubin level as clinically indicated; consider evaluation of infants born to O+ mothers; and give intramuscular Vitamin K. Current CNM home birth practices include all of these measures. With the exception of critical congenital heart disease screening, which is a new screening requirement in Maryland as of October 5, 2012, all of the mandated newborn screenings in Maryland are within the scope of practice for a CPM.

Two public comments regarding safety issues were submitted electronically. A Local Health Department Fetal and Infant Mortality Review Program in the Baltimore metropolitan region reported that three cases of fetal or infant mortality were associated with home births in

2010\2011. One was attended by a nurse-midwife licensed in another state but not licensed in Maryland. This case was referred to the Board of Nursing. Birth attendants in the other two cases were unknown. Two of these cases involved unsuccessful VBAC with uterine rupture. All three cases involved emergency transport. The second public comment on safety was from an obstetrician practicing on the Eastern Shore and was regarding the three home births on the lower Eastern Shore attended by an unlicensed midwife from the upper Eastern Shore that resulted in transport to the emergency room.

Workgroup members, individually, drew the following conclusions from presentations at meetings and discussion of peer-reviewed literature. These conclusions are the opinion of individual Workgroup members and do not reflect Workgroup consensus. DHMH was not able to verify the accuracy of all assertions presented by Workgroup members:

- The AABC representative to the Workgroup believes that the American Association of Birth Centers' UDS shows that CPMs' outcomes are as good as those of CNMs, and that, overall, freestanding birth centers continue to have excellent outcomes. (Study pending publication in the Journal of Midwifery and Women's Health, Jan./Feb. 2013).

- Studies show that planned home birth outcomes are the same or better than low-risk planned hospital births.

- Materials presented throughout Workgroup meetings have established the safety of births attended by CPMs in home and birth center settings.

- Of the states that have licensure programs for CPMs, seven began in the 1970s, three in the 1980s, eight in the 1990s and nine since 2000. With a long and rich history of regulation by state agencies, no state agency has advocated for the termination of these programs or indicated concern regarding the safety of births attended by their midwives.

- Licensing CPMs will increase access to community based midwifery care and reduce racial disparities in birth outcomes.

- Licensing CPMs will increase access to birth centers.

Home Births

- The safety of CNM care is well-documented in the research literature.

- Studies on birth center and home births attended by midwives have confirmed the safety of planned out-of-hospital births for healthy women experiencing normal pregnancies and births with midwives who have seamless access to and collaboration with qualified health care professionals and institutions within the health care system.

- Current research on home birth outcomes lacks power and uses incomplete data.

- Safety data from other countries is not a valid measure of the safety of home birth in the United States.

- A recent literature review (Wax et al. 2010) published in the American Journal of Obstetrics and Gynecology found a three times greater risk of neonatal mortality for planned home births versus hospital births for low-risk patients.

- Planned home birth is associated with a twofold to threefold increased risk of neonatal death when compared to planned hospital birth as noted in the ACOG Committee Opinion February, 2011 (Wax et al. 2010).

- Inconsistencies were noted in the Wax et al. 2010 study's methodology and implementation, which reported the significantly increased neonatal mortality among planned home births versus planned hospital births (Gyte et al. 2010, Kirby and Frost 2011, Michal et al. 2011).

- VBAC should only be undertaken in a facility with staff immediately available to provide emergency care as noted in the ACOG Practice Bulletin on VBAC August 2010.

- All women regardless of birth setting should go through a standardized process of risk assessment by their provider to establish appropriateness for birth in their chosen site and with their chosen provider and this process should be one that is well-documented throughout pregnancy, labor, birth and postpartum period.

- Care delivered to a neonate should be the same, independent of delivery site, and should follow the most current ACOG/AAP Guidelines for Perinatal Care.

- One person should be present at the delivery whose sole responsibility is to care for the infant, and who can perform neonatal resuscitation, including intubation.

- Prior arrangements should be made between the midwife provider and the accepting facility/providers, in the event that transfer is necessary.

<u>Proposed Options for Action</u>

- Define in statute the terminology such as "low-risk" and "high-risk" to provide guidance to consumers and providers; definitions suggested by a Workgroup member:

  Low-risk: An uneventful antepartum period, spontaneous labor between 37 and 42 completed weeks of pregnancy, cephalic presentation, and previous uncomplicated pregnancy.

  High-risk: VBAC, multiple gestation, birth under 37 weeks or after 42 weeks, placental abnormality, non-cephalic presentation, preeclampsia/eclampsia, gestational diabetes, pre-existing medical or surgical conditions, and morbid obesity.

- Require in regulation that licensed CPMs report standardized data to monitor safety.

- Assure complete and accurate transition of care to accepting pediatric provider, with reevaluation within 24-48 hours by a pediatric provider.

- Establish a peer review system for all cases of fetal, infant, or maternal death and in cases of infant and/or maternal transfer to a hospital.

- Conduct a review of the safety of hospital births and physician deliveries.

- Establish forums for consumers, obstetric providers, and hospitals to address concerns about obstetric care.

- Conduct morbidity and mortality reviews that monitor cesarean rates, VBAC rates, and discussions of unnecessary inductions, etc. and make data publicly available on a government web site.

- Establish a strategic plan for meeting the Healthy People 2020 goals for limiting unnecessary inductions and cesareans and increasing the number of VBACs.

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All Workgroup meeting agendas, minutes, materials, and available data can be accessed at: http://dhmh.maryland.gov/midwives/SitePages/Home.aspx.

Attachment 1

State Case Studies of Non-Nurse Midwives

State Case Studies of Non-Nurse Midwives

Prepared by DHMH staff for the Midwives Workgroup
Presented at the October 25, 2012 meeting.

The DHMH Midwives Workgroup, along with the Chair, requested case studies from states that license Certified Professional Midwives (CPMs), which could serve as models for Maryland. Ten states were selected for study. Each of the ten states has differing degrees of specificity in their laws and regulations that oversee midwives. Some laws/regulations focus more on the duties of the regulatory board or council, while others go into detail on the scope of practice for midwives. Every state has requirements related to application and renewal fees, but these are not mentioned in the comments section for the sake of brevity.

California - 1973

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Midwifery Advisory Council; members appointed by the Medical Board	Licensed midwife	Medical Board	NARM exam	No	3 year post-secondary midwifery education program (84 semester units or 126 quarter units)

Comments: Licensed midwives practice under the supervision of a licensed physician or surgeon and the ratio of midwives to supervising physicians may not exceed 4:1. Half of the Midwifery Advisory Council is made up of licensed midwives and the other half is licensees of the board and members of the public who have an interest in midwifery. Academic and clinical preparation must be equivalent to programs accredited by ACNM or deemed equivalent by the board if the applicant holds licensure in another state with licensing standards equivalent to those of California. Midwives who attend out-of-hospital births must report annually to the Office of Statewide Health Planning and Development on a criteria specified by the board. If a midwife fails to report, s/he will be unable to renew her/his license until the report is submitted. Licenses must be renewed every two years, along with proof of 36 hours of continuing education. Wherever possible, midwives must make a good faith effort to ensure that a second midwife, or qualified birth attendant certified in adult and infant CPR, is available during delivery. Midwives may provide care to a client with significant risk factors if the client provides informed refusal to be evaluated and transferred to a physician. Referrals to physician during antepartum care does not preclude the possibility of home birth if, after the referral, the client does not have or no longer has any of the conditions listed in the Standards of Care. Midwives must provide clients with informed consent if clients are attempting a VBAC.

Delaware – 1978

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Division of Public Health	Direct-entry/ non-nurse midwife	Department of Health and Social Services	CPM from NARM or CM from ACNMCC	No	Complete accredited midwifery program

Comments: Before a permit is granted, an applicant must provide proof the s/he has not been convicted of a felony; been professionally penalized or convicted of substance addiction; had a professional midwifery license suspended or revoked in this or another state; been professionally penalized or convicted of fraud; and is physically and mentally capable of engaging in the practice of midwifery. A collaborative agreement must be established with a physician who has obstetrical hospital privileges. An applicant must also submit a sample contract between the midwife and patient outlining scope of practice and potential risk factors and complications. Permits must be renewed annually. Any midwives practicing without a permit are subject to a fine.

Florida - 1995

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Council of Licensed Midwives; 9 members appointed by the secretary	Licensed midwife	Department of Health	NARM exam	No	3 year approved training program with clinical, didactic, and practical preceptorship; at least 21 years old

Comments: The Council of Licensed Midwives is made up of one physician who is certified by the American Board of Obstetrics and Gynecology and practices obstetrics, one physician who is certified by the American Board of Family Physicians, one physician who is certified by the American Board of Pediatrics, four licensed midwives, and one resident who is not a midwife and has no financial interest in midwifery practice or in any health care facility, agency, or insurer. The department sets the standards for midwifery training programs, which must incorporate the core competencies of MANA and ACNM, be at least three years long, and include basic nursing skills. In order to be accepted into an approved midwifery program, an applicant must have a high school diploma or equivalent and have taken three college-level credits each of math and English or demonstrated competencies in communication and computation. An applicant for licensure must be at least twenty-one years old, have a certificate or diploma from a foreign institution or out of state program that is substantially equivalent to the State's programs or hold a valid certificate or license to practice midwifery in another state if the requirements are equivalent to the State's, submit proof of completion of a four-month pre-licensure course, and pass the state exam. Student midwives must care for no less than fifty women in each of the prenatal, intrapartum, and postpartum periods and observe an additional twenty-five women in the intrapartum period. Of note is that any hospital or birth center that

receives public funds is required to provide student midwives access to observe labor, delivery, and postpartum procedures. Licenses must be renewed every two years, along with proof of continuing education (not to exceed 20 hours biennially). A licensed midwife may fulfill up to 5 hours of credits by providing pro bono services to indigent person or underserved populations in areas of critical need within Florida and may receive up to 3 hours of credits for presenting continuing educational programs. The department may issue temporary certificates to practice in areas of critical need (as determined by the department) for no more than two years. The midwife may only practice in those specific areas, under supervision of physician, CNM, or licensed midwife. Practicing midwifery unlicensed is a third degree felony.

