

## Colorado's Direct-Entry Midwifery Law and Program

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#### What is Elephant Circle?

Inspired by elephants who give birth within a circle of support, we work for a world where all people have a circle of support for the entire perinatal period. We call this Birth Justice. Birth justice occurs when everyone is equally capable of self-determination during the perinatal period, when their self-determination is supported and amplified.

To achieve this we need both the HOW and the WHAT of birth justice. How: strategies for tackling systems of power and oppression and strategies for change and resilience. What: expertise in health systems, legal systems and the perinatal period. Elephant Circle shares the how and the what so everyone can help bring about birth justice.

#### Why do we care about Colorado's Direct-Entry Midwifery Law?

Elephant Circle is a Colorado-based, national non-profit. Since midwifery is an essential part of birth justice, we prioritize working on Colorado midwifery issues. We worked on the 2011 and 2016 Direct-Entry Midwifery Sunset Bills. We are bringing together people who give birth in Colorado with Colorado midwives, and working together for policy change that will support both midwives and the people they serve.

#### The following people contributed to this report:

Indra Lusero, Esq., Director of Elephant Circle
Heather Thompson, MS, PhD., Deputy Director of Elephant Circle
Jen Anderson-Tarver, CPM, RM
Beth Karberg, MS, CPM, RM
Lo Kawulok, CPM, RM
Geneva Montano, CPM, RM
Stephanie Sibert, CPM, RM

#### **Table of Contents**

- (I) Health, Safety, Welfare and Conditions Related to Colorado's Direct-Entry Midwifery Program
- (II) Least Restrictive Form of Regulation Analysis
- (III) Efficiency and Effectiveness Analysis
- (IV) Economics and Competition Analysis
- (V) Complaints, Investigations, Discipline- Analysis
- (VI) Suggested Changes to Improve Operations and Enhance the Public Interest

### Health, Safety, Welfare and Conditions Related to Colorado's Direct-Entry Midwifery Program

# What's in this section on health, safety, welfare and conditions:

- Introduction to Midwifery
  - Steps to Midwifery
- Midwifery Integration
  - Midwifery Integration Report Summary
  - Colorado Integration Report Card
- History
  - A chart of the legislative history through 2010
  - An overview of the changes made to the law in 2011
  - A one-page overview of the history (in the form of a handout used during the 2011 Sunset process)
  - A history of direct-entry midwifery in Colorado written in 2010 by Elephant Circle Director, Indra Lusero
  - A 2000 Position Paper from the American Public Health Association
  - A map of State Trends in licensure of Certified Professional Midwives
- Midwifery Regulation
  - Principles for Model Legislation and Regulation
- Health, Safety and Welfare
  - The 2014 planned home-birth study
  - Slides from the webinar of the Committee on Assessing Health Outcomes by Birth Settings, February 6, 2020
  - o Infographic on the impact of place of birth on mistreatment
  - Best practice guidelines for transfer from planned home birth to hospital
  - Best practice guidelines for collaboration
  - o The 2008 report on evidence-based maternity care
  - Document on analyzing perinatal mortality in Colorado

#### Introduction to Midwifery

There are three types of midwifery credentials in the United States, Certified Nurse Midwife (CNM), Certified Midwife (CM), and Certified Professional Midwife (CPM). All three credentials meet the standards set forth by the International Confederation of Midwives.

Colorado's Direct-Entry Midwifery law was established before the CPM credential was developed, but now Direct-Entry Midwives in Colorado are required to have the CPM credential.

A Certified Professional Midwife (CPM) is a knowledgeable, skilled and professional primary maternity care provider. Certified Professional Midwives are trained and credentialed to offer expert care, education, counseling and support to people for pregnancy, birth and the postpartum period. CPMs practice as autonomous health professionals working within a network of relationships with other maternity care providers who can provide consultation and collaboration when needed.

All Certified Professional Midwives meet the standards for certification set by the North American Registry of Midwives (NARM), the certifying agency for certified professional midwives. NARM's CPM credential is accredited by the National Commission for Certifying Agencies. Midwifery institutions and programs whose graduates are eligible for certification by examination through NARM are accredited by the Midwifery Education & Accreditation Council (MEAC). MEAC is recognized by the U.S. Department of Education.

CPMs provide unique and critical access to normal physiologic birth, which is often not accessible with other providers. Physiologic birth profoundly benefits newborns, mothers, parents, and communities.

Although qualified to practice in any setting, CPMs have particular expertise in providing care in homes and free-standing birth centers, known collectively as "community birth." CPM is the only credential that requires experience in community birth settings. CPMs own or work in over half of the birth centers in the U.S. today.

# Steps to becoming a Direct Entry Midwife in Colorado

Apply to the Colorado Registry of Direct Entry Midwives	Department of Regulatory Agencies  The registrant must satisfy the requirements of the Colorado Revised Statutes, Direct-Entry Midwifery law including demonstrating knowledge, experience, the CPM credential, and red cross training in CPR and neonatal resuscitation. The registrant must maintain good standing and submit data on an annual basis with an application for renewal of their status. In addition, to maintain the CPM credential the midwife must obtain continuing education hours every three years.
Sit for the National Board Exam	The National Commission on Certifying Agencies (NCCA) has accredited over 180 credentials Including nurse-midwives nurse anesthetists nurse practitioners critical care nurses It has accredited the standardized examination system leading to the credential "Certified Professional Midwife" (CPM)  The 8 hour exam is the final step in the credentialing process It has been deemed psychometrically sound and legally defensible.  Written test specifications include suturing and IVs
Advance to Clinical Rotations	Completion of a minimum of 1350 Clinical Hours Clinical hours include prenatal exams, attending births, newborn exams, postpartum exams, and suturing, under direct supervision by a qualified preceptor. Proof of competency in all areas required for application to sit for NARM exam.  This is the only program that requires clinical experience in out-of-hospital settings.  Includes clinical training in suturing and IVs
Attend Midwifery School/Training <sup>1</sup>	3 – 5 Years of Didactic Study & Skills Training Anatomy & Physiology Physical Exam & Assessment Normal Labor & Birth Normal Labor & Birth Normal Newborn Breastfeeding Labs & Pharmacology Nutrition & Therapeutic Supplementation Counseling & Women's Mental Health Prenatal Complications of Labor & Birth Complications of Labor & Birth Complications of the Newborn Well Woman Care Professional Issues: Informed Choice, Charting, Ethics, Research, Cultural Competency Skills Practice Includes skills training in suturing and IVs

I Recognized by the U.S. Department of Education as a national accrediting agency for direct-entry midwifery education, the Midwifery Education Accreditation Council accredits ten programs/institutions, including four with a distance education option that allows students to combine local clinical preceptorships with their didactic studies. Three are degree-granting institutions offering entry-level and/or advanced degrees in midwifery.

#### Midwifery Integration

Increased access to and greater integration of midwives is associated with improved outcomes for families across birth settings.

In February 2018, "Mapping integration of midwives across the United States: Impact on access, equity, and outcomes", was published.<sup>1</sup> The report brought together experts using a formal decision making process, to develop a scoring system: the Midwifery Integration State Scoring (MISS) system. Each state is given a score out of a maximum of 100, they range from lowest at 17 (North Carolina) to highest at 61 (Washington). Colorado is in the middle, ranking 21st, with a score of 41.

How the CPM is regulated in Colorado contributed to the lower the score: Colorado CPMs are not yet covered by Medicaid, are not yet authorized to write prescriptions, don't yet have easy access to physical referrals, and are still restricted in their site of practice.

Improving midwifery integration in Colorado will improve outcomes for Colorado families: better rates of spontaneous vaginal delivery, vaginal birth after cesarean, and breastfeeding, as well as lower rates of: cesarean, premature birth, low birth weight infants, and neonatal death. Better integration of midwives can also counteract the impact of racism on disparate health outcomes.

All of the analysis and recommendations we make in this report are aimed at improving integration of midwifery in Colorado.

We are including the Colorado report card and a short summary of the study.

<sup>&</sup>lt;sup>1</sup> Vedam S, Stoll K, MacDorman M, Declercq E, Cramer R, et al. (2018) Mapping integration of midwives across the United States: Impact on access, equity, and outcomes. PLOS ONE 13(2): e0192523. <a href="https://doi.org/10.1371/journal.pone.0192523">https://doi.org/10.1371/journal.pone.0192523</a>



# Mapping integration of midwives across the United States: Impact on access, equity, and outcomes

Authors: Vedam, S. Stoll, K. MacDorman M, Declercq E, Cramer R, Cheyney M, Fisher T, Butt E, Yang T, Kennedy H.

We know that when there is a lack of coordination between care providers and across birth settings, and when women have trouble accessing care that mothers and babies have poorer health outcomes. This paper reviews state laws and incorporates information from state experts to describe the current maternity care system and options for care in each of the 50 states.

By gathering experts and using a formal decision making process, our team selected items to develop a scoring system: the Midwifery Integration State Scoring (MISS) system. Each state is given a score out of a maximum of 100, they range from lowest at 17 (North Carolina) to highest at 61 (Washington).

Higher scores are linked to higher rates of better outcomes for mothers and babies, including: spontaneous vaginal delivery, vaginal birth after cesarean, and breastfeeding, as well as lower rates of: cesarean, premature birth, low birth weight infants, and neonatal death.

States with more midwives per person and with access to care across birth settings also had higher MISS scores. The results in this paper also show that race is linked to newborn health outcomes by state, but higher levels of midwifery integration were linked to lower neonatal mortality, even after accounting for the proportion of black births in each state.

The research team has developed maps and accompanying State Report Cards that demonstrate the differences in available maternity care options and outcomes across the United States.

Click here to learn more about your state, or visit: www.birthplacelab.org/how-does-your-state-rank/

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UNIVERSITY OF BRITISH COLUMBIA
UBC MIDWIFERY, BC WOMEN'S HOSPITAL
SHAUGHNESSY BUILDING E416
4500 OAK STREET, VANCOUVER, BC, V6H 3N1 CANADA

#### Midwifery Integration State Scoring (MISS) System Report Card

#### Colorado

State Rank: #21 Integration Score: 41/100

41 out of a possible 100

Place of birth more than 97% hospital 1.6% home 0.5% birth center Certified Certified **Births Professional** Nurse Certified Midwife Midwife Midwife attended by midwives Licensed Colorado U.S. Average to practice Covered by Medicaid 10.3% Authorized to write prescriptions Easy access to physician referral No restrictions to site of practice CPM includes Direct Entry Midwives where applicable

Outcome Colorado US average		Outcome	Colorado	US average	
Cesarean	25.6%	32.2%	Spontaneous vaginal birth	57.4%	49.2%
Induction	20.3%	23.2%	VBAC	22.0%	11.3%
040		Breastfeeding at birth	92.5%	80.3%	
Low birth weight	8.8%	8.0%	Breastfeeding at six months **	30.3%	24.9%
Neonatal mortality *	3.7/1000	4.0/1000			



#### History

We are providing several documents related to the history of midwifery relevant to its current regulation in Colorado:

- A chart of the legislative history through 2010
- An overview of the changes made to the law in 2011
- A one-page overview of the history (in the form of a handout used during the 2011 Sunset process)
- A history of direct-entry midwifery in Colorado written in 2010 by Elephant Circle Director, Indra Lusero
- A 2000 Position Paper from the American Public Health Association
- A map of State Trends in licensure of Certified Professional Midwives

#### Legislative History Related to Direct-Entry Midwifery

	Description	Bill number	Process
1908	Midwifery treated as a profession considered a community service		
1915	New laws regulate the practice of midwifery – midwifery included in the definition of the practice of medicine		
1917	Board of Medical Examiners (BME) issues licenses to midwives		
1941	Law ends BME licenses to midwives with explicit goal of ending midwifery	SB640	
1976	Sunset law	24-34-104	
1976	no additional midwives were to be licensed by the board of medical examiners after 1941, and deletes references pertaining to such licensure.6 In four different parts of the law "to practice medicine, podiatry or midwifery" - crossed out midwifery	H.B. 1032  "A Bill for an Act Eliminating Licensing Requirements for Midwives"	Reading on 1-19-76 in the house - 0 no votes
1977	12-36-106(3) (medical practice act) amended to legalize nurse midwives (practicing under doctor supervision)	H.B. 1526	
1979	Colorado Midwives Alliance formed		
1982	Karen Cheney charged with practicing medicine without a license.		Threatened with a grand jury investigation, told she would have to reveal names and addresses of all practicing midwives she knew.  Eventually, sympathetic DA dropped criminal charges – but she had a permanent injunction and left the state.

