

HANDBOOK FOR RESEARCHERS INTERESTED IN OBTAINING ACCESS TO THE MANA STATS DATABASE

Specific procedures for requesting access to data for research purposes have been created by the Midwives Alliance Division of Research Coordinating Committee. These documents are contained in this Handbook and the related forms are available on the Midwives Alliance website: www.mana.org/DOR.

Midwives Alliance Division of Research
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Information for Researchers Requesting Access to the MANA Stats Database

The following information is intended as a guide for researchers interested in access to the MANA Stats database.

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Introduction

Thank you for your interest in the MANA Stats database! This is a rich, unique database that contains tens of thousands of records describing the pregnancy, birth and postpartum processes and outcomes of women who choose midwifery-led care in North America. The vast majority of the records in this database describe births that took place outside of the hospital setting, either in homes or in freestanding birth centers; however, midwives practicing in any location are able to contribute their data to MANA Stats.

Midwifery-led care, while common in many other countries, comprises a small percentage of pregnancies and births in the United States. The model of care provided by midwives is distinguished by a woman-centered, holistic style that differs in significant ways from the standard allopathic model of care in the U.S. For this reason, we believe that researchers will benefit from understanding this model of care in order to appropriately design their research proposals to evaluate the components of care and outcomes described in this database.

Finally, information about undisturbed, physiologic labor and birth is highly underrepresented in the maternal-child health literature. The majority of current research is conducted in settings where pregnancy, labor and birth are managed with a high rate of obstetric intervention, such that there is little knowledge of how outcomes might be different if nothing was done to disturb the natural course of events. This database contains a large number of records that can help to address the dearth of research on the characteristics of physiologic birth.

What is the Midwives Model of Care™?

The Midwives Model of Care™ is based on the fact that pregnancy and birth are normal life processes.

The Midwives Model of Care™ includes:

- Monitoring the physical, psychological, and social well-being of the mother throughout the childbearing cycle
- Providing the mother with individualized education, counseling, and prenatal care, continuous hands-on assistance during labor and delivery, and postpartum support
- Minimizing technological interventions
- Identifying conditions when women or babies would benefit from interprofessional collaborative care or referral to medical care, and initiating the consultation or referral process.

The application of this woman-centered model of care has been proven to reduce the incidence of birth injury, trauma, and cesarean section. Please see Appendix A for more information about the Midwives Model of Care™.

Community-Based Participatory Research

The Midwives Alliance DOR endorses the principles of Community-Based Participatory Research (CBPR), which is an orientation to research that focuses on relationships between researchers and community partners. CBPR is a collaborative approach in which research takes

place in community settings and involves community members in the design and implementation of research projects. Such activities demonstrate respect for the contributions made by community partners and for the principle of ‘doing no harm’ to the communities involved. The Midwives Alliance DOR is responsible for representing the midwifery community in its relationship with researchers. This community includes not only the midwife providers, but also their clients as equal partners. Please see Appendix B for more information about Community-Based Participatory Research.

Characteristics of MANA Stats Datasets

Any midwife providing care in North America may become a contributor to MANA Stats. There are no restrictions based on education, credential, primary place of deliveries, or legal status.

Midwives enroll as contributors, providing demographic information about themselves and their practice, and pledge to enter data on all clients who consent to participate. Each client must be logged into the system before her expected date of birth so that data on all birth outcomes are collected. Midwives are expected to complete the data form within 6 weeks of the final postpartum visit.

Midwives enter data on the demographic characteristics of participating women and families; pregnancy and general health history; components of prenatal, labor, birth, neonatal, and postpartum care by midwives; and maternal and newborn outcomes. Data is also collected about situations involving transfer of care to other providers in pregnancy, during labor, or in the immediate postpartum period, as well as intended and actual place of delivery.

The 2.0 data form first used when the web-based data collection system was launched in 2004 was derived from a paper form developed by the organization over previous years. A broadly revised 3.0 form was launched in May 2009, incorporating extensive branching to collect a large number of variables describing practice, as well as to update definitions and add detail. In May 2011, a much shorter 4.0 form was launched as an ongoing Minimal data form, in order to encourage universal data contribution.

Datasets available:

Dataset form 2.0 (births occurring 2004 –2009): 24,848 records available

Dataset form 3.0 (births occurring May 2009 – 2012): we anticipate that this dataset will be available to researchers in 2012.

Midwives are currently using data form 4.0 to collect data, and when a sufficient number of records is reached, we will release a new dataset for research.

Elements of the 2.0 Dataset (2004-2009)

List of data categories:

- Midwife credential: CPM, CNM
- Demographic: mother’s age; state or province of residence; mother’s education, occupation, race/ethnic origin, special group status (e.g. Amish); marital/ partner status;

partner demographics; family socio-economic level; primary and secondary sources of payment

- History: pre-existing health history; psycho-social history; previous pregnancy histories; height; weight
- Pregnancy care and problems: initiation of prenatal care; number of prenatal visits; ultrasounds; prenatal tests; maternal health issues; fetal problems; form of payment; drugs; maternal nutrition status & diet; maternal activity level; herbs/homeopathy used in pregnancy; fetal breech status in 3rd trimester, attempts to turn
- Planning Status: planned site of birth in last trimester, at onset of labor, and after first assessment in labor
- Labor and Birth: type of labor onset; length of labor; place of birth; type of delivery; gestational age at delivery; complications; procedures and processes of care; complications; transports
- Postpartum: Number & location of visits; maternal procedures; postpartum complications; newborn sex, birth weight, Apgars, and procedures; breastfeeding status at 72 hours and at final postpartum visit; health status of mother and infant at final visit; outcomes for mother and fetus/newborn. Extra set of questions for multiple births.
- Mortality variables: fetal and neonatal deaths are categorized by ICD-10 codes; maternal deaths are identified by ACOG categories; timing of death (ante partum, stage of labor, postpartum); gestational age at death; autopsy conducted; official cause of death; reviews conducted of death; qualitative details

A PDF of the paper version of this data collection form is available upon request.