Louisiana - 1985

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Louisiana Advisory Commission on Midwifery; 7 members appointed by the governor and confirmed by the senate	Licensed midwife/ apprentice midwife/ senior apprentice midwife	Board of Medical Examiners	NARM exam	No	Apprentice program; didactic and supervised clinical under MD, CRNM, or CM

Comments: The Louisiana Advisory Committee on Midwifery is made up of one physician, one pediatrician, one registered nurse with obstetrical experience or a certified nurse midwife, three midwives, and one consumer of midwifery services. A physician must determine whether a pregnant woman is essentially normal for pregnancy and childbirth initially and then again at thirty-six weeks of pregnancy. Full CPM credential is required for licensure. Permits must be renewed every two years, along with evidence of 30 contact hours of continuing education and current certification in CPR. Midwives are prohibited from providing prenatal and intrapartum care to patients who are attempting a VBAC, except upon the express approval of the board. The midwife or client may apply to the board if a physician has previously evaluated the client and determined that vaginal delivery represents no untoward medical/obstetrical risk for the client and is not contraindicated.

New Jersey - 2002

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Board of Medical Examiners, Midwife Liaison Committee	Certified midwife or certified professional midwife	Professions and Occupations	NARM, ACC, or ACNM	No	Complete accredited midwife program

Comments: The Midwifery Liaison Committee is made up of at least one certified nurse midwife, at least one certified professional midwife, at least one certified midwife, two other midwives, one certified nurse midwife who is a member of the Board of Medical Examiners, and two physicians, one of whom is a member of the Board of Medical Examiners and one of whom is Board-certified by either by the American Board of Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology, or any other certification organization with comparable standards. In addition to the application for licensure, the applicant must submit proof that s/he is over age eighteen; an official transcript form an accredited midwifery program; a notarized copy of Certification issued by either ACNM. ACC, or NARM; the applicant's curriculum vitae; and three photographs of the applicant, signed, dated, and notarized. Midwives must be affiliated with a physician who has hospital privileges in operative obstetrics/gynecology, has a binding agreement with a physician who has hospital privileges in operative obstetrics/gynecology, or holds hospital privileges in gynecology if a licensee limits his/her practice to non-obstetrical. Licenses must be renewed every two years. A midwife must manage antepartum patients who have had a previous cesarean delivery with a physician and may only deliver these patients in a licensed hospital.

New Mexico - 1978

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Licensed Midwifery Advisory Board; 9 members and 1 ex-officio member appointed by the division	Licensed midwife (CPMs must be licensed)	Public Health Division of the Department of Health	NARM exam	No	New Mexico midwifery standards

Comments: The Licensed Midwifery Advisory Board is made up of three licensed midwives, at least two of whom are actively practicing; one actively practicing certified nurse midwife; three consumers; one physician actively practicing obstetrics; one member from the division; and a representative of the Maternal and Child Health Bureau in the division who will be an ex-officio member. An applicant for an apprentice midwife permit must provide proof of high school diploma or equivalent. An applicant for midwifery licensure must pass the division-approved exam or submit proof of CPM certification, submit proof of current certification in CPR for adults and intravenous therapy, and submit proof of current recognition by the Neonatal Resuscitation Program of the American Academy of Pediatrics. Licenses must be renewed every two years must include proof of completion of thirty contact hours of continuing education, current certification in CPR for adults and intravenous therapy, current recognition by the Neonatal Resuscitation Program of the American Academy of Pediatrics, evidence of peer review participation with the last four years, and proof of having submitted quarterly reports to the division in the interim. Every woman seeking midwifery care must be referred at least once to a physician within four weeks of initiating midwifery care. It is the responsibility of the midwife to consult with a physician or refer/transfer to a physician/hospital if there are deviations from normal in either the woman or neonate.

Oregon - 1993

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
State Board of Direct Entry Midwifery; 7 members appointed by the governor	Direct entry midwife	Health Licensing Agency	NARM	No	Didactic and clinical requirement

Comments: Licensure is voluntary for purposes of reimbursement under Medical Assistance programs and is not required for practice of direct entry midwifery. Licensed midwives are permitted to use medications while unlicensed midwives are not. The State Board of Direct Entry Midwifery is made up of four licensed direct entry midwives, one certified nurse midwife, one physician involved in obstetrical care or education, and one member of the public. An applicant for licensure need only submit an application. Licenses must be renewed annually. Proof of current certification in CPR for infants and adults and continuing education that must include training in use of legend drugs and devices (number of hours are not specified in the regulations) must be submitted with renewal application. The CPM credential is accepted as meeting all licensure criteria. If a midwife has attended fewer than five births in the previous year, s/he must take an additional ten hours of continuing education as prescribed by the board.

Texas - 1983

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Midwifery Board; 9 members appointed by the commissioner	Licensed midwife	Department of Health Services	NARM exam or any other approved by the Board	No	NARM-approved or MEAC-accredited program, didactic and clinical training or apprenticeship

Comments: The Midwifery Board is made up of five licensed midwives, one physician who is certified in obstetrics and gynecology, one physician who is certified in family medicine or pediatrics, and two members of the public who are not health care professionals and one of whom is a parent of at least one child delivered by midwife. The midwifery board must prepare and publish reports on midwifery practice in Texas that include statistics on fetal morbidity and mortality. The board must approve any basic midwifery education offered in the state. In order to be accepted in to a midwifery training program, an applicant must have a high school diploma or equivalent and current CPR certification. Licensure is required to practice midwifery. In addition to submitting a dated application, an applicant must submit a statement that s/he read the Occupations Code and board rules and agrees to abide by both, proof of basic midwifery education, proof of proper training in newborn screening tests or arrangements for the performance of those tests, proof of current certification in CPR for health care providers, proof of current certification in neonatal resuscitation, and evidence of passing the jurisprudence exam.

The jurisprudence exam covers the Texas Midwifery Act, chapter, and other Texas laws that pertain to midwifery practice. Licenses must be renewed every two years and must include a statement of all misdemeanor and felony offenses for which the licensee has been convicted, proof of completion of at least twenty contact hours of continuing education in the last two years, proof of current certification in CPR, proof of current neonatal resuscitation, and proof of passing the jurisprudence exam in the last four years. If a midwife states or advertises that s/he is "certified", s/he must also include a statement that s/he is certified by the North American Registry of Midwives, not a governmental entity. A person who practices without a license is liable for a civic penalty. It is the midwife's responsibility to initiate emergency care. The midwife must recommend referral to patients who have had a previous cesarean section and the midwife must recommend transfer for patients who have had a previous cesarean section with a vertical or classical incision or any uterine surgery which required incision in the uterine fundus. In lieu of referral or transfer, a midwife may manage a patient in collaboration with an appropriate health care professional.

Virginia - 2005

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Advisory Board of Midwifery; 5 members appointed by governor with senate approval (NARM document incorrectly stated it was a 10-member board)	Certified professional midwife	Department of Health Professions, Virginia Board of Medicine	NARM	No	No educational requirement

Comments: The Advisory Board is made up of three certified professional midwives, one physician or certified nurse midwife who has experience in out-of-hospital birth settings, and one citizen who has used out-of-hospital midwifery services. An applicant must submit proof that s/he has obtained the CPM credential and that there has been no adverse action taken against the applicant based on a report from NARM. Licenses must be renewed every two years. Attestation of current, active CPM certification by NARM must be submitted with renewal.

Washington - 1991

Regulatory Body	*Title*	*State Oversight*	*Certification/ Exam*	*Prescriptive Authority?*	*Education/ Pre-requisites*
Midwifery Advisory Committee; 7 members appointed by the secretary	Midwife	Department of Health	NARM exam and state exam	No	High school diploma, certificate or a diploma from midwifery program accredited by the secretary, minimum of 3 years of training

Comments: The Midwifery Advisory Committee is made up of one physician who is practicing obstetrics, one practicing physician, one certified nurse midwife, three midwives, and one public member who has no financial interest in the rendering of health services. An applicant must obtain at least three years of midwifery training that includes the study of basic nursing skills. Student midwives must care for no less than fifty women in each of the prenatal, intrapartum, and postpartum periods and observe an additional fifty women in the intrapartum period. Applicants must also pass a state exam unless they are credentialed in another state and the secretary determines that the other state's credentialing standards are substantially equivalent to Washington's. In addition to submitting an application, an applicant must provide proof the s/he has received a high school diploma or equivalency, is at least twenty-one years of age, and has received a certificate or diploma from a midwifery program accredited by the secretary or a foreign institution on midwifery of equal requirements conferring the full right to practice midwifery in the country in which it was issued. Licenses must be renewed annually and must include the midwife's written plan for consultation with other health care providers, emergency transfer, transport of an infant to a newborn nursery or neonatal intensive care unit, and transport of a woman to an appropriate obstetrical department or patient care area. It is the midwife's duty to consult with a physician if a patient deviates from normal.