1983	"Concerning Midwifery" that midwifery is not the practice of medicine, that parents have the right to decide where, how, and with whom they give birth, and that midwifery shall be regulated by an Advisory Board under the Colorado Department of Health.	НВ 1528	Health and safety arguments on both sides. Pro: home birth is here to stay, risk of underground. Con: home never as safe as hospital always too risky. After two hours of debate a CNM proposed an amendment: to make midwives work under MD supervision. The bill passed 5-4, but the amendment killed the bill because it was unacceptable to the midwives.
1984	"concerning midwifery"	H.B. 3147	CMA did more work negotiating on the development of the bill in advance. Met with the nurses association, CNMs, and the Medical Assn's OB committee. The concerns: unsavory people, educational req. and physician supervision. After 7 hours of debate in committee it was indefinitely postponed. The rep who brought the bill was shocked - she didn't even get support of her party – she blamed heavy lobbying my the medical community.
1985	Sunrise Law	24-34-104.1	the incurcui community.
1985	Licensure under State Board of Nursing – board to create educational, training and exam requirements and disciplinary powers. Also an advisory committee	HB85-1338	Defeated in the House
1990	Litigation People v Rosburg Defendants: Jean Rosburg, Barbara Parker		
1992	Decriminalized and created a registry and disclosure requirements.	HB92-1010	Amended extensively during second reading to include an exam or similar competency

	Also People v Rosburg decided by the Supreme Court16		and giving DORA disciplinary powers, and making a birth cert requirement Passed House, defeated in Senate. Three readings in the House: 1-8-92, 2-3-92, 2-25-92 – passed. One reading in senate: 2-26-92  June 1992 Notes that registry of midwives conflicts with
1992	DORA Report		the regulatory scheme, would be a departure, would be hard Even unconstitutional. Recommends against it.
1993	This time application for a registry not licensing. Created the registration program within DORA – mandating education, training, exam and disciplinary provisions to be created by DORA.	НВ93-1051	Passed by the legislature in 1993 with considerable amendments.  Three readings in the house: 1-13-92, 4-19-93, (passed second reading 4-22-93), 4-23-93,(passed third reading 4-26-93, Senate readings: 4-27, 5-11, 5-12
1995	DORA report		DORA now acts like regulating midwives is no big deal – treats the practice as a profession, makes lots of recommendations to that end. Many of them are included in the law. Grounds for discipline, governmental immunity, confidentiality of records, denial of registration, waiting period for reinstatement, subpoena powers, ad law judges, training and education many are not: registration for apprentice midwives, emergency drugs, dual licensure (kind of)
1996	Bill to continue the program with modifications including clarifying prohibited acts and	SB96-49	Extensively amended. Some elements passed, dual licensure only for

	disciplinary options, grant subpeona powers, allow for denial of applicants, make investigations confidential, require a 2 year waiting period after revocation, grant governmental immunity, dual licensure and certain prescriptive authorities.		acupuncturists, oxygen allowed, data collection, gave program director authority to create education and training standards, also required medical malpractice insurance when available. Senate readings: 1-10, 2-15, 2-19 House: 3-18, 3-22, 3-25
2000	DORA report		Same as before, now fully in line with regulation, makes lots of recommendations, as before. Many not included in the law. Change registry to license increase education meds and suturing dual licensure remove lame section 109 technical updating
2001		SB01-118	Introduced in Senate Committee – amended, passed committee, amended passed on third reading by whole, introduced in house committee, amended, passed committee, passed on third reading by whole. Senate consideration of house amendments: laid over three times, not concur, sent to committee that made amendments. Sent to House w Senate committee amendments, house committee passed. Everyone signed.
2010	DORA		Same as before. Makes many recommendations: dual licensure, Rhogam, Vit K, antihemmorhagics.



#### 2011 Colorao Direct Entry Midwives Sunset Review Senate Bill 088 Overview

This bill passed both chambers with only two NO votes on 5/11/2011.

The law that regulates "direct entry" midwives in Colorado is part of Title 12 in the Colorado Statutes. Title 12 is called "Professions and Occupations." There is a "general" and "health care" component to Title 12. Direct entry midwives (DEMs), are in the Health Care section at Article 37. There are ten sections to the law regulating direct entry midwives in Colorado. The following chart illustrates the sections and denotes what changes Senate Bill 88 brought to each section. <sup>1</sup>

12-37-101 "Scope of Article"	The prohibition on being simultaneously licensed as a nurse and registered as a direct entry midwife has been eliminated. Doctors and Nurse-Midwives are still prohibited from being dually licensed, but nurses can also register as DEMs. The new law contains clarifying language that asserts that a DEM who is also a nurse cannot call themselves a nurse-midwife, and that their scope of practices are not expanded.
12-37-102 "Definitions"	A definition for "client" was added. A definition for "division" was added (referring to DORA). And the definition of "natural childbirth" was changed to reflect the new right to obtain and administer drugs.
12-37-103 "Requirements for Registration"	The section that prohibits reciprocity – meaning that being a licensed midwife in one state does not mean you are automatically a registered midwife in Colorado – was moved here.
12-37-104 "Mandatory Disclosure of Information"	Adding to the disclosures required at initial client contact: whether or not the midwife will administer vitimin K and Rhogam. If not, the midwife must provide a list of providers who will.
12-37-105 "Prohibited Acts – Practice Standards"	An exception to the prohibition on use of drugs is added – creating a 105.5 where the new drug scope of practice is delineated. The informed consent form must now include a statement confirming that the client knows they are not retaining a CNM. Midwives must now refer their newborns "to a licensed health care provider with expertise in pediatric care" within 7 days of birth. Cause of death and description of circumstances must be sent to DORA when perinatal deaths are reported.
	The new section 105.5 protects pharmacists from liability, delineates where midwives may obtain drugs, and allows

This chart reflect the final bill as passed by both chambers after the final conference committee. Minor grammatical and word-choice changes were made throughout. You can find the final bill and bill history here: http://www.leg.state.co.us/CLICS/CLICS2011A/csl.nsf/MainBills?openFrameset type in 088 to locate this bill. You can find information about amendments considered here: http://elephantcircle.net/?p=142

12-37-106 "Director"	them to obtain and administer Vitamin K, Rhogam, antihemorrhagic drugs, and eye prohylaxis. Documentation of informed refusal of Vitamin K and Rhogam is required. Immediate transport "in accordance with the emergency plan" is required when a client refuses antihemorrhagics. The emergency plan now needs to include a statement that uncontrollable postpartum hemorrhage requires midwives to initiate emergency medical treatment "which may include" antihemorrhagic drugs while initiating immediate transportation in accordance with the emergency plan. The emergency plan also need to note that the midwife can administer IVs if she experiences postpartum hemorrhage. This section also gives the director power to implement rules related to these provisions, including an IV course approved by the director, and a preferred drug list.  There is also a temporary section here that states that stakeholders will come together to reach an "accord" regarding suturing.  Allows the director to suspend a registration for failure to
12-37-107 "Disciplinary Action"	comply with an order of the director.  Gives the director the power to create a fine structure, and adds failure to respond in a material and timely manner and failure to comply with an order as grounds for discipline.
12-37-108 "Unauthorized Practice"	No changes.
12-37-109 "Assumption of Rick – No Vicarious Liability"	Three paragraphs were removed from this section eliminating: the legislative declaration that did not endorse midwifery, the exclusion of midwives from the liability cap on damages, and the exclusion of midwives from reimbursement by health insurers. This section also adds a provision encouraging doctors to accept referrals from midwives.
12-37-110 "Repeal of Article"	This section determines when the bill sunsets. The next sunset will be in five years, with the current law set to expire on 9/1/2016.



#### Historical Context of the Colorado Direct-Entry Midwifery Law<sup>1</sup>

pre-1900	1900	1915	1941	1976	1977	1993
Midwives attended most births	In the U.S. midwives attended 50% of births and doctors attended 50%	The Colorado Board of Medical Examiners started licensing midwives	The CO legislature stopped issuing new licenses to midwives. <sup>2</sup>	The CO legislature eliminated all references to midwifery licensure from the Medical Practice Act	The law that regulates Certified Nurse Midwives was enacted	The law that regulates Direct-Entry Midwives was enacted

#### Despite the history of midwifery that precedes medicine, midwifery is defined in relationship to medicine.

The Practice of Medicine includes midwifery, "§ 12-36-106 (1) For the purpose of this article, "practice of medicine" means: (f) The practice of midwifery. . ."So that medicine is the broadly defined health profession, midwifery is the narrowly defined profession.

Birth is a normal, spontaneous process that is physical, emotional, psychosocial, and spiritual, but the midwifery law defines natural birth as "the birth of a child without the use of prescription drugs, instruments, or surgical procedures" in order to set it aside from the practice of medicine (§ 12-37-102(4)).

Defining midwifery in relationship to medicine is not necessarily what is best for families, nor is it the only way to define the scope of this profession.

We can and should change regulatory systems that no longer meet our needs nor adequately define our reality.<sup>4</sup>

<sup>1</sup> Developed by Indra Lusero, J.D.

<sup>2</sup> Despite evidence that maternal and infant outcomes were better with midwives. See, for example, the White House Conference on Child Health and Protection from 1925 and 1932, referenced in Judith Pence Rooks, Midwifery and Childberth in America, 28-31 (Temple University Press 1997).