Elements of the 3.0 Dataset (2009-2012)

List of data categories:

- Midwife credential: CPM, CNM, CM
- Demographic: mother's age (as calculated from date of birth); state/ province, county and zip code of residence; mother's education, occupation, and race/ethnic origin according to U.S. Live Birth Certificate; special community (e.g. Amish); sexual orientation; marital/ partner status; partner demographics; primary source of payment.
- History: pre-existing health history; psycho-social history; previous pregnancies with histories; height & weight (BMI calculated)
- Current pregnancy: Drug/ alcohol/ cigarette exposure in pregnancy; nutrition status; screenings & tests performed in pregnancy; pregnancy care and complications (and resulting actions taken by the midwife); fetal loss
- Birth planning status: planned site of birth at start of care, at term, at onset of labor, and after first assessment in labor
- Labor and birth: type of labor onset; length of labor; place of birth; type of delivery; procedures and processes of care; complications and resulting actions taken by the midwife
- Postpartum: number of postpartum visits; maternal procedures; postpartum complications; newborn sex, weight, Apgars; newborn procedures; complications and resulting actions taken by the midwife; breastfeeding status at 72 hours and at final

postpartum visit; health status for mother and infant at final postpartum visit; outcomes for mother and fetus/newborn. Extra set of questions for multiple births.

- Transfers of care and transports: antepartum, intrapartum, and postpartum transfers of care; reason for transfer/ transport; return to care; labor stage at transport; transport reason(s); mode & timing of transport; subsequent care providers
- Mortality variables: fetal and neonatal deaths are categorized by ICD-10 codes; maternal deaths are identified by ACOG categories; timing of death for fetal/neonatal deaths (antepartum, intrapartum with stage of labor noted, postpartum with hours & days after birth noted); gestational age at death; autopsy conducted; official cause of death; etc.
- Format of variables: Y/N (some simple dichotomous, in others Y triggers follow-up questions), some multiple options (some select all that apply, some select one), few text boxes (e.g. mother's occupation), some selection from drop-down box (e.g., state of mother's residence), some fill-in dates, times, weights.

The 3.0 form employs some "smart form" features, including 7-8 major variables that utilize a branching feature (miscarriage, antepartum transfer of care, stillbirth, multiple birth, intrapartum transport and/or transfer of care, postpartum transport and/or transfer of care, c/section, maternal death). When any one of these complications is identified for the client, the smart form adds numerous fields to collect additional relevant data about the complication.

Other smart form features:

- Once a complication is identified in the antepartum, intrapartum, postpartum or newborn periods, the form asks for the: "Actions you took". The midwife can choose one or more of the following: none, treat, consult, collaborate, transfer care, or transport.
- Some variables are calculated by the system (mother's age, BMI, gravida/para)
- Some variables offer choice of metric or US/Imperial measurements
- In some cases, the web system enforces one choice if the options are mutually exclusive
- The smart form will identify selected inconsistencies in separate parts of form (e.g., entering a birth weight <2500g and failing to check "low birth weight" as a complication), or will indicate when a given answer is outside of an expected range in an attempt to catch inadvertent typing mistakes
- The smart form will also prompt the midwife to answer selected questions that are determined to be essential (i.e., the type of delivery). If the midwife doesn't have an answer, the form will prompt her to explain.
- Definitions and examples are provided on the midwife's screen via mouse-over pop-ups
- The form doesn't present questions that can't be answered (e.g, if cesarean was performed in first stage, the form won't ask how long second stage was)

To try out a demonstration version of the 3.0 web-based form, go to <http://demo.manastats.org>. This site operates exactly as the real site operates for midwife contributors, except that records created are not entered into the MANA Stats database and are erased periodically.

Data Review Procedures

While most records go directly into the database when the midwife submits the completed form, certain records are selected by the software, based on pre-determined objective characteristics,

for data review and quality assurance evaluation. Trained reviewers follow guidelines using specific and uniform protocols. Client records flagged for review include the following:

- Records that are missing data that was determined to be essential, or with values that fall outside of the expected range. The smart form asks the midwife to explain these situations, and a reviewer must look at all of these explanations.
- Forms with potential inconsistencies in certain areas are reviewed with specific review protocols.
- All maternal, fetal and newborn deaths are reviewed with an extensive review protocol (see below).

All maternal, fetal (>20 wks) and newborn deaths in the 2.0 and 3.0 datasets are reviewed using a protocol based on Fetal-Infant Mortality Reviews (FIMR). Trained data reviewers interview each midwife via telephone to ask additional questions about the circumstances of the death and categorize the death according to current ICD-10 codes (for fetal/newborn deaths) and ACOG categories (maternal deaths). This additional data is entered directly into the data form where a death was reported.