Acronyms:
ACC: American College of Nurse Midwives Certification Council
ACNM: American College of Nurse Midwives
CNM: certified nurse midwife
CPM: certified professional midwife
CPR: cardiopulmonary resuscitation
MANA: Midwives Alliance of North America
MEAC: Midwifery Education Accreditation Council
NARM: North American Registry of Midwives
VBAC: vaginal birth after cesarean

Attachment 2

HOME BIRTH:
An annotated guide to the literature

HOME BIRTH:

An annotated guide to the literature ©

Vedam S, Schummers L, Stoll K, Fulton C

SEPT 2012

BACKGROUND

This bibliography is offered as a resource for clinicians and others (researchers, educators and policy makers) who must, within their own context for work, assess the quality of the available evidence on planned home birth, for the purpose of clinical decision making or to contextualize the current international debate on safety, access, ethics, autonomy, and resource allocation with respect to birth place.

This document was originally developed in 1997 for the primary author's personal use in her clinical and academic work. Over time updated versions (2002, 2004, 2007, 2010) informed the development of clinical practice guidelines for various North American maternity professional associations, and served as a resource in midwifery, medical, and nursing educational institutions. As the requests and self-generated distribution of the document expanded, it became clear that a more comprehensive, formalized approach to updating the literature search and reporting results was necessary. In 2011, additional authors and external reviewers were recruited, and a search strategy for annual updates was formulated. To facilitate continued access by those readers who regularly utilize it, the authors decided to self-publish in electronic and print formats and provide open access to the bibliography.

CONTENTS

Within each section, papers are grouped according to study design and level of evidence, and presented in descending order by publication date.

METHODS

Search Strategy

Papers were identified through a comprehensive search of the following databases: **EBSCO (Academic Search Complete, Medline & CINAHL), PubMed, & Cochrane**, along with citation snowballing, and consultations with content experts and key informants. We included articles that were published in English between 1990-2012.

The following search terms were applied:

"home birth" or "home + childbirth" and safety, risk assessment, transfer criteria, outcomes, screening, satisfaction, demand, preference, and perception.

The most recent search (August 2010-March 2012) identified 320 articles for assessment, and resulted in the addition of 22 new citations (see diagram on page 2).

SECTIONS A-B

Original studies of outcomes from planned home births in high resource countries were selected for inclusion; studies describing data from developing nations were excluded because they did not meet the definition of planned home birth used for this review which specifies access to qualified attendants and the ability to transfer to a hospital when necessary.

Criteria for assessment

Included papers were independently appraised by three authors according to the algorithm to assess the quality of home birth research outlined by Vedam[1]. In addition, studies were assessed for appropriate application of analytic tools (statistics), and the extent to which the conclusions were based on the reported data. Differences were resolved by discussion. Prior to publication,

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METHODS BY SECTION

SECTIONS A-B CONTINUED

the bibliography was reviewed by 5 external reviewers with expertise in perinatal epidemiology, statistics, and research related to midwifery, obstetrics, bioethics, and health care delivery.

[1] *Vedam (2003) home versus hospital birth: questioning the quality of the evidence on safety. Birth, 30(1), 57-63.*

1. Study design should:

- Distinguish between planned home births and unplanned out-of-hospital births
- Discriminate data from different types of providers
- Provide relevant and consistent inclusion criteria for study subjects across comparison groups
- Adjust for differences in selection criteria for home birth and perinatal management
- Control for differences in transfer criteria and method
- Define terms, such as mortality and morbidity
- Select relevant and consistent outcome measures.

2. Analysis and discussion should examine the impact of:

- Lack of randomization
- Small and homogeneous sample sizes
- Retrospective and incomplete data in birth records or certificates
- Differences among community standards of care and/or county specific policies and protocols.

SECTIONS C-F

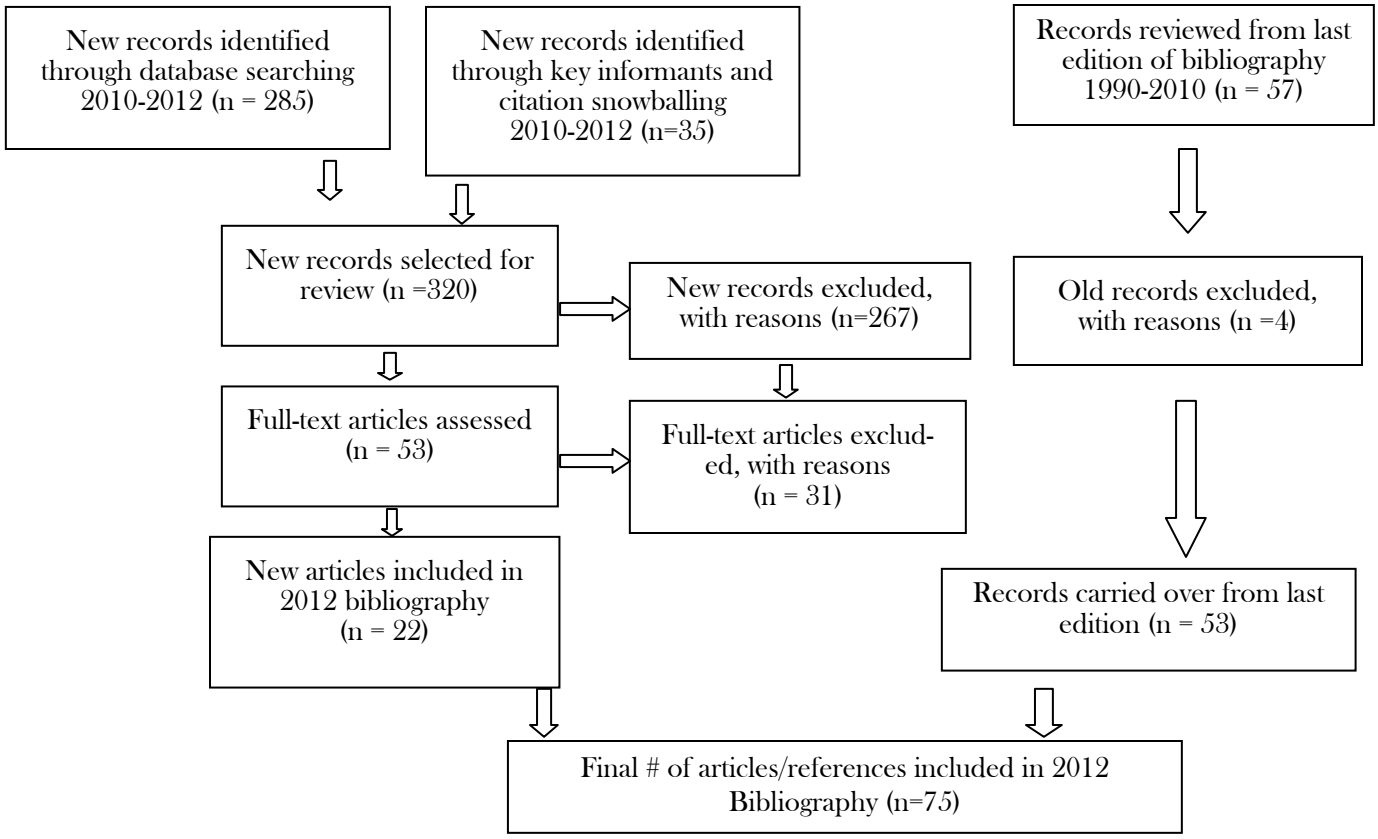
Section C describes articles which provide detailed appraisals of studies that are included in Section B.

Section D presents articles that were reviewed and selected by the authors for abstraction or listing if they describe original research, analyzed data from direct patient interviews, focus groups or surveys, and evaluated outcomes related to women's experience, perception, psycho-social effects or choice with respect to birth place. Publications prior to 2010 were not abstracted.

Papers in **Sections E-F** were selected for inclusion if they provide an evidence-based discourse analysis or commentary and have the potential to enhance the reader's understanding of key legal, policy, economic, and ethical issues, and innovative solutions to controversial topics related to home birth. Authorship by academic and maternity professional experts on birth place was a priority for inclusion.

ACKNOWLEDGEMENTS:

We would like to thank the Transforming Birth Fund for funding the updating and printing of the bibliography and Kerri Blackburn for her assistance in finalizing the bibliography.