<sup>3</sup> MANA Core Competencies available at: http://mana.org/manacore.html

<sup>4</sup> See Carol Sakala and Maureen Corry, Evidence-Based Maternity Care: What It Is and What It Can Achieve. (Milbank Memorial Fund 2008) available at <a href="http://www.childbirthconnection.org/pdfs/evidence-based-maternity-care.pdf">http://www.childbirthconnection.org/pdfs/evidence-based-maternity-care.pdf</a>.

lusero.indra@gmail.com

#### How Medicine and the Law (Almost) Killed Natural Birth in Colorado And What To Do About It

by Indra Lusero November 2010

#### I. Introduction

It's a dramatic title to be sure. People prefer to think of medicine and the law as protective not destructive, and no one likes to see birth and death in the same sentence. But the reality is that birth and death are too often partners either by accident, negligence, or design. In this case, medicine and the law have had a deliberately destructive impact. Destructive enough that medicine and the law almost killed natural birth. Natural birth, for the purposes of this paper, is the socially and legally recognized fact that birth is a normal physiological process that happens spontaneously and effectively. This paper focuses on Colorado, but the same general history could be told across the country. Medicine, not the science of it, and not the care providers so much as medicine the "hegemonic discourse - that it is laden with value choices and beliefs that masquerade as truth, nature, and biological 'fact,'" in collusion with the law set out to redefine birth as a medical event in order to establish itself as the preeminent profession over birth and scientific truth.

By charting the course of this effort in Colorado, from the times that indigenous tribes gave birth to the days of State making and into the modern era, it becomes clear that before truth, nature or biological facts were clearly known about birth, medicine set out to replace midwifery. As a result, the idea of birth as a normal physiological process that happens spontaneously and effectively was legally replaced with the idea of birth as a medical event. This "fact" was written into the law regulating, eliminating, and eventually re-regulating midwifery. It is a major misperception that childbirth is medicalized because that's what happened naturally as part of our evolution as humans. It wasn't "natural," it came out of a specific kind of process which I delineate in the "How Medicine and the Law Almost Killed Natural Birth" section below.

The chronological history is told in four parts: A) Childbirth Improved Medicine (and Not the Other Way Around), B) Funneling Birth into the Hospital and Creating a Monopoly of Ideas, C) Eliminating Families and The Legal Death of Natural Childbirth, and D) Legal Again: Risk and Regulation. Part A explains the history of childbirth and midwifery before Colorado became a state through to the turn of the 20<sup>th</sup> century. Part B describes what happened in the middle decades of the century until midwifery was legally eliminated in 1976. Part C describes the organizing efforts of midwives in the 80's and 90's and how a Colorado Supreme Court case declared natural birth legally dead. And finally, part D describes how midwifery was again legalized but how the conflict between medicine and natural birth was written into the law.

The "What to Do About It" section explains why professionalization of midwifery is

<sup>1</sup> Nancy Ehrenreich, Colonization of the Womb, 43 DUKE L.J. 492, at 509 (1993).

necessary to resuscitate natural birth in Colorado, and by examining the current state of things, several strategies for change emerge. That section ends with a detailed description of how to change the current midwifery law in the short and long terms. But the underlying assumption, which is suggested but not explored throughout, is that natural birth matters. There are many books, articles, movies and websites that explore natural birth, and it is important to consider the benefits of natural birth, and to compare the relative safety of natural birth to medical birth.<sup>2</sup>

This section from "Evidence Based Maternity Care: What It Is and What It Can Achieve" captures the essence of the evidence supporting natural birth:

Although most childbearing women and newborns in the Unites States are healthy and at low risk for complications, national surveys reveal that essentially all women who give birth in U.S. hospitals experience high rates of interventions with risks of adverse effects. Optimal care avoids when possible interventions with increased risk for harm. This can be accomplished by supporting physiologic childbirth and the innate, hormonally driven process that developed through human evolution to facilitate the period from the onset of labor through birth of the baby, the establishment of breastfeeding, and the development of attachment. With appropriate support and protection from interference, for example, laboring women can experience high levels of the endogenous painrelieving opiate beta-endorphin and of endogenous oxytocin, which facilitates labor progress, initiates a pushing reflex, inhibits postpartum hemorrhage, and confers loving feelings. . . Such physiologic care is also much less costly. . . Burgeoning research on the developmental origins of health and disease clarifies that some early environmental and medical exposures are associated with adverse effects in childhood and in adulthood.3

For those new to this subject, simply consider the possibility that natural birth is healthy, safe and good and there is scientific evidence to support that. But for the purposes of this paper

<sup>2</sup> Judith Pence Rooks, Midwifery and Childbirth in America, 25 (Temple University Press 1997); Marsden Wagner, Born in the USA: How a Broken Maternity System Must Be Fixed to Put Women and Children First, University of California Press (2008); Michel Odent, Birth and Breastfeeding: Rediscovering the Needs of Women During Pregnancy and Childbirth, Rudolph Steiner Press (2008); Carol Sakala and Maureen Corry, Evidence-Based Maternity Care: What It Is and What It Can Achieve. (Milbank Memorial Fund 2008); Rickie Solinger, A Short History of Reproductive Politics in America, New York University Press (2005); Katherine A. Taylor, Compelling Pregnancy at Death's Door, 7 Columbia J. of Gender and L. 85 (1997); Joyce Martin et. al. Births: Final Data for 2006, 57 National Vital Statistics Report 7, 16 (2009); Marian McDorman et. al., Trends and Characteristics of Home and Other Out-of-Hospital Births in the United States, 1990-2006, 58 National Vital Statistics Report 11 (2010); Deadly Delivery: The Maternal Health Care Crisis in the USA: Summary, Amnesty International (2010); American Public Health Association, Increasing Access to Out-of-Hospital Maternity Care Services through State-Regulated and Nationally-Certified Direct-Entry Midwives, January 1, 2001, <a href="http://www.apha.org/advocacy/policy/policysearch/default.htm?id=242">http://www.apha.org/advocacy/policy/policysearch/default.htm?id=242</a>; Citizens for Midwifery, Out-of-Hospital Maternity Care: Much Lower Rates of Cesarean Sections for Low Risk Women, May 11, 2010, <a href="http://cfmidwifery.org/Resources/Item.aspx?ID=99">http://cfmidwifery.org/Resources/Item.aspx?ID=99</a>.

<sup>3</sup> SAKALA AND CORRY *supra* note 2, at 4.

natural birth as a legally accepted concept (that birth is a normal physiological process that happens spontaneously and effectively) is important regardless of this evidence about health and safety because it protects the autonomy and dignity of parents and families. Without this legal concept, the bodies of women, infants and families are too easily swept under the control of the state to the physical and civil rights detriment of all.

#### II. How Medicine and the Law (Almost) Killed Natural Birth in Colorado

A. Childbirth Improved Medicine (and Not the Other Way Around)

Before Colorado was a state it was inhabited for centuries by indigenous people from tribes known as the Utes, Arapahoe, Kiowa, Cheyenne, Pawnee, Shoshone, and Aztec, eventually joined by Spanish settlers and finally other settlers of various races and ethnicities coming from the Eastern United States. Until the mid-19th Century childbirth was something that individual communities developed provisions for based on their cultural norms. I like to imagine my great grandparents, who were born in the 1870's near what is now Gardner, Colorado in Huerfano County. Even today there isn't a hospital for miles, and the arid and rocky terrain makes travel difficult. Though I don't know the details of how they were born or what the community of Spanish sheepherding families understood good maternity care to look like, they were certainly born at home without medical intervention. By the mid 1800's there were probably about 20-30,000 people in the region that is now Colorado and a number of them were regularly giving birth. This history is the backdrop for how medicine and the law (almost) killed natural birth in Colorado and it's a humbling reminder of our innate human capacity to reproduce.

The 1860's mark the beginning of this story since state-building and medicine both started around that time. There were about twenty physicians in Colorado mid-century and in 1860, one year before the territory of Colorado was formed, they started a medical society. The development of state infrastructure and the development of the medical infrastructure went hand in hand. In 1871 the Colorado Territorial Medical Society was formed and in 1876 Colorado became a state. The next 25-40 years were full of infrastructure building and growth on all fronts. In 1881 and 1883 the University of Denver and the University of Colorado, respectively, started medical schools. At the same time, the state began regulating the practice of medicine

<sup>4</sup> See generally, Katherine Lee Craig, Craig's Brief History of Colorado, Welch-Haffner Press (1923).

<sup>5</sup> See generally, Judy Barrett Litoff, The American Midwife Debate: A Sourcebook on its Modern Origins, Greenwood Press (1986)

<sup>6</sup> US Census Bureau, *Urban and Rural Population: 1900-1990* (Oct. 1995), <a href="http://www.census.gov/population/censusdata/urpop0090.txt">http://www.census.gov/population/censusdata/urpop0090.txt</a> (last visited Nov. 29, 2010). The area that is now Colorado was indigenous, French, Spanish, and Texan before it became a U.S. territory in 1861, so population data is hard to come by. I am estimating based on data from the 1860's and beyond done by the federal census.

<sup>7</sup> History of Colorado 1048 (Wilbur Fiske Stone, ed. Chicago: S.J. Clarke 1918-1919). See also Colorado Department of Personnel and Administration, Colorado State Archives: Colorado History Chronology <a href="http://www.colorado.gov/dpa/doit/archives/history/histchron.htm">http://www.colorado.gov/dpa/doit/archives/history/histchron.htm</a> (last visited Nov. 29, 2010).

<sup>8</sup> History of Colorado *supra* note 6 at 1050-51. Also note that the medical society excluded women for the first ten years, *see* Kimberly Jensen, *The Open Way of Opportunity*, 27 The Western Historical Quarterly 327 (1996). *See also, Colorado History Chronology, supra* note 6.

<sup>9</sup> HISTORY OF COLORADO *supra* note 6 at 1069.

through a licensing system.<sup>10</sup> In 1894 Colorado became the second state in the nation to grant suffrage to women (following Wyoming) and in 1897 the legal infrastructure expanded as the Colorado State Bar Association began.<sup>11</sup> At one point there were four medical schools in Denver, evidence of the explosion in medical training that put more medical schools in the United States than anywhere in the world.<sup>12</sup>

But this growth in medical training was more about the development of profession, a class of people, and a set of ideals than an increase in knowledge or experience, especially when it came to childbirth. By the turn of the century more and more physicians were attending women in labor (mostly at home as the infrastructure of hospitals were not designed to accommodate birth), but "as late as 1910, many medical school graduates began the practice of medicine having witnessed few or no births." Given this, it is surprising but important to note that midwives were only attending 50% of births at the time. If so few physicians were knowledgeable about birth, decisions about quality were likely not to blame for this change in care providers. In fact, "Several early twentieth-century studies revealed that maternal mortality rates were lowest in those localities reporting highest percentages of midwife-attended births." There were many variables contributing to this change in the culture of birth, and no one determining force, but quality of care was not a strong determinant.

The culture of birth, like the culture in general, was in a state of flux. During the first decade of the 20<sup>th</sup> century, Colorado saw its population grow from 539,000 to almost 800,000. <sup>16</sup> The mining industry that helped develop the State started doing battle with unions and dramatic conflicts ensued, culminating in substantial loss of life and the use of federal troops. <sup>17</sup> It had only been about twenty years since the Ute Indians were removed to reservations in Colorado, there were 46,000 farms operating, and the balance of urban and rural populations were shifting. <sup>18</sup> While women in Colorado could vote, suffrage was being debated on the federal level and women were still excluded from full citizenship in many ways. Women accounted for about seven percent of the physicians in Colorado (above the national average) <sup>19</sup> while the vast majority of midwives were women; the participation of women in medicine was suspect while their participation in midwifery was assumed. In the first decade of the century midwifery was treated as a profession and considered a community service but it presented a problem; not so much to the health of the community, but to the prestige of the medical profession. <sup>20</sup>

<sup>10</sup> Note that the licensing system required an "objective professional standard" and as a result, the medical society could no longer bar women from participation. *See* Jensen *supra* note 7, at 337-338.