Reviews are conducted to verify the accuracy of the data and may include email and/or phone contact with the midwife contributors. Specific review protocols are available upon request by the researcher. In addition, a methods article is in the publication process that will provide more details on data collection and review processes used with the 2.0 form.

Data Access Policy Synopsis

The MANA Stats database is proprietary and is owned by the Midwives Alliance of North America, who is responsible for the reliability, integrity, privacy and security of the data contained within it. This data contains information about women, newborns, pregnancy and birth experiences, their health care, and practices of the midwife contributors. It is made available through a written informed consent process with each client and includes a process of enrollment, data collection and entry by midwives.

The Midwives Alliance Board of Directors has designated the Coordinating Committee of the Division of Research as the stewards of the MANA Stats database and charges them to maintain and administer the database for research and statistical purposes.

All requests for data must be received and approved through the application process detailed below and shall at no time constitute direct access to the database itself. A brief synopsis of this process is as follows:

1. The applicant completes the application materials (including a detailed research proposal and demonstration of IRB approval from their home institution) and submits it to the DOR with the application fee (if applicable).
2. The DOR sends the application and research proposal to an external Research Review Committee (RRC) who reviews the proposal for adequate study design, scope and feasibility and either accepts it without revisions or asks the researcher(s) to make revisions and resubmit.

3. The Research Review Committee makes a recommendation to the DOR Coordinating Committee regarding the merits and feasibility of the proposal, including any recommended revisions or requests for clarification. The Coordinating Committee may ask the researcher for more information or clarification.
4. The DOR Coordinating Committee makes a recommendation to the Midwives Alliance Board of Directors (as the owners of the data) regarding approval or rejection of the final proposal.
5. The Board of Directors communicates its final decision regarding applicant approval to the DOR Coordinating Committee, who in turn communicates with the applicant.
6. If approved, the applicant pays the data access fee (if applicable), and signs a standard confidentiality/ non-disclosure statement and a specific data access contract.
7. The DOR generates a password-protected SPSS file containing the requested variables for the researcher.

Prior to releasing the requested data to approved researchers, the researchers must submit their IRB Certificate of Approval (or IRB exemption, if applicable), a copy of the approved protocol, and a summary of changes made in the protocol since RRC approval, as applicable.

Composition of the Research Review Committee (RRC)

Although the members of the RRC may change over time, there are certain criteria that the Committee as a whole must meet to ensure fair composition and diverse credentials are represented. The composition of the RRC is as follows: at least four of its six members must be qualified researchers (see below for definition); at least one member is both a Midwives Alliance member and a Division of Research member, and at least one member is a midwifery consumer. “Qualified researchers” shall be defined as individuals who have demonstrated scholarly activity including familiarity with processes, ethics and rigorous methodology for study design, implementation and/or knowledge translation phases of research. Qualified researchers hold advanced degrees in their profession and bring this expertise to the RRC. “Consumer” shall be defined as an individual who is not a midwife, but has utilized the services of a midwife.

Process for Evaluation of Requests for Data Access

Completed applications will be sent through a two-stage Research Review. For each proposal, the Research Director will request a blind review from a minimum of two independent external reviewers serving on the RRC; these individuals are selected based on their expertise with the study design and content of the proposed research. The full application will also be sent to the other RRC members for review.

After the Research Director has received recommendations from the blind reviews, the full RRC will meet in phone conference to review the proposals. It may recommend a proposal be accepted, rejected or accepted pending specified changes. These recommendations, along with the review scores and comments and the original application, will be sent to the DOR Coordinating Committee. Criteria will include standard considerations such as appropriateness of the study design to the research question and the feasibility of the investigators to complete the study, including demonstrated success across the research team with conducting research of

similar scope, as well as adequate facilities, infrastructure and financial support to ensure completion.

A specific data access contract will be signed by the reviewer and an official representative of the Midwives Alliance Board of Directors. A standard confidentiality/ non-disclosure agreement will be provided.

Submission Requirements:

To get started, please submit the following information:

- 1) Letter of intent, including:
 - a. Investigator affiliations
 - b. The nature and purpose of the proposed research, including:
 - i. Basic description of the study design and methods of analysis
 - ii. Time frame
 - iii. Specifics of data requested (year(s), intended site of birth, provider, etc)
- 2) Applicant Information Form – available for download at <http://mana.org/DOR/about/about-mana-stats/researchers/>
- 3) Copy of research proposal, to include the following:
 - a. Description of project and research questions
 - b. Project background, review of the relevant literature and significance
 - c. Methods and procedures
 - d. Variables requested for analysis, including any time or geographic limits
 - e. Risks/ benefits assessment
 - f. Research dissemination plan
 - g. Project timeline
 - h. Funding summary
 - i. Works cited
 - j. Relevant attachments
- 4) Documentation of Institutional Review Board approval or other mechanism for protection of human subjects
- 5) Supporting documents:
 - a. Researcher experience and qualifications (curriculum vitae)
 - b. Documentation of CITI course or NIH-approved equivalent for all applicants

Researchers wishing to conduct prospective research/ data collection should also submit the following:

- a. Detailed description of the subject identification and recruitment procedures planned
- b. Statement on compensation for participants
- c. Description of the informed consent process
- d. Methods for protecting anonymity and confidentiality

If a researcher foresees that additional data (additional years, geographic regions etc.) might be required during the course of the study, the possibility should be written into the original request. Should the researcher wish to study additional data variables that are not currently collected for a prospective study, the possibility exists that a specific research module could be added to the dataset for a period of time. This would need to be approved in advance of submitting a full

application, allowing time for the Division of Research to estimate the cost of the additional programming labor and give the researcher an estimate of additional charges.