SECTION A: BEST AVAILABLE STUDIES GROUPED BY DESIGN & LEVEL OF EVIDENCE

I: Meta-Analyses and Systematic Reviews

A) Olsen O, Jewell D. Home versus hospital birth. *Cochrane Database of Systematic Reviews* September 12, 2012. An updated systematic review of randomized controlled trials (RCTs) comparing planned home births to planned hospital births among women with uncomplicated pregnancies. The selection criteria were rigorous; only one trial met the inclusion criteria (n=11). The authors report a continued dearth of evidence from RCTs about the safety of home compared to hospital birth. Authors also conclude that evidence from increasingly well-designed observational studies suggests that low-risk women who plan a home birth experience significantly fewer interventions and complications than low-risk women who deliver in hospital. They provide a detailed discourse analysis of differing approaches to risk assessment, including the ethical application of clinically meaningful evidence, and the interaction of model of care with access to choice of birth place. They recommend that all countries facilitate evidence-based integration of home birth services into the health care system and inform all low-risk women of the option of planned home birth.

B) Leslie MS, Romano A. Birth can safely take place at home and in birthing centers. *J Perinat Educ 2007*;16(Suppl 1):81S-88S.16. A systematic review of home birth and birth center safety studies. The authors followed standard systematic review methods, including reporting levels of evidence, disclosure of inclusion and exclusion criteria and search strategies (detailed in a Methods article by Goer in same journal issue). Drawing on data from numerous studies, the authors compare incidence of interventions and perinatal outcomes between hospital births and home births and between hospital births and birth center births. The evidence for each outcome is graded for quality, quantity and consistency. This review reported that out-of-hospital births had similar perinatal outcomes to hospital births and fewer interventions.

C) Olsen O. Meta-analysis of the safety of home birth. *Birth 1997 Mar*;24(1):4-13; discussion 14-6. Meta-analysis of observational, comparative, original studies that met criteria for rigorous methodology and investigated differences in perinatal mortality and morbidity between planned home births and planned hospital births. Multivariate statistical analysis controlled for obstetrical background and perinatal factors. Analysis revealed no statistical difference in mortality between planned home and planned hospital birth and the confidence interval did not allow for extreme excess risks in any of the groups (OR=0.87, 95% CI=0.54-1.41). There were significantly fewer medical interventions, fewer severe lacerations, fewer operative births, and fewer low Apgar scores in the home birth groups.

II: Randomized Controlled Trials

A) Hendrix M, Van Horck M, Moreta D, Nieman F, Nieuwenhuijze M, Severens J, Nijhuis J. Why women do not accept randomisation for place of birth: feasibility of a RCT in the Netherlands. *BJOG 2009*;116:537-544. Based on Dowswell's findings the authors designed an RCT to compare home and home-like hospital births in the Netherlands for the following outcomes: interventions, satisfaction, referral to obstetricians, and costs. After 6 months, only one woman had enrolled in the study, therefore the trial was discontinued for lack of feasibility. The research team then re-designed their study to investigate the reasons women declined to participate in the RCT. The four main reasons that women indicated were: 1) they had already decided where to give birth prior to learning about the study, 2) they wished to choose their own place of birth 3) they wished to avoid delivering in the 'wrong' place for their first child, and 4) they were concerned about receiving an undesired treatment.

B) Dowswell T, Thornton JG, Hewison J, Lilford RJL. Should there be a trial of home versus hospital delivery in the United Kingdom? Measuring outcomes other than safety is feasible. *BMJ 1996*;312: 753-757. The authors of this small study (n=11) suggested that conducting a trial to assess birth outcomes by birth place (home versus hospital) would be feasible. Eleven subjects were recruited from a pool of 71 women who met the eligibility criteria for a home birth. This ratio suggested that a larger scale trial may be possible. The following outcomes were measured, following an intention to treat analysis: mode of delivery, obstetrical interventions, complications, and infant feeding (breastfeeding versus bottle feeding). However, the authors note that mortality is not an appropriate outcome variable to assess the safety of home birth with a randomized controlled trial because of the extremely large number of subjects required to compare such rare outcomes.

III: Cohort and Population-Based Observational Studies: North America

A) Janssen PA, Saxell L, Page LA, Klein MC, Liston RM, Lee SK. Outcomes of planned home births with registered midwife versus planned hospital birth with midwife or physician. *CMAJ 2009*;181(6):377-83. Prospective, five-year long cohort study comparing outcomes among midwife-attended planned home births (n=2802), midwife-attended planned hospital births (n=5984), and physician-attended hospital births (n=5985). Women in all three groups of the study met eligibility criteria for home birth, and thus had comparable maternal and fetal risk profiles. Women in the home birth group who

needed intrapartum transfer to the hospital were retained in their original cohort. This study reported similarly low rates of perinatal death in all three cohorts, and similar or reduced rates of adverse outcomes in the planned home birth group. Women in the planned home birth group had significantly fewer intrapartum interventions, including narcotic or epidural analgesia, augmentation or induction of labour, and assisted vaginal or caesarean delivery. In addition, women in the home birth group were less likely to suffer from postpartum hemorrhage, pyrexia, and 3rd or 4th degree tears. Babies of women planning a home birth were less likely to have Apgar scores of < 5 at one minute and the babies were less likely to need drugs for resuscitation. These differences were associated with planned place of birth and persisted regardless of actual place of birth.

B) Hutton E, Reitsma A, 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(3):180-89. Hutton et al. used the Ontario Ministry of Health Midwifery Program (OMP) database to compare outcomes of all women planning home births from 2003-2006 (n=6692) with a matched sample of women planning a hospital birth (n=6692.) Women with contraindications for home birth were excluded from the hospital sample. The primary outcome was a composite measures of perinatal and neonatal mortality or serious morbidity, i.e. the presence of one or more of the following: death (stillbirth or neonatal death 0–27 days, excluding lethal anomalies and fetal demise before the onset of labor); Apgar score of less than 4 at 5 minutes of age; neonatal resuscitation requiring both positive pressure ventilations and cardiac compressions; admission to a neonatal or pediatric intensive care unit with a length of stay greater than 4 days; or birthweight less than 2,500 g. The home birth group had lower rates of caesarean section (RR 0.64), and neonatal morbidity/mortality (RR 0.84) compared to low risk women who planned a hospital birth. Results suggest that Ontario midwives provide adequate screening and safe care for women planning home births.

C) Johnson K, Daviss BA. Outcomes of planned home birth with certified professional midwives: large prospective study in North America. *BMJ 2005*;330;1416. A prospective study of 5418 planned home births in a single year of mandatory data collection for all Certified Professional Midwives (CPMs) in 2000. The authors describe the design as a cohort study; however, the comparison group for rates of intervention was a composite of low risk term hospital births as reported by the National Center for Health Statistics in 2000, and intrapartum and neonatal death rates were compared with those in other North American studies of at least 500 births that were either planned out of hospital or low risk hospital births. In their sample of planned home births attended by CPMs, the transfer rate was 12%, the caesarean section rate was 3.7%, the neonatal mortality rate was 1.7/1000, and the intervention rates were lower among women who planned a home birth than low risk women who delivered at hospital in the US.

D) Janssen PA, Lee SK, Ryan EM, Etches DJ, Farquharson DF, Peacock D, Klein MC. Outcomes of planned home births versus planned hospital births after regulation of midwifery in British Columbia. *CMAJ 2002*;166(3):315-23. This study compared outcomes of 862 planned home births attended by midwives with hospital births attended by either midwives (n=571) or physicians (n=743). Women in the home birth group were matched with women in the physician- and midwife-attended hospital groups who met eligibility criteria for home birth. Women were matched according to age, partner status, parity, and hospital where midwives had privileges. Transfers from home to hospital were tracked, and subjects were retained in their original study groups for analysis. The study reports reasons for transfer, methods of transfer, and time spent in transfer. To assess similarity of groups, investigators also collected data on the process of midwifery care, on prenatal and obstetric history, and rates and indications for consultation or referral. Women in the home birth group were less likely to have epidural analgesia, experience induction or augmentation of labour compared to women in the physician attended group. Women in both midwife-attended groups had similar rates of obstetric procedures. There were no significant differences between home and hospital groups for the following outcomes: perinatal mortality, 5-minute APGAR scores, meconium aspiration syndrome, and need for specialized newborn care.

E) Schlenzka PF. *Safety of alternative approaches to childbirth* [Unpublished Dissertation]. Palo Alto, CA: Department of Sociology, Stanford University; 1999. Available from: http://vbfree.org/docs/schlenzka.htm#dnload In order to account for errors associated with relying solely on birth certificate data, Schlenzka merged birth certificate and hospital discharge data for California for 1989 and 1990, and by applying a comprehensive risk profile to cases, isolated a cohort of nearly 816,000 low risk births. Outcomes are reported according to planned and actual birth setting. Perinatal mortality was compared with two statistical approaches: indirect standardization using only birth weight, sex, race, age, education, and insurance as risk adjusters, and logistic regression controlling for all risk factors available in the database. No differences in perinatal mortality were found across birth sites, with lower rates of obstetric interventions in out of hospital groups.