<sup>11</sup> Colorado History Chronology, supra note 6, and Christopher R Brauchli, The Colorado Bar Association: A Brief History, 26 The Colorado Lawyer 1 (1997).

<sup>12</sup> HISTORY OF COLORADO *supra* note 6 at 1072.

<sup>13</sup> Litoff *supra* note 5, at 5.

<sup>14</sup> *Id*.

<sup>15</sup> *Id*.

<sup>16</sup> US CENSUS BUREAU supra note 5.

<sup>17</sup> See generally CRAIG supra note 3.

<sup>18</sup> Colorado History Chronology, supra note 6.

<sup>19</sup> Jensen supra note 7, at 336.

<sup>20</sup> Patricia G. Tjaden, *Midwifery in Colorado: A Case Study of the Politics of Professionalization*, 10 QUALITATIVE SOCIOLOGY 32 (1987).

In 1912 one of the leading obstetricians of the 20<sup>th</sup> century, J. Whitridge Williams, published an article called "Medical Education and the Midwife Problem in the United States," explaining why and how he sought to improve medical training and the status of obstetrics, which at the time was the least appreciated branch of medicine. Women midwives undermined the status of obstetrics because they were women, and because their role in childbirth was so pervasive it was hard to conceive of a man engaging with it, much less setting the terms. This is what led Dr. Williams to complain that "the obstetrician should not be merely a man-midwife," and to develop the profession of obstetrics as distinct from the womanly art of midwifery. Other commentators echoed this sentiment by arguing that "as long as women untrained in the medical sciences continued to attend one half of all births, the obstetrician would never receive his due recognition." Obstetrics was a developing profession highly motivated to distinguish itself. Midwifery, on the other hand was familiar, part of the domestic economy, and practiced by diverse and disconnected women without a network or professional organization. In this environment the regulatory scheme that almost killed natural birth was born.

After years of unregulated practice, in 1915 the midwives of Colorado had to take a test and apply for a license issued by the Board of Medical Examiners.<sup>24</sup> In a bold move by the legislature and the medical profession, instead of creating separate licensing laws, one for midwives, and one for doctors, midwifery was subsumed by medicine.<sup>25</sup> In the act defining the boundaries of the medical profession, medicine became the broad overarching umbrella term for all kinds of healing arts, and midwifery fell *under* it, as it does today<sup>26</sup>. The law was also careful to ensure that midwives were prohibited from using the drugs and instruments that doctors used to distinguish themselves, and that consumers began to equate with progress and modernization.

In terms of public health and the state of science at the time, medicine was not the superior form of maternity care and midwifery did not merely inform it, though that's what the legal framework implied. It was also clear from the obstetricians of the day that midwifery was not regarded as the practice of medicine. This licensing scheme was the first in a series of legal maneuvers used to bring midwifery under the control of medicine. At this moment in history doctors were not the experts in childbirth, nor were they champions of women's rights and autonomy. This licensing scheme was a strategic decision undertaken to advance obstetrics and not necessarily to advance women's health and family's lives. By the 1920's childbirth was helping to improve medicine, but medicine was not improving childbirth.<sup>27</sup>

<sup>21</sup> Litoff supra note 5, at 5-7.

<sup>22</sup> Litoff *supra* note 5, at 5.

<sup>23</sup> See generally Litoff supra note 5. Some midwives still bartered for compensation, obstetricians blamed midwives for making it hard for them to make high fees. However, some immigrant women trained in the more established midwifery tradition in Europe were well paid and well respected in their communities. Midwives were also blamed for threating poor women who might otherwise provide "clinical material" for medical students.

<sup>24</sup> I actually have two dates for this, Tjaden *supra* note 19 gives 1915 and Colorado Dept. of Regulatory Agencies, Colorado Midwives Registration Program: 2000 Sunset Review (2000) gives 1917.

<sup>25</sup> Tiaden supra note 19, at 32.

<sup>26</sup> Colo. Rev. Stat. § 12-36-106. "(1) For the purpose of this article the 'practice of medicine' means:... (f) The practice of midwifery..." this part is now followed with exceptions for midwives and nurse midwives.

<sup>27</sup> For emphasis, consider the impact of childbirth on medicine today: one fourth of the annual cost of all health

#### B. Funneling Birth into the Hospital and Creating a Monopoly of Ideas

At the turn of the century, and into the 1920's maternity care was a contested field where doctors were making headway into territory previously held by midwives. Neither doctors nor midwives could entirely remove the pain of childbirth, nor the risks of death and injury that both mothers and babies faced. Though they each had their strategies, some of them overlapping, neither had the clear upper hand. Doctors used drugs to help reduce pain and forceps for manual delivery when the baby was stuck. Midwives continued to trust the natural process of birth and did things to facilitate it, like providing nourishment, encouragement, and gravity. Before the impact of these different approaches was fully understood, and without scientific support for a new mode of childbirth, doctors undertook a concerted effort to eliminate midwifery. The effort to eliminate midwifery helped create a monopoly that impacted the marketplace of ideas in much the same way that a monopoly impacts the marketplace of goods: prices increase, quality decreases, and there are less producers.

But the effort to eliminate midwifery was only one of the forces contributing to this childbirth cartel; in the period between the 1920's and the 1950's multiple forces created sufficient power to exclude other actors and ideas from the childbirth "marketplace." These forces included social and political upheaval, hospitals, transportation, and the science of medicine, and all of them warrant a deeper analysis than I provide. My goal is to sketch out some of the forces contributing to this transformation in the culture of childbirth, with particular attention to the ways the law was complicit.

The social and political context of the 1920's through the 1950's is significant: By 1940 the urban-rural balance in Colorado tipped so that fifty-two percent of the State's population of over one million, lived in cities and forty-seven percent were rural. World War I and the Great Depression were over, and World War II was about to begin.

1935 was the first year that statistics of home versus hospital births were kept and the national rate of hospital births that year was 36.9%.<sup>28</sup> In 1946 the Hill-Burton Act provided federal funds for hospital development and provisions for medical care of the poor.<sup>29</sup> It is one of the major legal forces contributing to the transformation in childbirth. The shift from home to hospital that took place in this era is what gives rise to the present-day terms "homebirth" and "homebirth midwife." Earlier in the century this would have been a meaningless distinction since most births were at home regardless of the care provider. Even in the 1940s those terms would not have made much sense with only 44% of births taking place in the hospital, but by 1955 the rate was 99%.<sup>30</sup>

Transportation to those hospitals was a challenge for many (and still is for some in the U.S. today, and for many people worldwide). Investment in roads had been in the works for years and federal attention increased in this era. It not only provided money but also captured the

care is related to maternity care. Childbirth is a billion dollar a year industry. See Sakala and Corry supra note 2, at 10-11.

<sup>28</sup> Litoff supra note 5, at 12.

<sup>29</sup> Harry Perlstadt, *The Development of the Hill-Burton Legislation: Interests, Issues and Compromises*, 6 Journal of Health and Social Policy 77 (1995).

<sup>30</sup> McDorman supra note 2.

imagination of people who started thinking and planning more for transportation by car. <sup>31</sup> The interstate system started building momentum with the 1938 Federal Highway Act, but it wasn't just about rural access, planning for roads also impacted urban development. "In this setting, the proposed interregional highway system looms as perhaps the most plausible solution to the transportation deficiencies of the modern urban area. If the cities so determine, the interregional highway system can provide an unparalleled opportunity for rebuilding along functional lines, following rational master plans." <sup>32</sup> This development grew even during the wartime years of the 1940's and culminated in 1956 with the Federal Highway Act. As Colorado's population shifted from rural to urban and it's population grew, the development of roads coincided with the development of hospitals and both contributed to the transformation in the culture of childbirth.

The final factor is what I call the science of medicine, I call it this to distinguish between the profession of medicine and it's scientific basis because the two have not developed in tandem.<sup>33</sup> One example of this, particularly important to childbirth, is the discovery in 1847 that simple hand washing could dramatically reduce the rates of childbed fever, a disease that was particularly prevalent among women who gave birth in hospitals.<sup>34</sup> Unfortunately, this discovery was disregarded by the medical profession for many years and didn't become accepted until after Louis Pasteur developed the germ theory twenty years or so later.<sup>35</sup> Germ theory paved the way for another critical development in the science of medicine, antibiotics. These reached widespread use in the 1940's just as birth in the United States and Colorado was moving out of the home and into the hospital.<sup>36</sup> But the forces that directed childbirth into the hospital had begun long before.

Maternal and infant mortality rates did improve during this time, not so much because of obstetric management but because of the antibiotic revolution, the use of blood and blood substitutes, and things like improved nutrition and antiseptic procedures.<sup>37</sup> Obstetric

<sup>31</sup> See generally Lee Mertz, Origins of the Interstate, U.S. Department of Transportation Federal Highway Administration, Federal Highway Administration (modified Sept. 15, 2009) <a href="http://www.fhwa.dot.gov/infrastructure/origin.htm">http://www.fhwa.dot.gov/infrastructure/origin.htm</a> (last visited Nov. 29, 2010).

<sup>32</sup> See Mertz supra note 31, quoting an address from 1944 to the American Society of Civil Engineers.

<sup>33</sup> Note, that the development of pain reduction drugs is not included here as part of the development in the science of medicine – although it is another great example of how the medicine and the science develop disproportionately. Pain during childbirth was not then, and remains, not well understood. Despite this, and partly due to the urgings of some feminists who envisioned liberation from the pain of birth, "Twilight Sleep" became a common childbirth drug. It was a combination of morphine and scopolamine that reduced consciousness and increased memory loss. It also loosened inhibitions, so women ended up being strapped to gurneys for hours, laboring alone. It alone could be a paper, and in fact, Edith Wharton wrote a novel in 1927 called Twilight Sleep. See Tina Cassidy, Taking Great Pains: An Abridged History of Pain Relief in Childbirth, <a href="http://wondertime.go.com/learning/article/childbirth-pain-relief.html">http://wondertime.go.com/learning/article/childbirth-pain-relief.html</a> (last visited Nov. 29, 2010).

<sup>34</sup> Semmelweis Society International, Dr. Semmelweis' Biography, <a href="http://semmelweis.org/about/dr-semmelweis-biography/">http://semmelweis.org/about/dr-semmelweis-biography/</a> (last visited Nov. 29. 2010) (childbed or puerperal fever was transmitted by doctors who worked on cadavers prior to attending women in labor).

<sup>35</sup> Id. Dr. Semmelweis was ignored, rejected and ridiculed, and died in a mental institution.

<sup>36</sup> Margaret C. Fisher, *The History of Antibiotics, Immunizations and Infectious Diseases: An Informed Parents Guide*, American Academy of Pediatrics, 2006. <a href="http://www.healthychildren.org/English/health-issues/conditions/treatments/pages/The-History-of-Antibiotics.aspx">http://www.healthychildren.org/English/health-issues/conditions/treatments/pages/The-History-of-Antibiotics.aspx</a> (last visited Nov. 29. 2010).