Upon approval of a research application, access will be predicated on the signing of a Data Access Contract as well as a standard Confidentiality and Non-Disclosure Agreement.

The requested data will be exported as a .csv file coded for import into SPSS. Other formats may be possible; researchers should inquire if they need a special format.

Fees:

Application fee: \$50

Data access fees (to cover administrative time for the retrieval and sending of data files):

- Individual researchers: \$250
- Institutions: \$1000

Data access fees are waived for Midwives Alliance members, but application fees still apply. All fees are waived for community research conducted by midwives of color who demonstrate need.

E-mail all documents as attachments to:

Melissa Cheyney, PhD, LM, CPM

Research Director, Midwives Alliance Division of Research

research@mana.org

Receipt will be acknowledged by email.

Send \$50 application fee to:

Midwives Alliance Treasurer

611 Pennsylvania Ave

Suite 1700

Washington, DC 20003-4303

Make check payable to Midwives Alliance, with ‘data access application’ in the memo.

Receipt will be acknowledged by email and the Division of Research will be notified.

For questions about this process, contact Dr. Cheyney at the email above.

APPENDIX A

Midwives Model of Care™ Summary

The Midwives Model of Care™ is based on the fact that pregnancy and birth are normal life processes.¹

The Midwives Model of Care includes:

- Monitoring the physical, psychological, and social well-being of the mother throughout the childbearing cycle
- Providing the mother with individualized education, counseling, and prenatal care, continuous hands-on assistance during labor and delivery, and postpartum support
- Minimizing technological interventions
- Identifying conditions when women or babies would benefit from interprofessional collaborative care, or referral to medical care, and initiating the consultation or referral process.

The application of this woman-centered model of care has been proven to reduce the incidence of birth injury, trauma, and cesarean section.

The Midwives Model of Care includes prenatal visits and "hands-on" care throughout labor, birth and the postpartum period. It results in fewer interventions and healthier birth outcomes for mother and baby.

Based on a growing body of global research, women are aware of evidence-based options for birth place, including home, birth center, and hospital. Women labor most efficiently in a place where they feel free, safe and private, with attendants whom they know and trust. Many women find that they feel most comfortable at home or in a birth center, with the ongoing attention and nurturing care of a midwife or doctor trained in gentle, natural, and often unmedicated childbirth – a provider who is an expert in normal birth and provides the Midwives Model of Care.

¹ This definition is copyrighted by The Midwifery Task Force, Inc. 1996-2008, All Rights Reserved. See <http://cfmidwifery.org/mmoc/define.aspx>

Caregivers who provide the Midwifery Model of Care have committed to offer families:

- Respectful communication
- Personal attention
- Enough information to facilitate informed decision-making
- Appropriate monitoring throughout the pregnancy, birth, postpartum, and neonatal period
- Confidence in the physiologic processes of pregnancy and birth
- A variety of non-pharmaceutical or natural measures to promote comfort and progress
- A care provider who will be in attendance continuously throughout labor and delivery

Understanding the Midwives Model of Care for Research

An understanding of the social context in which births occur is integral to high quality research on maternal-child health, midwives, and birth setting. The Midwives Model of Care and out-of-

hospital birth differs substantially in a variety of ways from hospital birth and medical care, and there is considerable social science literature that documents midwifery care as a unique paradigm distinct from the dominant medical model of birthing care (see Appendix C: Annotated Bibliography of Research on Home Birth). While comparisons between hospital and home or birth center birth remain possible, these analyses must be developed within a framework that considers how the models differ in practice.

Globally, midwifery and obstetric care are both seen as viable, distinct (though sometimes overlapping) models for the provision of care. Further, an understanding of the Midwives Model of Care and birth setting will provide the researcher with a more nuanced and ethnographically meaningful context from which to develop research questions and to select and analyze variables. The Division of Research of the Midwives Alliance of North America believes that high-quality, reliable and valid research that aims to contribute to local, national and global maternal-child health evaluation must be developed with an understanding of the conditions that produce the data to be analyzed.

APPENDIX B

Community-Based Participatory Research (CBPR) Summary

Community-based participatory research (CBPR) is research committed to equality in partnerships between researchers and members of the community/organization in which the research phenomenon is placed. In CBPR projects, the community/ organization participates fully in all aspects of the research process, including the development of research questions, methodologies, literature reviews, data analysis, and publication.

CBPR is a ground-up, collaborative approach, where researchers work intimately with the community/organization along each step of the project. The goal of CBPR is to produce research outcomes and projects that are applicable and meaningful to the community/organization being studied, moving beyond research for knowledge's sake and moving towards critical praxis or the practical application of research findings to policy change, program reform or social justice goals such as decreasing health disparities or promoting equality in maternal-child health. CBPR recognizes that health care, outcomes, and behaviors are influenced and inseparable from social, cultural, political and economic systems. CBPR values the importance of mixed methods approaches, often incorporating both qualitative and quantitative data. Creating collaborative, sustainable partnerships requires a sharing of power, resources, knowledge, credit and results.

The WK Kellogg Foundation Community Health Scholars Program (2008) defines CBPR in health arenas as a: "collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities."