IV: Cohort & Population-Based Observational Studies: International

A) Birthplace in England Collaborative Group. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. ***BMJ 2011*****;343:d7400.** A prospective cohort study in England from April 2008-April 2010 compared perinatal and maternal outcomes and interventions by planned place of birth at the onset of care during labour (planned home birth, free-standing midwifery birth centers, alongside midwifery units and obstetric units). The study included 64,538 low-risk women with a singleton pregnancy at term. The primary study outcome was a Composite Index combining intrapartum stillbirth, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, and birth related injuries including brachial plexus injury, fractured humerus or clavicle. Stillbirths before onset of labour were excluded. The researchers found that the incidence of the composite outcome measure was low for the entire sample (4.3/1000 births). In the overall sample, there were no statistically significant differences in the odds of the primary outcome in home, free-standing birth centers or alongside midwifery units when compared with planned birth in obstetric units. However, when the sample was split into nulliparous and multiparous women, the adverse outcome measures during planned home birth were higher than for hospital birth for nulliparous, but not for multiparous women. There was no evidence of a difference in adverse outcomes for freestanding or alongside midwifery units compared to obstetric units. Of women who started labour in obstetrical units, 20% had at least one complicating condition compared with less than 7% in other settings. For low-risk women birthing in an obstetric unit, the odds of receiving augmentation, epidural, spinal analgesia, general anesthesia, vacuum or forceps delivery, caesarean section, episiotomy, and active management of third stage were higher than all other settings. The study concludes that for healthy women with low risk pregnancies, the incidence of adverse perinatal outcomes is low in all settings and therefore the results support offering healthy low-risk nulliparous and multiparous women a choice of birth setting. Given the rarity of events for any of the included perinatal outcomes, and as some of them typically appear as co-morbidities, a composite index might inflate some differences in outcomes as attributable to place of birth. It is unclear how some of the items selected for inclusion in the composite index relate specifically to place of birth causality rather than skill of provider.

B) van der Kooy J, Peoran J, de Graff JP, Birnie E, Denktas S, Steegers EAP, Gouke JB. Planned home compared with planned hospital births in the Netherlands: intrapartum and early neonatal death in low-risk pregnancies. ***Obstet Gynecol 2011*****;118:1037-46.** In this retrospective cohort study, records of 679,952 low risk women from the Netherlands Perinatal Registry (2000-2007) were analyzed to compare intrapartum and early neonatal mortality rates (0-7 days after birth) of planned home versus planned hospital births attended by midwives. Outcomes for a third group of women, for which the planned place of birth was unknown, were also reported. The hospital cohort was used as the comparison group in all analyses. The authors used two methods for analyzing data: a 'per protocol analysis', or 'perfect guideline approach', which examined outcomes from only those low risk women who were eligible for planned home birth according to Dutch guidelines (n= 602,331) and a 'natural prospective approach', which looked at outcomes for all women who planned a home birth under the care of midwives (n=679,952) The per protocol analysis excluded midwifery clients with one or more of the following conditions: intrauterine death, prolonged rupture of membranes, gestational ages < 37 weeks and > 41 weeks. Results revealed a significantly decreased risk of intrapartum and early neonatal mortality in the home birth cohort, using the natural prospective approach (RR = 0.80; 95% CI: 0.71-0.91). When the authors calculated RRs using the perfect guideline approach, and adjusted ORs using either approach, they found no increased risk/odds of intrapartum and early neonatal death in the home versus the hospital setting. These findings align with those reported by De Jong et al (2009) using a similar cohort of women (2000-2006). A problematic secondary analysis of data was also reported (***See review: Section B, III, A)***

C) de Jonge A, van der Goes B, Ravelli A, Amelink-Verburga M, Mol B, Nijhuis J, Bennebroek Gravenhorst J, Buitendijk. Perinatal mortality and morbidity in a nationwide cohort of 529,688 low-risk planned home and hospital births. ***BJOG 2009*****; DOI: 10.1111/j.1471-0528.2009.02175.x.** Retrospective cohort study of 529,688 low-risk women in the Netherlands who were in primary midwife-led care at labour onset. This study compared perinatal mortality and morbidity between planned home births (321,301; 60.7%), planned hospital births (163,261; 30.8%), and unknown place of birth (45,120; 8.5%), using the national perinatal and neonatal registration data from 2000-2006. The following differences between groups were controlled for using logistic regression: parity, gestational age, maternal age, ethnic background, and socio-economic status. Inclusion criteria ensured the subjects were strictly low-risk. The main outcomes were intrapartum death, intrapartum and

neonatal death within 24 hours and 7 days after birth, and admission to a neonatal intensive care unit. No significant differences were found between planned home and planned hospital births for any of the main outcomes. The authors concluded that planned home birth in a low-risk population is not associated with higher perinatal mortality rates or an increased risk of admission to a NICU compared to planned hospital birth.

D) Kennare R, Keirse MJ, Tucker GR, Chan AC. Planned home and hospital births in South Australia 1991-2006: differences in outcomes. *Med J Aust 2009*;192(2):76-80. Retrospective population based-study of all births and perinatal deaths from 1991-2006 in South Australia. 1141 planned home births and 297,192 hospital births were included. Planned home birth was defined as any birth that was intended to occur at home at the time of antenatal booking; 30.6% of the planned home births occurred in hospital. Perinatal outcomes studied were: perinatal death, intrapartum death, intrapartum asphyxiation, Apgar of <7 at 5 minutes, use of pediatric or specialized neonatal care. Maternal outcomes studied were: operative delivery, postpartum hemorrhage and perineal trauma including episiotomy (1998-2006 only). Results: Post-term pregnancy (≥42 weeks) was more common in the home birth group; 58% (n=25/43 post-term pregnancies) delivered at home. Perinatal mortality rates (including intrapartum fetal death and stillbirth) were similar between home and hospital groups (7.9 vs. 8.2 per 1000). There was no statistical difference in perinatal mortality between the home and hospital group (4.6 vs. 6.7 per 1000 respectively). Intrapartum fetal death was higher in the home birth group (1.8 vs .8 per 1000), though the absolute numbers were small. Cases of intrapartum death were not necessarily contingent upon place of birth. Of the 9 perinatal deaths total, 3 were antepartum (occurred after transfer to hospital and were unrelated to antenatal care), 2 were attributable to fetal congenital anomaly, and 4 occurred after the parents refused/delayed transfer or declined intervention after transfer. These deaths might indicate a lack of integration of South Australian midwives into the health care system or an underlying distrust of hospitals for parents. The home birth group had lower rates of caesarean delivery (aOR= .27), instrumental delivery (aOR= .33), and episiotomy (aOR= .14).

E) Chamberlain G, Wraight A, Crowley P. Home births: Report of the 1994 confidential enquiry of the National Birthday Trust Fund. Cranforth, UK: Parthenon;1997. Comprehensive investigation of the characteristics and outcomes of planned home births across the United Kingdom, endorsed by the Royal Colleges of Obstetricians, Midwives, and General Practitioners. A prospective trial of 6044 planned home births in Great Britain compared mortality and perinatal outcomes with a low risk hospital group and found no significant differences in mortality. The home birth group experienced significantly fewer medical interventions and perinatal complications. The study report is published as a book.

F) Ackermann-Liebrich U, Voegeli T, Gunter-Witt K, Kunz I, Zullig M, Schindler C, Maurer M. Home versus hospital deliveries: follow up study of matched pairs for procedures and outcome. Zurich Study Team. *BMJ 1996*;313(7068):1313-18. Prospective matched cohort study of 489 planned home and 385 planned hospital births. The study design carefully attended to issues of planning status, transfer criteria, and actual place of delivery. The groups were matched according to age, parity, gynecologic and obstetric history, medical history, partner situation, social class, and nationality. The main outcome measures were need for medication and/or intrapartum intervention, duration of labor, severity of lacerations, hemorrhage, neonatal condition and perinatal mortality. They found a lower incidence of interventions, medications, lacerations and higher Apgar scores in the home birth group and no differences in birth weight, clinical condition, or gestational age between groups. There were no differences in mortality between groups.

G) 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(7068):1309-13. Prospective cohort study of 1836 women with low risk pregnancies (1140 planned home and 696 planned hospital births). The design controlled for provider type, parity, social, medical and obstetric background. The authors developed a tool that assigns an overall perinatal outcome index score based on "maximal result with minimal intervention". This tool assigns scores for each of 22 intrapartum variables (indicating risk factors and intervention), 9 items on the condition of the newborn, and 5 postpartum outcomes/conditions to assign an overall perinatal outcome index. The authors assert that this tool allows researchers to evaluate factors that detract from optimal perinatal health as well as to weight each variables' clinical significance and cumulative effect. The optimality index has subsequently been adapted and validated for North American and international contexts with evidence based rationale for the exclusion or inclusion of each variable. This study found no relationship between planned place of birth and perinatal outcomes in nulliparas when controlling for background variables (more or less favourable background); multiparas had significantly better perinatal outcomes in the home setting, regardless of background.

H) Northern Region Perinatal Mortality Survey Coordinating Group. Collaborative survey of perinatal loss in planned and unplanned home births. *BMJ 1996*;313(7068):1306-09. The Coordinating Group collected and analyzed data for 558,691 births over 14 years in the UK (1981-1994), with 2888 booked for home delivery at term. They found perinatal mortality in the planned home birth group was less than half the average for all births even when the cases referred to hospital were included. Mortality for unplanned home births was four times as high as for all registered births. Perinatal mortality for women booked for home delivery was judged mostly unavoidable and not associated with place. Home birth critics often misquote this study as 134 losses in 3466 births, but 97% of those losses occurred in unplanned home births. The remaining losses were due to causes unaffected by birth site. Further analysis comparing data from the planned home birth group to low risk term hospital births concluded that there were no significant differences in rates of perinatal mortality.