<sup>37</sup> Litoff supra note 5, at 13. Post-partum bleeding remains one of the leading causes of maternal mortality in the

management of birth and these scientific advances are two separate things but they overlap in such a way as to support the pervasive idea that childbirth is not safe unless it is medically supervised. Whether or not birth is medically supervised women can bleed to death. Medical supervision doesn't change that fact. And the fact that women can benefit from blood products and antibiotics in pregnancy and birth remains true whether or not midwives attend them at home or doctors attend them in the hospital. Part of what happened during this era was the monopolization of ideas about childbirth. In an open marketplace of ideas these new scientific discoveries could be evaluated along with a wide range of observations, practices, lived experiences, cultures and belief systems in order to solve problems. It's the difference between problem solving to make scientific advances accessible to the masses versus problem solving to make scientific advances accessible only to one class of people who can then control the access of everyone else.

All of these factors were at play in Colorado when in 1941 Senate Bill 640 proposed a revision to the Medical Practice Act that would end midwifery licenses with the goal of eliminating midwifery completely<sup>38</sup>. The law was passed with a grandmothering provision that allowed already licensed midwives to practice but no new midwives to take their place. This law firmly positioned medicine as the only legally recognized form of care for childbirth in Colorado. Following the 1941 elimination of new licenses for midwives, both midwives and homebirths virtually disappeared in Colorado. <sup>39</sup>

I think of my grandma, who worked right next to the riveters on an assembly line during the war, and how she was unconscious for the births of all four of her sons, including my dad, which was common. She was part of this generation of women who strongly identified with modernization, progress and the benefits of industrialization. My maternal grandmother also gave birth in the hospital during this time, though she lived a seventy minute drive from the nearest hospital and stayed with a family in town at the end of her pregnancies. Both of my grandmothers were from small towns and modest means, themselves born at home. They are typical of this generation of women in the United States who started giving birth en masse in the hospital. Retrospective studies point out that "there is no clear-cut evidence which demonstrates that hospital managed births afforded healthy mothers with normal pregnancies a safer maternity, and there is some evidence to suggest that women who went to hospitals faced greater perils than their neighbors who chose to give birth at home."

Nonetheless, medicalization was part of progress and modernization and people like my grandparents didn't need evidence to support that claim, society was being structured along those lines in many ways. In fact, even as the medicalization of birth was being solidified through the infrastructure of hospitals, medical training, and laws like the 1941 Colorado Medical Practice Act, a burgeoning movement for natural birth emphasized how the culture of birth remained contested.

United States today, and all over the world.

<sup>38</sup> Tjaden supra note 19, at 33.

<sup>39</sup> Tjaden supra note 19, at 33 from a personal interview.

<sup>40</sup> Litoff supra note 5, at 12.

In the 1930's a British Obstetrician, Grantly Dick Reed published a book called Childbirth Without Fear: The Principles and Practices of Natural Childbirth but it wasn't published in the United States until 1944. That book opened the door for Denver doctor Robert Bradley to publish his book called Husband-coached Childbirth in 1965. After starting his obstetrics practice in Denver in 1952 he and his nurse Rhondda Hartman created the Bradley Method' of natural birth which became well-known across the country. Alondda Hartman went on to write Exercises for True Natural Childbirth, and became a national figure in the natural birth movement. But by the time they were promoting natural birth in Colorado midwifery was a nonissue, and thanks to the medical-legal infrastructure described above, medicine had a monopoly over birth. In 1976 the Colorado legislature made a decisive move in support of this monopoly and erased the history of midwifery from the Medical Practice Act, deleting the section on midwifery licensure and all references to it.

C. Eliminating Families and The Legal Death of Natural Childbirth

Despite this history, midwifery had not disappeared in Colorado, it just moved
underground, and along with it, homebirth. My brother was born at home in Longmont,
Colorado, 1977, the same year that certified nurse midwives lobbied for and won legalization. <sup>46</sup>
By 1979 midwives began organizing through the Colorado Midwives Association (CMA). <sup>47</sup> In
1982, my sister was born at home in the same county where Karen Cheney a founding member
of the CMA, was charged with practicing medicine without a license. <sup>48</sup> Her experience of being
threatened with a grand jury investigation and having to leave her Colorado practice catalyzed
the CMA into action and they proposed the first bill to make midwifery legal again in Colorado
in 1983. <sup>49</sup>

House Bill 1528 "Concerning Midwifery," carried by a state representative from Boulder proposed an Advisory Board under the Colorado Department of Health to regulate midwifery, defined midwifery as not the the practice of medicine, and included a provision stating that parents have the right to decide how they give birth. <sup>50</sup> The House Health, Environment, Welfare and Institutions Committee held a hearing on March 23, 1983 that 150 people attended. Medical professionals including nurses, doctors and nurse midwives spoke in opposition to the bill, the

<sup>41</sup> Pence Rooks supra note 2, at 33.

<sup>42</sup> Pence Rooks *supra* note 2, at 33. *See also* Robert A. Bradley, Husband-coached Childbirth, Harper & Row (1965).

<sup>43</sup> Beth DeFalco, Obstretrician Robert Bradley Dies at 81, Denver Post, December 30, 1998, at B9.

<sup>44</sup> RHONDDA HARTMAN, EXERCISES FOR TRUE NATURAL CHILDBIRTH, Harpercollins (1975).

<sup>45</sup> H.B. 1032, 50th Gen. Assemb.. 2nd Sess. (Co. 1976)

<sup>46</sup> H.B. 1526, 51<sup>st</sup> Gen. Assemb, Reg. Sess. (Co 1977) (amended the Medical Practice Act and created a licensing scheme for advance practice nurses trained in midwifery, under the Board of Nursing). The history of how nurse-midwifery intersects with and diverges from the history of midwifery in the United States is described by Pence Rooks *supra* note 2. An important difference is that nursing involves medical training and is also part of the medical system's hierarchy with doctors at the top. Nurse-midwifery is also an important subject and an important part of the natural birth options in Colorado – but it's inclusion is beyond the scope of this paper.

<sup>47</sup> Tjaden supra note 19, at 34.

<sup>48</sup> Id. at 36.

<sup>49</sup> *Tjaden supra* note 19, at 36.

<sup>50</sup> Id. at 37.

CMA, a homebirth father, and an OB nurse were in favor; everyone expressed concern about health and safety. After two hours of debate the bill was killed when a nurse midwife proposed an amendment that would put midwives under the control of doctors. <sup>51</sup> Although this mirrored the regulatory scheme under which nurse midwives practiced, it was contrary to the intention of the bill: to clarify that midwifery is not medicine, and families have a central role in birth.

The CMA tried again the following year. This time they did more work in preparation for running the bill, including talking with the opposition about their concerns, which included the risk of "unsavory" people becoming midwives, educational requirements, and physician supervision. These concerns were taken into account in House Bill 3147 which included a requirement of moral turpitude, educational standards, a different configuration on the Advisory Board, and work with a physician or the State Board of Health. The bill reaffirmed the fact that midwifery is not the practice of medicine, but attempted to address educational and physician supervision concerns. Education was a big deal because there were no formal midwifery programs in Colorado (and few in the country), and most Colorado midwives learned by apprenticeship, a model of learning that dates back to the origins of midwifery. Most midwives envisioned physician backup as an ideal, but felt physician supervision was both impossible (few doctors were willing) and unnecessary since midwifery is not the practice of medicine and birth is not a medical event.

After a seven hour debate in the House State Affairs Committee on January 16, 1984, the bill was "indefinitely postponed" much to the shock of the representative who carried it and failed to win the support of even members of her own party on the committee. The medical community lobbied heavily in opposition and one member of the committee remarked that "the number of home births and lay midwives in Colorado just doesn't warrant such legislation." It is worth noting that it wasn't consumers or consumer groups who were lobbying against the regulation of midwifery, it was the medical profession. Families consistently played a part in the efforts to legalize midwifery, and by extension, carve out protections for their own autonomy and dignity. Following the decisive failure in 1984, House Bill 1338 in 1985 was different in that it proposed licensure and educational requirements under the Board of Nursing, but that bill was also defeated.

Despite the relative lack of urgency on the part of the Colorado legislature the midwifery community was under duress, not only from the medical community who opposed them at the capitol *and* in the hospitals where midwives sometimes needed to bring their clients, but also from the State which was continuing to prosecute midwives for practicing medicine without a license. In 1990 two midwives who were prosecuted under the Medical Practice Act, Jean Rosburg and Barbara Parker, appealed their cases to the Supreme Court. <sup>55</sup>

At trial they argued that the Medical Practice Act was unconstitutionally vague: the act

<sup>51</sup> *Id.* The bill passed out of committee with a 5-4 vote, but because the amendment defeated the purpose it was later dropped.

<sup>52</sup> Id. at 37-39.

<sup>53</sup> Tjaden supra note 19, at 39.

<sup>54</sup> *Id.* From an interview with a Republican representative who opposed the bill.

<sup>55</sup> People v. Rosburg, 805 P.2d 432 (1991).

says that midwifery constitutes the practice of medicine and practicing medicine without a license is prohibited. This is the point that midwives were trying to make in the bills of 1983-85, and stems from the problem created in 1915 when the Colorado legislature subsumed midwifery into the practice of medicine despite the fact that the professions were distinct. The midwives argued that the act and the medical board failed to define midwifery with sufficient specificity. But the court found that the common definition of midwifery (a woman assisting another woman in childbirth) was sufficiently clear under every possible standard. Although the court noted that there are exceptions to the law for those who attend childbirth in emergency situation, it did not address the potential problems with the gendered definition, and the court seemed unconcerned about the implications of such a regulatory scheme, where any woman assisting a woman in birth would need to be licensed to practice medicine.

The court was more concerned with and perhaps distracted by the standing argument brought by the midwives.<sup>57</sup> The midwives sought standing to assert the rights of pregnant women whose right to privacy was violated by the Medical Practice Act's determination of who may attend them in birth. The court found that the midwives did have standing to assert the rights of pregnant women, but found that the Medical Practice Act did not violate the privacy rights of pregnant women. The court spent four pages discussing the standing issue and less then a page on the substantive privacy issue. The court used *Roe* to establish that "the state's interest in the life of the fetus superseded the pregnant woman's privacy right" post-viability, and that therefore the regulations of the State at childbirth could not violate the privacy rights of pregnant women. The court noted that the "right of privacy has not been interpreted so broadly," without noting that the right of the State had never been interpreted to so broadly either, infringing on childbirth and the right of families to determine the terms of their own reproduction.<sup>58</sup>

This is the what I call the legal death of natural birth in Colorado. Here the Supreme Court uses a medical model to define and constrain childbirth and the lives of all who participate in it. Read broadly this decision has enormous consequences. It suggests that because fetuses turn into babies who are potentially alive, the entire post-viability process of reproduction falls under the domain of the state, defining birth as a medical and public enterprise, not a private one. It fails to take into account the extensive line of cases that preceded *Roe*, cases that sketch out a more comprehensive right to privacy, reproduction, bonding, and parenting decision making. <sup>59</sup>

<sup>56</sup> Id. at Fn8 439.

<sup>57</sup> Id. at 435

<sup>58</sup> Rosburg at 438. The midwives also argued on appeal that the Medical Practice Act violated Equal Protection since it discriminates between midwives and nurse midwives. The court applied the rational basis test, finding no fundamental right or suspect class, and finding that it was "beyond question that the state has a legitimate interest in protecting the health and safety of the mother and her child," after noting the educational differences between nurse midwives and the midwives in question, noting the nurse midwives' training was very reasonable and rational.