Utilizing Community-Based Participatory Research (CBPR)

Community-Based Participatory Research (CBPR) remains integral to high-quality research that is scientifically valid, reliable and applicable to all participants. A CBPR approach helps insure that research is grounded, analyzed and interpreted in the context where the phenomenon under study occurs. Researchers who engage CBPR are able to draw on community/organization experts to more fully understand the research phenomenon, allowing researchers to better choose variables for analysis and relevant research questions. The community/organization, in turn, is able to strengthen and improve its systems with the valuable knowledge and data produced by the researchers.

In sum, CBPR is essential for developing research projects that are ethical, reliable, valid, and applicable to all involved. The Division of Research of the Midwives Alliance of North America (MANA) supports these values, and requests that researchers develop data applications with the goals of CBPR in mind.

Recommended Readings about CBPR:

(Books)

- Blumenthal, Daniel S., and Ralph J. Diclemente. 2003. *Community-Based Health Research: Issues and Methods*. New York: Springer Publishing Company, Inc.
- Israel, Barbara A., with Eugenia Eng, Amy J. Schulz, and Edith A. Parker. 2005. *Methods in Community-Based Participatory Research for Health*. San Francisco: John Wiley and Sons, Inc.
- Minkler, Meredith, and Nina Wallerstein. 2008. *Community-Based Participatory Research for Health: From Process to Outcomes*. 2nd Edition. San Francisco: John Wiley and Sons, Inc.

(Articles)

- Aaron, Kaytura Felix, and Daniel Stryer. 2003. Moving from Rhetoric to Evidence-based Action in Health Care. *Journal of General Internal Medicine* 18(7):589-591.
- Ahmed, Syed M., with Barbara Beck, Cheryl A. Maurana, and Gail Newton. 2004. Overcoming Barriers to Effective Community-Based Participatory Research in US Medical Schools. *Education for Health* 17(2):141-151.
- Aronson, Robert E., with Anne B. Wallis, Patricia J. O'Campo, Tony L. Whitehead, and Peter Schafer. 2007. Ethnographically Informed Community Evaluation: A Framework and Approach for Evaluating Community-Based Initiatives. *Maternal Child Health Journal* 11:97-109.
- Cargo, Margaret, and Shawna L. Mercer. 2008. The Values and Challenges of Participatory Research: Strengthening Its Practice. *Annual Review of Public Health* 29:325-350.
- Lantz, Paula M., with Edna Viruell-Fuentes, Barbara A. Israel, Donald Softley, and Ricardo Guzman. 2001. Can Communities and Academia Work Together on Public Health Research? Evaluation Results from a Community-Based Participatory Research Partnership in Detroit. *Journal of Urban Health* 78(3):495-507.
- O'Toole, Thomas P., with Kaytura Felix Aaron, Marshall H. Chin, Carol Horowitz, and Frederick Tyson. 2003. Community-Based Participatory Research: Opportunities, Challenges, and the Need for a Common Language. *Journal of General Internal Medicine* 18:592-594.
- Schell, Lawrence M., Julia Ravenscroft, Mia Gallo, and Melinda Denham. Advancing Biocultural Models by Working with Communities: A Partnership Approach. 2007. *American Journal of Human Biology* 19:511-524.

APPENDIX C

HOME BIRTH: An annotated guide to the literature

MAY 2011

The most updated version of this guide can be found at <http://www.bcmidwives.com/>

This bibliography was published by the Division of Midwifery in the Faculty of Medicine, University of British Columbia in collaboration with the American College of Nurse-Midwives and the Midwives Alliance of North America.

This annotated bibliography provides citations and critical appraisal of original studies on home birth. Study selection was based on comprehensive searches of the following databases: EBSCO (Academic Search Complete, Medline & CINAHL), PubMed, & Cochrane. The following search terms were used: “home birth”, or “home + childbirth” and safety, risk assessment, transfer criteria, outcomes, screening, satisfaction, demand, preference, and perception. Studies were assessed by two authors independently, according to the algorithm to assess the quality of home birth research outlined by Vedam in *Birth* 2003; (30):1 (see below Section 1J, page 8). The final sections provide a list of citations for legal, ethical, and policy publications for maternity providers.

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Laura Schummers, BSc, SM(student), is the Research Coordinator at the Division of Midwifery, University of British Columbia. She will be a Master of Science student in the Epidemiology department at the Harvard School of Public Health in 2011.

Colleen Fulton, BA, MA, BMW(student) is a midwifery student and Research Assistant at the Midwifery Program at the University of British Columbia.

SAFETY & OUTCOMES, HIGH QUALITY STUDIES

Section 1:A META-ANALYSES & SYTEMATIC REVIEWS

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. This systematic review of home birth and birth center safety studies followed standard methods, including reporting levels of evidence, disclosure of inclusion and exclusion criteria, and search strategies (detailed in a Methods article by Goer in the 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 claim 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.

Olsen O, Jewell MD. Home versus hospital birth. *Cochrane Database of Systematic Reviews* 1998, Issue 3. Art. No.: CD000352. DOI: 10.1002/14651858.CD000352. Meta-analysis of randomized controlled trials comparing planned home births to planned hospital births for the following outcomes: interventions, complications, and morbidity. The selection criteria were rigorous. Only one trial was included (n=11). The sample was too small to draw any conclusions about the safety of home birth. Authors note that parturient women’s strong opinions about birth place may contribute to the small sample size.