V: Descriptive Studies & Registry Reports Observational Studies: International

A) MacDorman, M, Declerq E, Menacker, Fay. Trends and characteristics of home births in the United States by race and ethnicity, 1990-2006. *Birth 2011*;38(1):1-7. MacDorman et al. used data from the U.S National Center for Health Statistics to examine the trends and characteristics of home births in the United States from 1990 to 2006 with a focus on race, ethnic and geographic differences. Home birth was more common among non-Hispanic white women, over the age of 30, multigravid, married, delivering a singleton, term baby, and delivering with midwives. While home birth rates steadily increased for non-Hispanic whites, they declined for all other races and ethnic groups. Home births to non-Hispanic white women were mostly attended by midwives and were less likely to be preterm. Home births for all other ethnic groups were more likely to be preterm and delivered by either physicians or 'other' attendants, suggesting that these births were likely 'unplanned' emergency home births. Birth certificates in many states in the US currently do not distinguish between planned and unplanned home births.

B) Declercq E, MacDorman M, Menacker F, Stotland N. Characteristics of planned and unplanned home births in 19 states. *Obstet Gynecol 2010*;116(1):93-9. Declercq et al. used data from the 2006 U.S. vital statistics in 19 states to compare the sociodemographic profiles of women choosing planned home births with women who had unplanned home births. Approximately 83.2% (n= 9,810) of the total home births occurring in the 19 states (N=11,787) were planned home births. Women in the unplanned home birth group were more likely to be non-white, younger, unmarried, foreign-born, smokers, have no prenatal care and no college education. Unplanned home births are more likely to be pre-term, and attended by someone who is listed as 'other' or unknown on the birth certificate. The majority of planned home births were attended by "other midwives". Birth certificate data do not include information about planned or unplanned home birth transfer to hospital, nor can they guarantee the accuracy of the planning status variable.

C) Amelink-Verburg MP, Verloove-Vanhorick SP, Hakkenberg RMA, Veldhuijzen IME, Bennebroek Gravenhorst J, Buitendijk SE. Evaluation of 280 000 cases in Dutch midwifery practices: A descriptive study. *BJOG 2008*;115:570-78. This study discusses the importance of effective home birth risk selection in the Dutch obstetric system. The authors found that the current selection process results in a small number of urgent referrals and favourable perinatal outcomes for home births.

D) Murphy PA, Fullerton J. Outcomes of intended home births in nurse-midwifery practice: A prospective descriptive study. *Obstet Gynecol 1998*;92(3):461-70. Prospective study describing various outcomes of home births attended by CNMs during 1994-1995 (n=1404). Of those beginning labour at home, 102 (8.3%) were transferred to the hospital in labour, 10 (0.8%) were postpartum transfers and 14 (1.1%) infants were transferred. For the whole sample of women beginning labour at home, fetal and neonatal mortality was 2.5/1000. For those actually birthing at home this mortality was 1.8/1000. Intrapartal problems were positively associated with transfer to hospital-based care, and overall outcomes were consistent with expected outcomes for low-risk birth.

E) Cawthon L. Planned home births: Outcomes among Medicaid women in Washington State. Olympia,WA: Washington Department of Social and Health Services; 1996. This study described perinatal data for 2,054 Medicaid women who were cared for by licensed midwives between 1989 and 1994. Births were categorized by birth place, maternal characteristics, prenatal care; outcomes between planned home births and births in birth centers or in hospitals were compared. Researchers compared all women receiving some care from licensed midwives, women receiving care from certified nurse-midwives, and all other Medicaid women and found no statistically significant differences in mortality rates. Congenital anomalies and SIDS caused the majority of deaths. The number of stillbirths or neonatal deaths among women who delivered at home was zero (0), and the rate of transfer to hospital

delivery for the women who experienced fetal or neonatal death was 100%, suggesting appropriate screening and site selection by licensed midwives.

F) 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(6):483-92. A retrospective survey study of perinatal outcomes associated with 11,788 planned home births attended by certified nurse-midwives (CNMs) from 1987 to 1991. Over 60% of identified CNM home birth practices participated in this study. Perinatal mortality rates were very low: 0.9 per 1,000, excluding deaths due to congenital anomalies. Nurse-midwives who offer home birth utilized standard risk-assessment criteria, and were prepared for immediate resuscitation of the newborn and maternal complications. The authors conclude that planned home birth with qualified care providers is a safe alternative to hospital birth for low risk women.

SECTION B: STUDIES WITH ERRORS IN DESIGN, ANALYSIS OR REPORTING

I: Meta-Analyses and Systematic Reviews

A) 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 meta-analysis. *Am J Obstet Gynecol 2010*;203:243.e1-8. This article presents a meta-analysis of the safety of planned home versus planned hospital birth. The authors conclude that planned home births are associated with similar maternal outcomes, but with a threefold increase in neonatal mortality. The methodology and statistical analysis employed in this systematic review were flawed. This meta-analysis contains calculation and numerical errors, selective and mistaken inclusion/exclusion of studies when analyzing specific outcomes, as well as logical flaws in terms of definitions. Many of the odds ratios (ORs) and confidence intervals (CIs) were calculated incorrectly. In some cases, this was the result of errors apparently made in the extraction of data from the original studies. In addition, the software tool used to calculate the statistics had embedded errors that can dramatically underestimate confidence intervals (CIs), and resulted in at least 1 false statistically significant result.

Wax et. al defined perinatal death as loss of a newborn of at least 20 weeks or 500 g, or death of a liveborn infant within 28 days of birth. Neonatal deaths were defined as deaths of

liveborn infants within 28 days of delivery. This means that neonatal deaths should be reported as a subset of perinatal deaths. However, the paper reports that for planned home births, the neonatal death rates are far higher than the corresponding perinatal death rates. In addition, perinatal death statistics are derived from more than 500,000 births, whereas the neonatal death statistics are drawn from fewer than 50,000 births. Hence the conclusions on comparative neonatal death rates offered by the authors cannot be defended. Most notably, the de Jonge study, which contributed more than 95% of the births used in the analysis, did not define perinatal death according to the same definitions. It is unclear why Wax and colleagues excluded this study from the calculations for neonatal mortality but included the study for perinatal mortality. According to Michal et al. "If that study were removed from the calculations for the 2 outcomes for which it was erroneously included, the total number of births included in the meta-analysis would have been reduced from nearly 550,000 to just 65,000. This dramatic reduction in the size of the dataset would have significantly reduced the impact of any findings of the meta-analysis. On the other hand, if Wax and colleagues had defined perinatal death and neonatal death according to definitions used by de Jonge and associates, the conclusions for these outcomes would have been quite different."

A more detailed critique of this article, authored by a team of experts in the field (including the principal investigators of studies included in the meta-analysis), is cited in Section C.I.A .

II: Cohort & Population-Based Observational Studies—North America

A) Chang JJ, Macones GA. Birth Outcomes of planned home births in Missouri: A population-based study. *Am J Perinatol. 2011*;28(7):529-536. A retrospective cohort study to compare outcomes between planned home births attended by non-CNMs, physicians, and CNMs to outcomes of births in hospitals and birth centers attended by physicians and CNMs. Data was collected from linked Missouri live birth and fetal death files, for the years 1989 through 2005. The study sample included singleton pregnancies, delivered between 36-44 weeks gestation. Pregnancies with major fetal anomalies and breech presentation were excluded. Authors found that planned home birth by non-CNMs, physicians and CNMs was protective against selective obstetric procedures and complications such as fever, moderate to heavy meconium, and dysfunctional labour, but that planned home births attended by non-

CNMs were associated with prolonged labour, and fivefold increased odds of newborn seizure. Planned home births attended by all three groups (physicians, CNMs and non-CNMs) held a higher risk of intrapartum death. There are several weaknesses in the design and interpretation of data in this study. The subset of non-CNM attended home births was too small for meaningful analysis of rare perinatal outcomes, and the authors used an unconventional definition of 'low-risk', which includes all births from gestational ages of 36-44 weeks. Further, there are multiple issues of data validity using birth record data related to identification of planned home births and type of attendant. Authors suggest the non-CNM group may include certified professional midwives but there were none in practice in Missouri at the beginning of the study period; and the CPM credential was not accepted for licensure in Missouri until 2008. Even today there are not enough Missouri based CPMs to attend the number of births indicated as attended by 'other midwives'. Prior to legislation families who delivered outside the hospital filled out their own birth certificate record. Several of those births may be misclassified unplanned accidental home births, or attended by someone without credentials. Most importantly, given the sample size and wide confidence intervals, misclassification of even a few records could skew results.