<sup>59</sup> Meyer v. Nebraska, 262 U.S. 390 (1923) (defining liberty broadly); Moore v. East Cleveland, 431 U.S. 494 (1977)(the constitution prevents East Cleveland from standardizing its children and its adults by forcing all to live in certain narrowly defined family patterns); Pierce v. Society of the Sisters, 268 U.S. 510 (1925) (stating that the constitution prevents the standardization of children and adults), Loving v. Virginia, 388 U.S. 1 (1967) (recognizing the freedom to marry a person of another race).; Griswold v. Connecticut, 381 U.S. 479 (1965) (recognizing the right to privacy in the use of contraceptives by married people); Eisenstadt v. Baird, 405 U.S.

The court failed to take these cases into account because of the regime of childbirth that had been in development for almost one hundred years as medicine and the law acted in concert to narrow the field of maternity care and take charge. Instead of interpreting the privacy claim as inclusive of the rights of parents to make decisions about their families, the court interpreted the privacy claim as an uncontested medical matter. The *Roe* court relied on the scientific idea of "viability" and doctor-patient decision making to avoid the stickier 'nature of life' issues presented. The Colorado Supreme Court was supported by this and a century of State regulation and this allowed them too to avoid open questions: about the rights of parents to make decisions about how their babies are born; and (in contrast to *Roe*) the right of people in labor to do what their bodies naturally do.

#### D. Legal Again: Risk and Regulation

By 1993 midwives were legal again in Colorado. In the two years following the Colorado Supreme Court's *Rosburg* decision two bills were considered by the House, and the Colorado Department of Regulatory Agencies released their first report on direct entry midwives. In the end, the midwives who had been organizing for over a decade won the basic protections they were seeking. In the process, not only did some of the ideals initially sought go by the wayside, but the social and political conflict that had been brewing for most of the century was written into the law. Susan Erikson, a medical anthropologist and Amy Colo, a Colorado midwife describe what happened with legalization: midwifery was "forced to appear to be something much less than it is in order to be palatable to the legislators." 60

Essentially, this is also what happened at the turn of the century when midwifery was subsumed under the practice of medicine, midwifery was forced to appear to be something much less than what it is, in order to be palatable to the medical community. This is also one way to describe the experience of women under patriarchy: being forced to appear to be much less than they are. Ultimately, the tension between what you are and how you are forced to appear takes a toll and in this case it impacts not only the practice of midwifery but Colorado families.

In 1992 House Bill 1010 "Concerning the Practice of Midwifery" was introduced by Representatives Owen and Kopel and given three readings in the House Judiciary committee between January 8<sup>th</sup> and February 25<sup>th</sup>. The bill initially sought to exclude the "unlicensed" practice of midwifery from the medical practice act (decriminalizing what midwives had been prosecuted for in the preceding decade) while requiring midwives to register (or face criminal penalties), and disclose their professional information and affiliations to consumers. 62

The bill was amended extensively in ways that would isolate and minimize the practice of midwifery while framing it within a medical-legal risk model. Where the initial bill only

<sup>438 (1972) (</sup>privacy right to contraceptive use by single people). *See also* Troxel v. Granville, 530 U.S. 57 (2000) (protecting parents from being second-guessed by judges who think they know better), and Lawrence v. Texas, 539 U.S. 558 (2003) (recognizing that even sexual deviants can decide how to conduct their private lives).

<sup>60</sup> Susan Erikson with Amy Colo, *Risks, Costs, and Effects of Homebirth Midwifery Legislation in Colorado*, Mainstreaming Midwives: The Politics of Change, 298 (Robbie Davis Floys, Christine Barber Johnson Eds., Routledge 2006).

<sup>61</sup> H.B. 1010, 58<sup>th</sup> Gen Assemb., 2<sup>nd</sup> Sess. (Co. 1992).

<sup>62</sup> Id.

#### Indra Lusero

required midwives to disclose their name, address, and education, the amended bill required midwives to disclose "that the practice of midwifery is not regulated" and that registry "does not constitute licensure" (but that complaints could be registered and violations could result in revocation). The amended version also increased the disciplinary powers of the Director, and stated that the proposed law "does not constitute an endorsement of such practices;" reasserting the "unlicensed" status of midwives and explicitly excluding them from the insurance provisions of Colorado law. This version passed the House, but was defeated in the Senate on February 26, 1992.

The question of midwifery registration was then referred to the Department of Regulatory Agencies for a "Sunrise Review" to evaluate the need and potential benefits of regulation and evaluate whether other more cost effective methods could adequately protect the public. <sup>64</sup> The report defined midwifery, summarized contemporary perspectives on it and maternity care in general (with particular attention to rural maternity care), surveyed other state midwifery laws, provided a short history of previous requests for regulation, analyzed the proposed regulation and identified problems. The report recommended that the state "not sanction the practice of direct entry midwifery in Colorado." <sup>65</sup> It found that such regulation "unfairly favors one class of providers. . . and is therefore unconstitutional." <sup>66</sup> The report went on to clarify that "creation of legalized lay midwifery in Colorado would require a significant change in the way this state views the regulation of occupations in general as well as a change in the specific philosophy of regulating health care. . ."

The report does not explain what is meant by the philosophy of regulating health care or the regulation of occupations in general, nor how it could be unconstitutional to regulate midwives. But based on the foregoing description of the history and some sections in the report, it becomes clear that the department was identifying the problem created when midwifery was subsumed under the practice of medicine. Within that framework, there was only one kind of maternity care, the medical kind, which fit within the structure and hierarchy of medical training and practice.<sup>68</sup> That structure is inherently at odds with the idea of midwifery as a form of health

<sup>63</sup> Id.

<sup>64</sup> In 1985 the "Sunrise" process was added to the Colorado Sunset Law, Colo. Rev. Stat. § 24-34-104.1. The sunset law creates a process for the automatic review and termination of certain regulations and agencies (see Title 24 "Government" Article 34 "Department of Regulatory Agencies.") The Sunrise component requires review of proposed regulation of occupations and professions. This was not yet a law when the three bills concerning midwifery were introduced to the legislature in the 1980's, which is why the 1992 report is the first time the department made a report on midwifery.

<sup>65</sup> COLORADO DEPT. OF REGULATORY AGENCIES, COLORADO MIDWIVES REGISTRATION PROGRAM: 1992 SUNSET REVIEW (1992) at I.

<sup>66</sup> *Id.* The report did not include an analysis of this constitutional claim.

<sup>67</sup> *Id* at 11.

<sup>68</sup> The report was particularly concerned with nurse-midwifery, and this may be where the concerns of fairness and constitutionality come in, "Colorado has chosen one accepted path to the practice of midwifery. Certified nurse-midwives must acquire additional training beyond the nurse's degree and they must be then certified as a nurse-midwife. . . it should also be noted that nurse-midwives practice in Colorado under a medical model that includes physician oversight. . ." at 12 Nurse-midwives' pursuit of greater professional autonomy is often at odds with the efforts of direct entry midwives because of the inherent tensions in this regulatory scheme. The

service that is not the practice of medicine but rather the art of facilitating natural birth. Ultimately, this tension is not resolved by the law but ends up being written into it.

In 1993 the bill that would finally legalize midwifery again in Colorado was introduced. Representative Owen proposed House Bill 1051 in much the same form that it had after the House amended it in 1992 but with even more provisions that would isolate and minimize the practice of midwifery, while framing it within a medical risk model and attaching heightened punishments.<sup>69</sup> The bill was read in the House Judiciary committee three times and amended extensively there.<sup>70</sup> Once it passed the House it was given three readings in the Senate Health, Environment, Welfare and Institutions committee where further amendments were made: it was passed on May 12, 1993 (and became effective July 1<sup>st</sup> of that year).<sup>71</sup> Looking at the language of the bill that finally passed, and comparing it to the 1992 version and other laws, it becomes clear that the struggle was over professional turf and liability more than the health and welfare of women and families. Just as the boundaries of maternity care over the last century has been about professional turf and liability more than the health and welfare of women and families. The law passed in 1993 remains in much the same form today.

One of the most interesting but subtle changes between H.B. 1010 and H.B. 1051 is the definition of midwifery. In 1010 midwifery is defined as "giving the necessary supervision, care, and advice to a woman during normal pregnancy, labor and the postpartum period." This is not unlike the definition of midwifery that the Colorado Supreme Court used in the *Rosburg* decision to overcome the vagueness challenge. The problem with that definition, even though, as the court found, it is commonly accepted, is that is sweeps in an exceptionally broad range of acts and people. My mom, sister, female partner have all been midwives under this definition. And in that way the definition *is* tied to its traditional roots where midwifery existed within the domestic economy and the lines between familial and maternity care roles were not so distinct. But as a legal matter, that definition presents problems: it doesn't fit within the framework of regulation and professionalization. To accommodate this, the 1993 bill replaced the word "midwife" throughout the bill with "direct-entry midwife," so that instead of defining midwifery, the law can simply define "direct entry midwifery" as a specific kind of job. <sup>72</sup>

The term "direct entry" is in itself a term that only makes sense in the context of medicalized birth because it refers to practicing midwifery directly instead of through a nursing program. <sup>73</sup> By replacing midwifery in the bill with "direct entry midwifery," it has the effect of

report also notes "should Colorado grant direct entry midwives the authority to practice under complete independence, it would mark a significant shift in the state's regulatory philosophy." Nurse-midwives had only been granted licensure in 1977. It is worth noting that nurse-midwives have been able to expand their scope of practice and reduce physician oversight in Colorado. Today, among other things the only free standing birth center in Colorado is run by Certified Nurse Midwives. See 25-3-101 and 102 giving authority for licensing of birth center's to the Department of Public Health and Environment. The Department's "Standards for Hospital and Health Facilities" Chapter XXII covers Birth Centers.

<sup>69</sup> H.B. 1051, 59th Gen. Assemb., Reg. Sess. (Co. 1993).

<sup>70</sup> Id.

<sup>71</sup> Id.

<sup>72</sup> H.B. 1051 supra note 69.

<sup>73</sup> Pence Rooks supra note 2. There are many different terns for midwifery as an attempt to distinguish the range of

defining a profession, and making it distinct from an art or an activity that anyone could do. The definition was changed in 1993 to "the advising, attending or assisting of a woman during pregnancy, labor and natural childbirth at home and during the postpartum period" for compensation. <sup>74</sup> Despite years of opposition from the medical community, one of the major accomplishments of this bill was that it carved out a niche for the independent practice of midwifery as a recognized profession.

This was and is a triumph, but a tenuous one. The midwifery community did not succeed in clarifying that midwifery was distinct from the practice of medicine. Instead, in order to gain protection from the penalties of practicing medicine without a license, midwifery had to act more like the practice of medicine and fit within the regulatory scheme by becoming a "profession." The definition is just one way in which the law reveals this trade-off.