Olsen O. Meta-analysis of the safety of home birth. *Birth* 1997 Mar;24(1):4-13; discussion 14-6. Meta-analysis of the most methodologically sound, observational, comparative, original studies that investigated differences in perinatal mortality and morbidity between planned home births and planned hospital births. Multivariate statistical analysis controlled for obstetrical background, perinatal factors, comparable populations, inclusion criteria, transfer criteria, and outcome measures. 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=0.541.41). Moreover there were significantly fewer medical interventions, fewer severe lacerations, fewer operative births, and fewer low Apgar scores in the home birth groups.

Section 1:B RANDOMIZED CONTROLLED TRIALS

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 randomized according to 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 indicated 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 the extremely large number of subjects required to compare rare outcomes would not be feasible.

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, indicating that an RCT was not a feasible study design for this question. The research team then re-designed their study to investigate the reasons that women chose to decline participating in the RCT. They developed and administered a postal questionnaire. 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 wished to avoid receiving an undesired treatment.

Section 1:C NORTH AMERICAN COHORT STUDIES

Janssen PA, Saxell L, Page LA, Klein MC, Liston RM, Lee Sk. Outcomes of planned home births with registered midwife versus attended by regulated midwives versus planned hospital birth in British Columbia. *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 cesarean 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.

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 home birth group had lower rates of cesarean section (RR 0.64), maternal morbidity/mortality (PP 0.77) and neonatal morbidity/ mortality (RR 0.80). Results suggest that Ontario midwives provide adequate screening and safe care for women planning home births.

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 in 2000. Describes a 12% transfer rate, a 3.7% c-section rate, 1.7/1000 neonatal mortality rate, and lower intervention rates for planned home births compared to low risk hospital births in the US. Sometimes criticized because the authors describe the design as cohort study but 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.

Janssen PA, Lee SK, Ryan EM, et al. Outcomes of planned home births versus planned hospital births after regulation of midwifery in British Columbia. *CMAJ* 2002;166(3):315-23. Outcomes of 862 planned home births attended by midwives compared 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 the eligibility criteria set for home birth subjects. Women were matched according to age, partner status, parity, and hospital where study subject's midwife 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, or episiotomy compared to women in the physician 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.

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 from California for 1989 and 1990 to identify a comprehensive risk profile for a cohort of nearly 816,000 low risk births. Planned and actual birth setting are reported and intrapartum transfers to the hospital were allocated to the originating 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.

Section 1: D INTERNATIONAL COHORT STUDIES

de Jonge A, van der Goes B, Ravelli A, Amelink-Verburg M, Mol B, Nijhuis J, et al. 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 is the largest study on the safety of home birth to date. 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.

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 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 birth occurred in hospital. Perinatal outcomes studied: perinatal death, intrapartum death, intrapartum asphyxiation, Apgar of <7 at 5 minutes, use of pediatric or specialized neonatal care. Maternal outcomes studied: 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) 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). Excluding congenital anomalies, 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 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 cesarean delivery (aOR .27), an instrumental delivery (aOR .33), and episiotomy (aOR .14).

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 across 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 less medical interventions and perinatal complications. Full study report published as book.

Ackermann-Liebrich U, Voegeli T, Gunter-Witt K, et al. 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.

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 trial that studied 1836 women with low risk pregnancies, 1140 home and 696 hospital. The design controlled for provider type, parity, social, medical and obstetric background. Researchers developed a tool that assigns an overall perinatal outcome index score based on “maximal result with minimal intervention”. This tool integrates data from 22 items on intrapartum course, nine items on the condition of the newborn, and five items from the postpartal period. It allows researchers to evaluate factors that detract from optimal perinatal health as well as their clinical significance. This study found no relation between planned place of birth and perinatal outcome in primiparas ($t=1.99$, $p<.05$) when controlled for favorable or less favorable background, and significantly better perinatal outcomes in multiparous women ($t= 5.56$, $P<0.001$) with or without controls.

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 the first 14 years (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.

Section 1:F DESCRIPTIVE STUDIES & REGISTRY REPORTS

Declercq E, MacDorman M, Menacker F, Stotland Nb. 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 from 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. The demographics of 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 on the accuracy of the planning status variable.

MacDorman, M, Declercq 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 highly correlated with being non-Hispanic white, over the age of 30, multigravida, married, singleton birth over 37 weeks of gestation and delivered by midwives. While home birth rates steadily increased for non-Hispanic whites, they declined for all other race 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' attendant, suggesting that these births were likely 'unplanned' emergency home births. Most current Birth Certificate in the U.S. do not distinguish between planned and unplanned home births, thus further data is needed to conclude any differences.

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.

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 (N1404). Of those beginning labor at home, 102 (8.3%) were transferred to the hospital in labor, 10 (0.8%) were postpartum transfers and 14 (1.1%) infants were transferred. For the whole sample of women beginning labor at home, fetal and neonatal mortality was 2.5/1000. For those actually birthing at home this mortality was 1.8/1000. Intrapartum problems were positively associated with transfer to hospital-based care, and overall outcomes were consistent with expected outcomes for low-risk birth .

Davies J, Hey E, Reid W, Young G. Prospective regional study of planned home births. Home Birth Study Steering Group. *BMJ* 1996;313(7068):1302-06. Examines experience and outcome of pregnancy, indications for hospital transfer, and attitudes of mothers and providers in the Northern Region Perinatal Mortality study.

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 1989-1994. Births were then categorized by birth place type; and maternal characteristics, prenatal care, and birth outcomes were compared between planned home births and births in birth centers or in hospitals. 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.