B) Evers A, Browers H, Hukkelhoven C, Nikkels P, Boon J, van Egmond-Linden A, Hillegerberg J, Snuif Y, Sterken-Hooisma S, Bruinse H, Kwee A. perinatal mortality and severe morbidity in low- and high-risk term pregnant women in the Netherlands: a prospective study. ***BMJ 2010;*****341:c5639doi:10.1136/bmj.c5639.** This was not a study of home birth safety but rather focused on primary and secondary care referrals. This cohort study compared the incidences of perinatal mortality and severe perinatal morbidity between low-risk term pregnancies in primary care with a midwife and high-risk secondary care with an obstetrician. The study found that infants of low risk women who started labour under primary care of a midwife had a significantly higher risk of perinatal death than infants of high risk women whose labour started in secondary care under the care of an obstetrician. While NICU admission rates did not differ between groups, infants who were referred to a physician by a midwife during labour had a 3.66 times higher risk of related perinatal death. Infants of nulliparous women had a significantly higher risk of NICU admission than infants of multiparous women. The most common reason for admission was asphyxia. Because data were extracted from a large birth registry database , adjustment for confounders, including appropriate referrals from primary to secondary care before and during the onset of labour, was not possible. These findings do not correspond with any previous studies of the Dutch maternity care system. The results may mostly be a reflection of the inter-professional relationships that are specific to the Utrecht region.

C) Malloy MH. Infant outcomes of certified nurse midwife attended home births: United States 2000 to 2004. ***J Perinatol 2010;*****30(9):622-27.** A retrospective cohort study using linked US birth and death certificate files from the National Center for Health Statistics from 2000-2004, to compare the safety of CNM deliveries at home to CNM deliveries in hospital (data also examined delivery outcomes of 'other' midwives' in hospital and home). Malloy concludes that neonatal mortality rates of certified nurse midwives or 'other' midwives are higher in out of hospital settings (home/ birthing center) compared to deliveries at the hospital. Method of selection did not distinguish planned from unplanned home birth nor if hospital birth CNMs were actually in attendance at home births or solely appeared on birth certificates as the certifier of the birth having occurred. Analysis does not distinguish between "other midwife" attendant and no attendant.

D) 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.** A retrospective population-based cohort study to evaluate perinatal mortality by place of birth (hospital, birth center, home) using 2006 U.S. birth certificate data from 19 states available through the CDC. Of 745,690 total births included, 733,143 occurred in hospital, 4661 in freestanding birth centers, and 7427 at home. Excluded from the study were: preterm (<37 weeks), smokers, women with Type I, II or gestational diabetes, either chronic or pregnancy induced hypertension and a prior caesarean section. The authors concluded that home births are associated with less frequent adverse perinatal outcomes (chorioamnionitis, fetal intolerance of labour, meconium staining, assisted ventilation, NICU admissions and birthweights of <2500g), but more frequent abnormal labours and 5-minute Apgar scores of <7 and birth weight >2500g. The study does not differentiate between planned and unplanned home births, and does not provide data about home to hospital transfers.

E) Pang J, Heffelfinger J, Huang G, Benedetti T, Weiss N. Outcomes of planned home births in Washington state: 1989-1996. ***Obstet Gynecol 2002;*****100(2):253-59.** Method of selection did not distinguish between planned home births, out-of-hospital births that had no attendant, or births with unknown or unnamed attendants. Premature births occurring before 37 weeks were incorrectly included in the initial analysis. A higher incidence of congenital heart disease in the home birth population could partially explain the higher neonatal mortality and would reflect a difference in populations.

SECTION B: STUDIES WITH ERRORS IN DESIGN, ANALYSIS OR REPORTING

III: Cohort and Population-Based

A) van der Kooy J, Peoran J, de Graff JP, Birnie E, Denktas S, Steegers EAP, Gouke JB. Planned home compared with planned hospital births in the Netherlands: Intrapartum and early neonatal death in low-risk pregnancies. ***Am J Obstet Gynecol 2011*****;118(5):1037-46.**
(See review of study: Section A, IV, B.)
In addition to reporting the usual statistics (RRs and adjusted ORs) to compare perinatal outcomes across birth settings, the authors performed additional analyses, e.g. they divided the crude mortality rates of the home and hospital groups by the prevalence of the 'Big 4' (congenital anomalies, IUGR, preterm birth, Apgar < 7; these 4 conditions accounted for 85% of the neonatal mortalities in the sample) to 'obtain case mix adjustment'. The rationale for this adjustment was to remove clinical determinants of neonatal mortality, and focus on 'setting' dependent mortality. Using this approach, the authors reported up to 20% excess mortality in the home setting, leading the authors to conclude that women with certain risk factors (e.g. pregnancy duration more than 41 weeks and having an infant that is small for gestational age) can reduce their risk of intrapartum and early neonatal death by planning a hospital birth. It should be noted that the index does not allow for assessment of statistical significance (and thus more emphasis should be placed on the adjusted ORs reported in tables 2 and 3). As the authors themselves note in post-publication correspondence, "In both RCT and observational designs, post-hoc exclusion of patients or replacement of treatment allocation by the treatment actually received is not allowed under the intention-to-treat principle"; hence, at minimum the analysis and reporting of outcomes should have been limited to their "perfect guideline approach".

SECTION C: EVALUATING THE QUALITY OF HOME BIRTH RESEARCH

I: Critical Appraisal of Studies in Section B

A) Carl MA, Janssen PA, Vedam S, Hutton EK, de Jonge Ank. Planned home vs hospital birth: A meta-analysis gone wrong. See : http://www2.cfpc.ca/local/user/files/%7B1E683014-14EB-489F-99CE-B5A2185A6FC5%7D/Medscape%20%20Wax%20Critique%20-%20Michal,%20Janssen,%20Vedam,%20Hutton,%20de%20Jonge.pdf
For a detailed analysis of the 2012 Wax meta-analysis see Section B.I.A. Authors include principal investigators for 3 of the original studies included in the meta-analysis. Each of the significant numerical, statistical and logical errors, errors in definitions, errors in inclusion/exclusion of data for analysis, and mistaken conflation of association with causation, are delineated. Methodological problems and a faulty computational tool are described.

B) Gyte G, Newburn M, Macfarlane A. Critique of a meta-analysis by Wax and colleagues which has claimed that there is a three-times greater risk of neonatal death among babies without congenital anomalies planned to be born at home [Internet]. ***NCT 2010*** **[cited 2011 March 1]:1-8. Available at:** http://www.scribd.com/doc/34065092/Critique-of-a-meta-analysis-by-Wax. Detailed review of Wax's meta-analysis outlining a range of data reporting errors and methodological weaknesses, which include: insufficient details about choice of included and excluded studies, lack of clarity or consistency about the definition of neonatal mortality, including whether stillbirth data were included. Wax misclassified singleton newborns with a gestational age of 34 wks who were born after transfer from home as 'planned' home birth if birth certificate indicated delivery was initially attempted at home. Gyte argues that the authors' conclusion that "less medication intervention during planned home birth is associated with a tripling of neonatal mortality rate" is unsupported by the poor quality of their data and that the article should not have been accepted by AJOG.

C) Keirse MJ. Home birth: Gone away, gone astray, and here to stay. ***Birth 2010*****;37(4):341-46.** Commentary on Wax JR et al. Maternal and newborn outcomes in a planned home birth vs. planned hospital birth. Keirse highlights the weakness and results of Wax et al.'s meta-analysis of home birth. Keirse examines which studies Wax included and excluded from his meta-analysis in order to conclude that home birth is related to a 2.6 increase of maternal mortality and a tripling of neonatal mortality. Keirse also cites either statistical errors or reporting errors of data present in the study that contribute to his results. Wax's meta-analysis refers only to planned home birth but includes statistics from U.S. birth certificates that do not differentiate between planned and unplanned home birth, and this inclusion significantly contributes to the higher rate of neonatal mortality. Although useful when randomized control trials are unavailable, meta-analyses need to consider the impact culture, geography, and health care systems have on data when consolidating smaller studies.

D) de Jonge A, Mol BW, van der Goes B, Nijhuis J, van der Post J, Buitendijk S. Too early to question effectiveness of Dutch maternity care system. ***Commentary on:*** **Perinatal mortality and severe morbidity in low- and high-risk term pregnant women in the Netherlands: A prospective study.** ***BMJ 2010*****;341:c7020.** Detailed review of prospective cohort study

by Evers et al. that identifies several weaknesses in the study's methodology which include: a retrospective definition of "population of risk" despite claims that the study is a prospective cohort study; all intrapartum deaths were included but not all births; for midwives whose practices cross boundaries, deaths outside catchments were included in the study but not births, which hence artificially inflated the mortality rate. The neonatal mortality rates in this region are twice as high as the rates of previous national studies, which requires further investigation. In the Netherlands primary maternity care often is equated with midwifery care. Evers et al. suggest that home birth is the cause of increased perinatal morbidity, but there is no data presented that links site of birth or planning status to the reported outcomes. Data of a large birth registry database were used and adjustment for confounders, including appropriate referrals from primary to secondary care before the onset of labour, was not possible. Given so many discrepancies from national studies, the authors find that Evers et al.'s conclusion that "the obstetric care system in the Netherlands possibly contributes to the high perinatality mortality rate" is not supportable.