The other places the law demands that midwifery act more like the practice of medicine include:

- Detailed educational requirements including training in the recognition of abnormalities and risk assessment to determine certain medical conditions that would warrant referral of a client for more medical maternity care.<sup>75</sup>
- Data collection, charting, collecting specimens for screening, submitting birth certificates, and providing public health measures like prophylactic eye ointment for newborns.<sup>76</sup>
- A clear disciplinary regime including administrative, civil, and criminal penalties.<sup>77</sup>
- Participation in a professional liability insurance program. 78

Even if midwifery had developed as an independent profession outside the framework of medicine these elements may have naturally evolved. But what makes these requirements interesting is how they are combined with other limitations and proscriptions that write the conflicted relationship between midwifery and medicine into the law.

For example, while the law requires that midwives carry professional liability insurance, it also excludes midwives from the professional insurance infrastructure and then goes on to make midwives "disclose" their outsider insurance status to consumers. The bill amended an article of the law regulating insurance in Colorado to state, "no medical malpractice insurer shall be required to provide liability coverage for unlicensed midwives who are registered and providing services. . . nor shall any medical malpractice insurer be required to include in any rate setting or classification both licensed physicians or certified nurse midwives and unlicensed midwives." The section went on to prohibit rate setting that would "subsidize the risks of

mode and contexts in which midwives practice. Traditional birth attendant is another term, along with "lay" midwife, there are also regionally specific terms like granny midwife, partera, or dai.

<sup>74</sup> H.B. 1051 *supra* note 69 ("for compensation" was removed in 2001).

<sup>75</sup> Colo. Rev. Stat. §12-37-103.

<sup>76</sup> Colo. Rev. Stat. §12-37-105.

<sup>77</sup> Colo. Rev. Stat. §12-37-103, 107 and 108.

<sup>78</sup> Colo. Rev. Stat. §12-37-109.

<sup>79</sup> H.B. 1051 supra note 69, (section 3 referring to 10-4-403 and adding 2.1(e)(I))

unlicensed midwives."<sup>80</sup> It reveals the deeply conflicted posture of the legislature over this issue. On the one hand midwives should be required to have liability insurance because that's what professionals do, but on the other hand, the insurance industry shouldn't be required to provide that insurance, and certainly shouldn't include midwives in the same group as other health care providers. "Section 109 contains conflicting provisions that do not represent clear public policy regarding the regulation of midwifery."<sup>81</sup>

In fact, the law also explicitly excludes midwives from the Health Care Availability Act, which was created in 1988 to keep the costs of medical malpractice insurance low and maintain practices in critical areas like maternity care in rural communities. 82 An amendment to the Health Care Availability Act in H.B. 1051 made sure that the term "health care professional" excluded "a registrant conducting unlicensed midwifery." This essentially meant that midwives, who make far less per birth than doctors, have a much lower annual salary, and no professional liability insurance, would be penalized. Where doctors could enjoy a million dollar cap on damages in the case of a baby born with brain damage for example, midwives could not. "The limitation on liability provided" in that section "is predicated upon full licensure, discipline, and regulatory oversight and that the practice of unlicensed midwifery by registrants. . . is authorized as an alternative to such full licensure. . . and is therefore not subject to the limitations provided. . ."83 The law goes on to say that "nothing in this article shall be construed to indicate or imply that a registrant. . . is a licensed health care provider for the purposes of reimbursement by any health insurer, third party payer, or governmental health care program."84 So that not only would midwives by excluded from the professional liability framework, but consumers would be excluded from health insurance reimbursement.

This "alternative to full licensure" idea is clearly a mark of the tenuous compromise. In 2000 the Department of Regulatory Agencies itself recommended that it be changed from a "registry" to a "licensure" program since "a true registration program requires no education or experience standards" and that furthermore:

It makes economic sense to allow direct entry midwife attended birth as an option for consumers who are eligible for Medicaid and other third party insurance. . . The state expends large amound of resources on low income births and low birth weight infants. It would seem to be in the best interest of the state to utilize a safe, effective, low cost alternative to physician attended births in low risk pregnancies rather than legislating against such a practice. 85

This illogic remains in the law and demonstrates how the law embodies the conflict between medicine and midwifery, despite, not because of, the health and welfare of women and families, not to mention the economy. While this provision doesn't make much of a difference practically speaking (a family who sued an uninsured midwife would be very unlikely to actually get

<sup>80</sup> Id.

<sup>81</sup> Colorado Dept. of Regulatory Agencies, 2000 supra note 19, at 37.

<sup>82</sup> Dick Cooper, *Doctors Insurance Rates Drop by 10% - Cap on Malpractice Awards Aids reduction*, Denver Post, August 5, 1989.

<sup>83</sup> COLO. REV. STAT. §12-37-109(1)(b).

<sup>84</sup> Colo. Rev. Stat. §12-37-109(2).

<sup>85</sup> Colorado Dept. of Regulatory Agencies, 2000 supra note 19, at 38

damages of more than one million dollars, even it was awarded by the court), the symbolic significance of it's inclusion in the law was clear: midwifery presented a "risk" that the state was unwilling to bear. <sup>86</sup>

This sense of risk is expressed elsewhere in the law as well. In the section inserted in 1992 to express that registration "does not constitute an endorsement of such practices" the law also asserts that midwives will be liable for their own negligence and that "no licensed physician, nurse, prehospital emergency medical personnel, or health care institution" would be liable for midwives. This section also refers to a well established part of medical malpractice law that makes doctors vicariously liable to all practitioners under their supervision by clarifying that consultation with and education of midwives does not create a supervisory relationship. It's not that these provisions are unreasonable, of course it makes sense that midwives should be liable for their own negligence. But the fact that such standard rules of law are stated and restated here reveal more than just the technical requirements of law making. There are no comparable provisions in the laws regulating acupuncturists, massage therapists, chiropractors, podiatrists, dentists, doctors or physical therapists.

The closest thing I could find is from the law regulating advance practice nurses which says "Nothing in this section shall be construed to confer liability on an employer for the acts of an advanced practice nurse that are outside the scope of employment. . ."90 The language in the midwifery law goes well beyond this and has a punitive, moralizing tone as if midwives and their clients don't deserve the protection of the law because what they are doing (natural birth at home) is so unconscionable. To restate an important point, this fear is not based on any evidence that natural birth is any more risky at home than at a hospital, or that it is safer with doctors than with midwives. This is a fear about the professional boundaries of medicine that is being couched in arguments about health and safety.

Another place where the law expresses disapproval of midwives and their clients is the extensive "informed consent" requirement. This part of the law requires midwives to inform their clients of their educational background, training, contact information, liability insurance, emergency plan and how to file a complaint, but also requires them to inform their clients about the alternatives to direct entry midwifery, the risks of birth with attention to home versus

<sup>86</sup> I am not aware of any actuarial data to suggest that direct entry midwives added a risk of higher malpractice insurance rates. In fact, I am aware of a company looking into providing professional liability insurance to homebirth midwives, and generally, because of the client based and method of care there is reason to believe that both liability insurance and the costs of heath care insurance to consumers would be lower for direct entry midwives than medical providers.

<sup>87</sup> Colo. Rev. Stat. §12-37-109(1)((a).

<sup>88</sup> Colo. Rev. Stat. §12-37-109(1)(a), this provision makes it possible for midwives and doctors to cultivate collaborative relationships, but within the context of the language this mention has a minor impact.

<sup>89</sup> See generally Title 12 "Professions and Occupations."

<sup>90</sup> Colo. Rev. Stat. §12-38-111.8.

<sup>91</sup> Some medical professionals would certainly debate this point; the American College of Obstetricians and Gynecologists and the American Medical Association have explicit policies against home birth. But the World Health Organization, the American Public Health Association, the British Royal College of Obstetricians and Gynecologists are some of the examples of organizations that support home birth. McDorman *supra* note 2, at 6.

hospital, and the fact that doctors won't be vicariously liable. <sup>92</sup> Not only do they have to get consent for each item with the client's initial, one by one, they also have to read it aloud to their clients. <sup>93</sup> Again, there is nothing inherently wrong about informed consent. It is a part of the standard of care for both doctors and midwives. And it is particularly important to midwives whose core competencies include these guiding principles: <sup>94</sup>

- Midwives work in partnership with women and their chosen support community throughout the caregiving relationship.
- Midwives respect the dignity, rights and the ability of the women they serve to act responsibly throughout the caregiving relationship.
- Midwives understand that physical, emotional, psychosocial and spiritual factors synergistically comprise the health of individuals and affect the childbearing process.
- Midwives recognize the empowerment inherent in the childbearing experience and strive to support women to make informed decisions and take responsibility for their own well being.

But no other health care provider regulated in the State of Colorado has such requirements written into the law. The Medical Practice Act doesn't say anything about informed consent at all.<sup>95</sup>

There are informed consent requirements in the laws of some of the other alternative health care providers, but they are not quite so extensive, and certainly aren't so paternalistic. The Acupuncturists' informed consent provision requires disclosure of educational background, training, contact information, and how to file a complaint; it also requires a statement indicating that the client is entitled to information about the therapy and a second opinion, that the client may stop therapy at any time, and that sexual relationships with the acupuncturist are not appropriate. These aren't unreasonable requirements, though they do go beyond the informed consent requirements written into the law regulating doctors and they suggest an uneasiness with the profession and practice of acupuncture. But even that doesn't go as far as the midwifery law that requires enumeration of risks and reference to vicarious liability, as well as line item initialing and oral reading.

This is notable not only because it implies that midwives and their clients can't make good decisions, but also because it creates only one path for good decision making; a risk-based, medical, legal, liability oriented path. And the law does this at the site of women's bodies, in one of the most potentially empowering moments of her life at a foundational moment in the life of the family. This risk model is built into the law through these liability components and the informed consent facade, but mainly in it's prohibition against midwives attending to any woman with "increased risk of medical or obstetric or neonatal complications." This hearkens back to

<sup>92</sup> Colo. Rev. Stat. §12-37-105(5)(III).

<sup>93</sup> COLO. REV. STAT. §12-37-109(5)(a)(III) and 12-37-109(5)(b).

<sup>94</sup> COLORADO DEPT. OF REGULATORY AGENCIES, supra note 104, (appendix C).

<sup>95</sup> See Colo. Rev. Stat. § 12 -36.

<sup>96</sup> Colo. Rev. Stat. § 12-29.5-103.

<sup>97</sup> Colo. Rev. Stat. §12-37-105(3). Limiting their scope of practice to "low-risk" and "normal" birth is one of the

the 1915 law which subsumed midwifery under the practice of medicine despite the fact that midwifery was the safer and more established form of maternity care. The reality is that there is more than one way to make good decisions about pregnancy and birth. 98 The Colorado midwifery law, uncomfortable with this, strikes a compromise: tacit acceptance of the possibility that there might be other ways to make good decisions, as long as they are framed within the medical-legal risk-model. It is a fraught compromise that constrains the decision making of not only midwives but also the families they serve. But it is a compromise that ushers midwifery in Colorado into the 21st Century and provides a measure of protection and opportunity for natural birth.