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. Similar findings as the more recent prospective study by Murphy and Fullerton.

Section 1:H INTEGRATED REVIEWS

Fullerton JT, Navarro AM, Young SH. Outcomes of planned home birth: an integrative review. *J Midwifery and Women's Health* 2007, 52 (4): 323-333.

Vedam, S., & Burkhardt, P. (2004). Evidence-based home birth practice. In Gruer, J., et.al. (Eds.). *ACNM Home Birth Practice Handbook (2nd ed.)*. Washington, D.C.: ACNM Publications.

Section 1:I EVALUATING THE QUALITY OF HOME BIRTH SAFETY RESEARCH

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 from: <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.

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 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.

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 Evers et al prospective cohort study 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 numbers; the neonatal mortality rates of catchment are twice as high as the rates of previous national studies, which requires further investigation. In the Netherlands primary maternity care often is equated to women who attended by midwives. 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 conclusion that "the obstetric care system in the Netherlands possibly contributes to the high perinatal mortality rate" is not supportable by this study alone.

Vedam, S. Home versus hospital birth: questioning the quality of the evidence on safety. Birth 2003; 30(1):57-63. Detailed review of Pang study, including well acknowledged errors in methodology and definitions. Outlines flaws associated with using birth certificate data to study outcomes of planned home births. Includes algorithm for evaluating quality of trials on home birth safety. Studies must adhere to following study design criteria in order to avoid common confounding factors: 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.

SAFETY & OUTCOMES, STUDIES WITH ERRORS IN DESIGN, ANALYSIS, OR REPORTING

Section 2:A META-ANALYSES & SYSTEMATIC REVIEWS

Wax JR, Lucas FL, Lamont M, Pinette MG, Cartin A, Blackstone J. Maternal and newborn outcomes in planned home birth vs planned hospital births: a metaanalysis. Am J Obstet Gynecol 2010;203:243.e1-8. This article presents a purported 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 deeply flawed. This meta-analysis is fraught with calculation errors, with selective and mistaken inclusion/exclusion of studies when analyzing specific outcomes, as well as logical flaws in terms of definitions. A more detailed critique of this article, authored by a team of experts in the field (including the authors of studies included in the meta-analysis), can be accessed at: <http://www.medscape.com/viewarticle/739987>

Section 2:B DESCRIPTIVE STUDIES & REGISTRY REPORTS

Chang JJ, Macones GA. Birth Outcomes of Planned Home Births in Missouri: A Population-Based Study. Am J Perinatol. 2011;[Epub ahead of print]. OI:10.1055/s-0031-1272971. 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 birth attended by physicians and CNMs. Data was collected from linked Missouri live birth and fetal death files, for the years 1989 through 2005. Study sample included singleton pregnancies, delivered between 36-44 weeks gestation. Pregnancies with major fetal anomalies and breech 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, dysfunctional labour, but that planned home births attended by non-CNMs was associated with prolonged labour, and a fivefold odds of newborn seizure, and planned home births attended by all three groups (physicians, CNMs and non-CNMs) held a higher risk of intrapartum death. There are several weaknesses of the design and interpretation of data in this study. The small numbers for non-CNM attended home births do not meet power requirements, 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.

Evers A, Browsers 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. A purported prospective cohort study to compare 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 significant higher risk of perinatal death than infants of high risk women who 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. Nulliparous women had a significantly higher risk of NICU admission than multiparous women. The most common reason for admission was asphyxia. Data extracted from a large birth registry database and adjustment for confounders, including excluding appropriate referrals from primary to secondary care before and during the onset of labour, was not possible. These findings do not correlate to any previous studies of the Dutch maternity care system. The results may be mostly of a reflection of the inter-professional relationships that are specific to the Utrecht region.

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 cesarean. Conclusion: home births are associated 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.

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 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 'other' midwives' deliveries in hospital and home). Malloy concludes that neonatal mortality rates of certified nurse midwives or 'other' midwives at home births and at birthing centers are statistically higher than in hospital births attended by certified nurse midwives or 'other' midwives. Method of selection did not distinguish planned from unplanned home birth nor if hospital birth CNMs were in attendance at home births or appeared on birth certificates as certifier. Analysis does not distinguish between "other midwife" attendant and no attendant.

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 the planned home births, out-of-hospital births that had no attendant, or births with unknown or unnamed attendants. Premature births occurring between 34 and 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.

Bastian H, Keirse MJ, Lancaster PAL. Perinatal death associated with planned home birth in Australia: Population based study. *BMJ* 1998;317(7155):384-88. Reported outcomes of births attended by unregistered midwives, many of whom had limited training, experience, and no access to resuscitation equipment. Births occurring without qualified attendants are not consistent with definitions of planned home birth in most countries.

Schramm WF, Barnes DE, Bakewell JM. Neonatal mortality in Missouri home births, 1978-84. *Am. J. Public Health* 1987;77(8):930-35. Compared planned home and planned hospital births in Missouri. Within the group of the planned home births attended by physicians, certified nurse-midwives, and licensed midwives, the differences in neonatal mortality when compared with physician-attended hospital births were not significant. Any increased relative risk shown was attributable to unskilled providers.

Burnett CA, 3rd, Jones JA, Rooks J, Chen CH, Tyler CW, Jr., Miller CA. Home delivery and neonatal mortality in North Carolina. *JAMA* 1980;244(24):2741-45. Examined planned and unplanned home births in North Carolina in a demographically high-risk group of women. When unplanned home births and high-risk births were excluded, there were no significant differences in neonatal mortality between planned home and planned hospital births.