E) Vedam, S. Home versus hospital birth: questioning the quality of the evidence on safety. ***Birth 2003;*** **30(1):57-63.** Detailed review of Pang's study, including well acknowledged errors in methodology and definitions. Outlines flaws associated with using birth certificate data to study outcomes of planned home births and includes an algorithm for evaluating quality of studies on home birth safety. Studies must adhere to following study design criteria in order to avoid errors and bias: 1) differentiate between planned and unplanned home births, 2) accurately discriminate between provider types, 3) use consistent inclusion criteria across groups, 4) adjust for home birth selection criteria, 5) control for transfer criteria and 6) select consistent outcome measures. Compares the methodology used by Pang with the methodology of other commonly cited home birth studies, with examples of reliable and unreliable designs.

SECTION D: SELECTED STUDIES ON PATIENT CHOICE & SATISFACTION

I: Studies of Patient Demand & Satisfaction. Autonomy & Experience

A) Jackson M, Dahlen H, Schmied V. Birthing outside the system: Perceptions of risk amongst Australian women who have freebirths and high risk homebirths. ***Midwifery 2012.*** **Jan 31. PubMed PMID: 22300611.** A qualitative study using open ended questions examined 20 Australian women over 18 years of age who chose to have an unattended home birth (freebirth), or an attended high risk home birth despite having medically defined risk factors, or care provider recommendations for a hospital birth. Of note in this study is the participants' average age (34) and level of education, where more than 70% of the women had tertiary qualifications. All were living in urban settings within 30 minutes of emergency care. 17 of 20 women were multiparous. Researchers found that the women who chose an unattended birth attributed this choice to a previous traumatic hospital birth or because of a belief that the interventions and interruptions of hospitals increase risk. The study found that women who freebirth tend to perceive risk differently, and that these women believe they are making a choice to protect their babies. For these women, birth in the hospital is less safe than birthing at home. The women in this study directly connected their experiences during labour and birth to their experience of mothering both immediately and long term. This study also aims to dispel a belief that women who freebirth are poorly informed and undereducated because study participants were more educated than the Australian public and had attended formalized training in obstetric emergencies and neonatal resuscitation.

B) Blix E. Avoiding disturbance: Midwifery practice in home birth settings in Norway. ***Midwifery 2011;*****28(5):687-692. PubMed PMID: 20637533.** Qualitative study of 17 Norwegian midwives to examine how midwifery care promotes and supports normal labour and birth and why these births are associated with lower rates of interventions compared with hospital births. The study highlights the connection between the calm, undisturbed environment available to women at home with fewer interventions in childbirth. Strengths of this study include its detailed discussion of how the home and its particular setting might augment "normal birth".

C) Catling-Paull C, Dahlen H, Homer CS. Multiparous women's confidence to have a publicly-funded homebirth: A qualitative study. Women Birth. 2011 Sep;24(3):122-8. Epub 2010 Oct 12. Erratum in: ***Women Birth. 2011 Dec*****;24(4):180. Homer, Caroline C S E [corrected to Homer, Caroline S E]. PubMed PMID: 20943450.** A qualitative study of 10 multiparous Australian women who chose a publicly-funded, planned home birth with the St. George Hospital Homebirth Program. The study found that multiparous women who have had at least one previous normal birth feel a strong confidence to birth at home. The women cite hospital back up, trust in the skill of their midwives, and their own personal strength as sources of confidence to have a normal birth at home. None of the women felt that they were at an increased risk of birth complications due to having a baby at home.

D) Stramrood CA, Paarlberg KM, Huis In 't Veld EM, Berger LW, Vingerhoets AJ, Schultz WC, van Pampus MG. Posttraumatic stress following childbirth in homelike- and hospital settings. *J Psychosom Obstet Gynaecol. 2011 Jun*;32(2):88-97. PubMed PMID: 21557681. A qualitative cross-sectional study of 428 Dutch women who completed surveys 2-6 months post-partum to compare the rate of post-traumatic stress disorder (PTSD) in home-like settings to the hospital. The study found that women who had home deliveries had the lowest rate of PTSD symptoms compared to women who were either transferred to care in the hospital during labour but who remained in primary care (under the care of a midwife) or to those who gave birth in secondary or tertiary care (either under the care of an OB/GYN or at a university referral centre). Home deliveries also had a lower rate of PTSD compared to those with pregnancy or delivery complications at the hospital. However, no difference was found in the scores between women who delivered in primary care with a midwife either at home (planned home birth) or the hospital (planned hospital birth). The study also found a strong association between the development of PTSD and the reported intensity of labour pain, leading researchers to speculate whether there is a difference between women requesting pain medication and the role this might play in the development of PTSD for certain women.

E) Symon A, Winter C, Donnan PT, Kirkham M. Examining autonomy's boundaries: A follow-up review of perinatal mortality cases in UK independent midwifery. *Birth. 2010 Dec*;37(4):280-7. doi: 10.1111/j.1523-536X.2010.00422.x. PubMed PMID: 21083719. A qualitative review using thematic analysis and grounded theory to examine the case notes of midwives involved in 15 instances of perinatal mortality at home births in the UK between 2002 and 2005. Researchers noted that in 13 of the 15 cases significant antenatal risk factors were present (4 sets of twins, 3 VBAC, 3 Breech, 5 maternal illness) and 8 of 15 women had declined some, or all, routine antenatal screening. Strengths of this study are that it provides a detailed examination into perinatal deaths at home and examines why some women might choose high-risk home births even after antenatal risk factors have been identified, or care providers have encouraged a transfer to the hospital. It illustrates the challenge that independent midwives face balancing informed consent/refusal with providing care. This study also examines how issues regarding transfer of care, inter-professional communication, and a deep mistrust of NHS by some women can led to a delay in care and poorer outcomes. Limitations of this study are its small sample size, but also that it is only a study of the midwives' notes and does not include hospital notes or family accounts.

F) Hendrix M, Pavlova M, Nieuwenhuijze MJ, Severens JL, Nijhuis JG. Differences in preferences for obstetric care between nulliparae and their partners in the Netherlands: A discrete-choice experiment. *J Psychosom Obstet Gynaecol. 2010 Dec*;31(4):243-51. PubMed PMID:21067473. A prospective cohort study to examine the differences between low-risk pregnant women and their partners' preferences regarding obstetric care and place of birth and the extent to which these preferences are influenced by obstetric care and socio-economic factors. The study employed a method of "discrete choice" to assess preference. Data were collected at 32 weeks from 321 pregnant women and 212 of their partners. This study found that overall women prefer to be assisted by a midwife during birth and they also prefer to give birth in a home-like setting. Women also place importance on having influence over the decision making process and the possibility of pain relief (though the study does not specify what kind of pain relief). Their partners' preferences where similar; high value was placed on a midwifery assisted birth in a home-like setting, and control over decision-making. Partners had a preference for no out-of pocket payments and a higher preference for access to pain relief.

G) Hildingsson I, Rådestad I, Lindgren H. Birth preference that deviate from the norm in Sweden: Planned home birth versus planned cesarean section. *Birth 2010*;37(4):288-95. Descriptive and comparative study using data from questionnaires of women who had a planned home birth (n=671) and women who had an elective caesarean section (n=126) between 1997and 2008. In Sweden, the current medical context neither promotes home birth nor elective caesarean section. The study found significant socioeconomic differences between the two groups of women. Compared to women who chose an elective caesarean, women who chose planned home birth were more educated, had a lower BMI, were less likely to smoke, felt less threat to baby's life during the birth, felt more in control, and were more satisfied with their overall birth experience. Women in the home birth group reported a higher intensity of pain, but a more positive experience of that pain than women who gave birth via caesarean.

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Attachment 3

Joint Statement on Planned Home Births

Joint Statement on Planned Home Births

This Joint Statement on Planned Home Births is issued by multiple Maryland-based health organizations in response to reports of adverse pregnancy outcomes resulting from planned home childbirths.

The Joint Statement on Planned Home Births is endorsed by the Maryland Board of Nursing (MBON), the Maryland Association of County Health Officers (MACHO), the Maryland Affiliate of the American College of Nurse-Midwives (ACNM), and the Maryland Department of Health and Mental Hygiene (DHMH).

Further, the Joint Statement on Planned Home Births is consistent with the national statement of the American College of Nurse-Midwives which notes, "The evidence indicates that appropriate client selection, attendance by a qualified provider, sound clinical judgment, and transfer to a receptive environment when necessary, promote safe outcomes."

Joint Statement

I. During the course of prenatal care, a pregnant woman considering a home birth should consult with a licensed physician or licensed certified nurse midwife in order to be assessed as a candidate for a home birth.

Factors critical to reduced risk of adverse outcomes associated with home births are:

- Individualized screening of all risk factors for home birth,
- Availability of a licensed and certified nurse-midwife or physician practicing within an integrated and regulated health system,
- Ready access to consultation, and
- Assurance of safe and timely transport to a nearby hospital if needed.

II. To ensure the health and safety of the mother and infant, all planned home deliveries must be attended by a licensed physician or licensed certified nurse midwife.

III. It is unlawful for a physician or midwife to practice in Maryland without a valid Maryland license.

Consumers can verify the Maryland licensure status of any physician at www.mbp.state.md.us/bpqapp and any nurse midwife at www.mbon.org/main.php under “Look Up a Licensee.”