Wax JR, Lucas FL, Lamont M, Pinette MG, Cartin A, Blackstone J. Maternal and newborn outcomes in planned home birth vs planned hospital births: a metaanalysis. *Am J Obstet Gynecol* 2010;203:243.e1-8. This article presents a purported 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 deeply flawed. This metaanalysis is fraught with calculation errors, with selective and mistaken inclusion/exclusion of studies when analyzing specific outcomes, as well as logical flaws in terms of definitions. A more detailed critique of this article, authored by a team of experts in the field (including the authors of studies included in the meta-analysis), can be accessed at: <http://www.medscape.com/viewarticle/739987>

PATIENT SATISFACTION, PROVIDER OPINION, & LEGAL CONTEXT

Section 3:A STUDIES OF PATIENT DEMAND & SATISFACTION, WOMEN'S CHOICE, & PROVIDER ATTITUDES

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 secondary data analysis (questionnaires) of women who had a planned home birth (N=671) and women who had an elective cesarean (N=126) between 1997-2008. In Sweden the current medical context neither promotes home birth or elective cesarean. Study found significant socioeconomic differences between the two groups of women. Compared to women who chose an elective cesarean, women who chose planned home birth were associated with a higher level of education, lower BMI, lower smoking rate, felt less threat to baby's life during the birth and a higher satisfaction with their overall birth experience. Women in home birth group reported a higher intensity of pain, but more positive experience of that pain than cesarean group. Women in home birth group also felt higher sense of control.

Lindgren H, Erlandsson K. Women's Experiences of Empowerment in a Planned Home Birth: A Swedish Population-based Study. *Birth* 2010;37(4):309-17. Descriptive study using secondary data analysis (questionnaires) of women who had a planned home birth between 1992-2005 (N=735). Birth stories were analyzed using content analysis and descriptive statistics. Demographics of women who birth at home tended to be older, multiparous, higher level of education, and not born in Sweden, with a lower family income. Study found that women who birth at home felt empowered by their environment and from the people who are supporting them at the birth (midwives, partners, family). Birth stories rarely mentioned pain or suffering and stressed the importance of an undisturbed space and sense of control. Surveys highlighted the importance of support and guidance and trust in their attendants to feel safe. Feeling disempowered was related to a poor choice of attendants and the absence of partner support. The response rate of the study was 99%. Limitations: small scale study might not be generalizable to general Swedish population or international context.

Janssen P, Henderson A, Vedam S. The experience of planned home birth: Views of the First 500 Women. *Birth* 2009;36:4:297-304. A qualitative study that aims to describe the experiences of women who had planned a home birth with a regulated midwife in British Columbia. Methods: data analysis was an adaptation of interpretive description of anonymous questionnaire distributed by clients' midwives. Study found that these women were overwhelmingly positive about their experience. Main themes that emerged included: clients' confidence in midwives skill, a sense of empowerment from being a decision maker in their own care, a sense of emotional and informational support, a feeling that they received 'holistic' care, which included comprehensive post-partum care at home and a sense of confidence from feeling like they had access to their midwives. Other themes included the confidence they felt from birthing in a familiar, family-centred space, and viewed birthing in the home as a way of maintaining control while avoiding interventions. When women transferred to the hospital women felt supported and able to transition smoothly. No single theme emerged from the 7 negative comments. Study was limited by initial failure of some midwives to distribute study in the early stages of the study but of those who received the questionnaires the response rate was 82%.

Vedam S, Stoll K, White S, Aaker J, Schummers L. American Nurse-Midwives' Experiences with Planned Home Birth: Impact on Attitudes and Practice. *Birth* 2009;36(4):274-82. Survey-based study of Nurse-Midwives' experiences with and attitudes toward planned home birth. Study found strong correlation between choice of practice site and comfort with planned home birth and the amount of exposure to home birth during education, practice experiences, and inter-professional, logistic, and environmental factors

Lindgren HE; Radestad IJ; Christensson K, Wally-Bystrom K, Hildingsson IM. Perceptions of risk and risk management among 735 women who opted for a home birth. *Midwifery* 2010;26(2):163-72. Using data from a national survey of all women who birthed at home in Sweden between 1992 and 2005, this study aims to describe women's perceptions of risk and risk management related to childbirth. Categories of perceived risk related to hospital and home births emerged. Perceived risks of hospital births included loss of autonomy, impersonal care, and subjection to interventions; perceived risks of home birth included centered around difficulty accessing emergency care in a worst-case scenario. The study found that women avoided discussing risks with care providers (other than their homebirth midwife) as a strategy to manage perceived risks.

Boucher D, Bennet C, McFarlin B, Freeze R. Staying home to give birth: why women in the United States choose home birth. *Journal of Midwifery & Women's Health* 2009. 54(2): 119-126. Qualitative descriptive secondary analysis of survey data: sample size 160, 508 separate statements submitted to content analysis. Most common reasons given for wanting to birth at home were: 1) safety ; 2) avoidance of unnecessary medical interventions common in hospital births 3) previous negative hospital experience; 4) more control; and 5) comfortable, familiar environment. Another dominant theme was women's

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Section 3:B LEGAL, POLICY, & ETHICS

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POLICY

Section 4:A PROFESSIONAL ORGANIZATION POLICY STATEMENTS

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