# III. What to Do About It

Part of what transpired in the virtual death of natural birth was the transition of birth out of the domestic economy and into the public one. There are those that even today argue that childbirth should not be regulated at all, and that professionalization does nothing but harm midwifery and families. There were midwives who opposed the efforts to get legalized in the 80's and 90's and are still opposed to regulation today, arguing that it doesn't improve midwifery. In 2001, Kathy, a homebirth midwife in Colorado for 10 years, told anthropologist Susan Erikson, "And could we actually provide better care with an improved law? No!" A 1997 interview with Barbara a homebirth midwife for 16 years, captures the tension between being outside the law versus within it, "When I was illegal, whatever I did was illegal. I could do twins or breeches or whatever I did. It didn't matter because I was already illegal. Now I have something I want to protect: being legal." Now I have

Ultimately, the question of what maternity care is and should be has not been resolved. Ideally, the role of the state would be to protect and facilitate the conditions necessary for optimal maternity care. For this reason, it's important to continue to create legal pathways to midwifery. Without that, alternatives to medical birth will continue to be dismissed and as a culture and a country it will be hard to learn more about what optimal care looks like. Legalizing and professionalizing midwifery does have costs, but the benefits of having legal

fundamental ways that direct entry midwives have come back from the brink of extinction and achieved legalization all over the country. It has become the standard, accepted framework. And though it suggests a kind of collaboration between midwives and doctors that doesn't fully exist yet, few people questions this framework today. But there remains a wide range of issues the medical community defines as high risk that midwives do not. And so, this problem, that midwifery is beholden to medicine, remains. Examples of places where there is disagreement: vaginal birth after cesarean, breech birth, multiples, and "post-dates" (the amount of time past the due date that a woman and her baby can safely go before going into labor). Midwives in Oregon have filed a case against the regulatory agency there that hinges on this kind of disagreement. *See* Amended Complaint and Request for Injunctive Relief, Gallardo v. OHLA, Civ No. 10-6258-AA (Or. Sept. 16, 2010).

<sup>98</sup> Another core competency for midwives is to "synthesize clinical observations, theoretical knowledge, intuitive assessment and spiritual awareness as components of a competent decision making process." Colorado Dept. of Regulatory Agencies, *supra* note 104, (appendix C). This model of decision making was actually one of the main reasons I chose to give birth at home with a midwife. This decision making model feels safer and more reasonable to me.

<sup>99</sup> Erikson *supra* note 60, at 305. 100*Id*. at 304.

protections for natural birth outweigh them. The following three sections will explain A) the current state of things, B) strategies for change, and C) specific changes that should be made to the Colorado midwifery law.

# A. Back to the Future

Today over a quarter of all Colorado births are surgical, and it is estimated that 75-95% of births nationwide involve drugs and technology. <sup>101</sup> Homebirths have increased slightly in the last few years, and Colorado has a higher than average rate of homebirth compared with other states. <sup>102</sup> The field of maternity care remains contested but dominated by the medical model and a legal framework that constrains our decision making in accordance with medicine. The Colorado midwifery law hasn't changed significantly since the governor signed it in 1993, though the section on disciplinary actions has been revised five times (in 1996, 2001, 2003, 2004, 2006) and educational requirements have increased. <sup>103</sup> The Department of Regulatory Agencies has promulgated regulations consisting of over a dozen rules detailing educational standards and practice restrictions and requirements, and has released three "Sunset Review" reports on the status of the midwifery registry program. <sup>104</sup>

I first set eyes on the Colorado midwifery law in 2003 after the birth of my youngest son, at home, with the assistance of a direct entry midwife. I was intrigued by the profession and first went looking for information about what is required to become a midwife, but also became interested in why and how the law worked as it did. "Midwives have to chose between following the letter of the law and practicing what they and the parents believe is best for all concerned. The ideological spaces and birth arts that homebirth midwives preserve are significant, yet legalization has forced many midwives to abandon some midwifery arts practices, or at the very least strategically remove certain aspects from public view." <sup>105</sup> My experience with these contradictions as a homebirth parent and other experiences I had as a doula supporting women in labor at home and in the hospital inspired me to understand what role the law was playing in how childbirth happens.

Before I started reading the DORA reports from 1995 and 2000 I assumed that they would be one source of the problem, making it hard to bring needed changes to this law. But the 1992 Sunrise Report recommending against the "sanction" of midwifery was anomaly, it seems. Since then the DORA reports have readily accepted the practice of midwifery and made exactly the kinds of recommendations for improvement to the law that I would have made (though without quite as comprehensive an analysis into the history and philosophical implications).

In the 1995 Sunset Report, made after only two years of regulation DORA acts like regulating midwives is no big deal, treats the practice as a profession, and makes lots of recommendations to that end. Many of them are included in the law like grounds for discipline, governmental immunity, confidentiality of records, procedures for denial of registration, waiting

<sup>101</sup>See generally, SAKALA AND CORRY supra note 2.

<sup>102</sup> McDorman supra note 2.

<sup>103</sup>Colo. Rev. Stat. §12-37-107 and 12-37-103.

<sup>104 4</sup> CCR 739-1 (2007) and the Colorado Dept. of Regulatory Agencies, *supra* notes 19 and 65. Colorado Dept. of Regulatory Agencies, Colorado Midwives Registration Program: 2010 Sunset Review (2010). 105Erikson *supra* note 60, at 305

period for reinstatement, subpoena powers, the role of administrative law judges, and modifications to training and education. Other recommendations DORA made do not survive the extensive readings and amendments in the House and Senate that preceded passage of Senate Bill 49. The recommendations that never made it were: create a registry of apprentice midwives; allow other licensed care providers to be simultaneously registered as midwives, and expand of the scope of practice to permit use of four emergency and prophylactic drugs. 109

The medical lobby was still fighting hard to constrain midwifery even in the face of this new nonpartisan entity, the Department of Regulatory Agencies. In it's 2000 report DORA noted that not only did six years worth of data suggest home birth midwives had better outcomes than births in Colorado hospitals, but that "consumers do not file the majority of complaints received by the program. Most complaints are filed by hospital administrators or medical professionals. . " and "many of the complains by medical professionals are not found to be violations of the act." Data from the 2010 report show that this trend remains, as the majority of complaints were filed by medical professionals. Regulation had provided a measure of protection, but had also provided a new avenue for harassment by those who would maintain the medical stranglehold on birth.

So despite the fact that DORA made extensive recommendations for improvement to the law in 2001, and that the Colorado Alliance of Independent Midwives<sup>113</sup> were pushing for expanded practice of the use of the nationally recognized Certified Professional Midwives credential, the Colorado Midwives Association did not recommend any changes to the law, hoping instead to win a ten year Sunset.<sup>114</sup> Which they did. Only changes to the educational requirements made it into Senate Bill 118, which, after several readings and amendments passed (despite continued opposition from the medical community<sup>115</sup>), increasing educational requirements for midwives but without expanding or clarifying their scope of practice.<sup>116</sup> Unfortunately, most of the eight extensive and well argued recommendations of the DORA

<sup>106</sup> COLORADO DEPT. OF REGULATORY AGENCIES, 1995 supra note 65.

<sup>107</sup> S.B. 49, 60th Gen. Assemb., Reg. Sess. (Co. 1996).

<sup>108</sup> Part of this recommendation passed: licensed acupuncturists could be licensed and registered as midwives.

<sup>109</sup> COLORADO DEPT. OF REGULATORY AGENCIES, 1995 supra note 65.

<sup>110</sup> Colorado Dept. of Regulatory Agencies, 2000 supra note 19, at 17-23.

<sup>111</sup> COLORADO DEPT. OF REGULATORY AGENCIES, 2010 supra note 104 (additional data on file with the author).

<sup>112</sup> One of the most egregious examples of unnecessary complaints made against midwives by the medical community is from 2007 when a registered midwife who was herself pregnant and under the care of a registered direct entry midwife went to the hospital after she could no longer find fetal heart tones. Her baby was stillborn and subsequently, a complaint was filed by the hospital who treated her against *her* as a midwife: she was the patient. She was also a grieving mother suddenly under professional duress on top of it all. She no longer practices midwifery. Personal communications on file with the author.

<sup>113</sup> During the process of legalization the midwifery community in Colorado became divided and another professional organization CAIM came into being. The Erikson article provides a good explanation of this history.

<sup>114</sup> See generally Erikson supra note 60.

<sup>115</sup> Senate Health, Environment, Children & Families - Bill Summary 01/25/2001

<a href="http://www.leg.state.co.us/2001/inetcbill.nsf/fsbillcont/A9200FE27739F8648725697E004910FC?">http://www.leg.state.co.us/2001/inetcbill.nsf/fsbillcont/A9200FE27739F8648725697E004910FC?</a>

Open&target=/2001/inetcsum.nsf/GetVotes?OpenAgent&billnum=SB01-118

<sup>116</sup> Erikson *supra* note 60, at 302 and S.B. 118

report went unconsidered. 117

The law has been amended several times since 2001 and rulemakings have been contested, like Rule 12 providing regulation for direct-entry midwives to attend vaginal births after cesareans (VBACs), but the ten year sunset has brought a measure of calm to the midwifery community. DORA released it's report on the midwifery law in October 2010, and similar to previous years made several recommendations for improvement. The main recommendations echo those made in 1995 and 2000, so three reports over the course of fifteen years recommend that direct entry midwives in Colorado:

- Be able to be simultaneously licensed as a nurse.
- Carry and use emergency and prophylactic drugs including Rhogam, antihemmorhagics, and Vitamin K<sup>119</sup>

In addition, these recommendations have been made in at least one DORA report but have not been added to the law:

- Establish a registry for apprentice midwives. 120
- Change references from registered to licensed. 121
- Eliminate the reporting requirements for renewal of registration. 122
- Remove unnecessary restrictions on recognition of midwifery as a health care profession. 123

The 2010 report also recommends technical improvements like changing the "habitual intemperance" language, adjusting the fining language, increasing complaint response provisions, and allowing the director to suspend a license for failure to comply with an order. So with these reports and the history in mind, what can be done to resuscitate natural birth in Colorado?

# B. Strategies for Change

Several strategies will be needed to resuscitate natural birth in Colorado: correcting the misperception that medical birth is the natural state of things, capitalizing on the changing health care landscape and the diversity of the health care profession in order to expand the marketplace of ideas, bringing families back into play not only as advocates but also as the focus of all maternity care, and finally, changing the law. First I will discuss the non-legal components and then I will discuss the strategies for legal change in more detail.

<sup>117</sup> COLORADO DEPT. OF REGULATORY AGENCIES, 2000 supra note 19.

<sup>118</sup> Colo. Rev. Stat. §12-37-103(3), 12-37-107, and some other administrative changes to other sections have since been made. Cite Regs.

<sup>119</sup> Colorado Dept. of Regulatory Agencies, *supra* notes 19, 65 and 104 (1995 recommendations 10-12, 2000 recommendations 3 and 4, 2010 recommendations 2-6). The 1995 report recommended that midwives be allowed to carry and use oxygen, which was added in 1996. The 2010 report seeks to add the ability to procure the eye prophylactic ointment that is already required by the law. The reports have argued for the inclusion of these drugs in various ways and the 2010 report is the most comprehensive, but also does not name any specific antihemmorhagics.

<sup>120</sup> Colorado Dept. of Regulatory Agencies, 1995 supra note 65 (recommendation 9).

<sup>121</sup> COLORADO DEPT. OF REGULATORY AGENCIES, 2000 supra note 19 (recommendation 1).

<sup>122</sup> COLORADO DEPT. OF REGULATORY AGENCIES, 2000 supra note 19 (recommendations 5, referring to 12-37-105(12)).

<sup>123</sup> COLORADO DEPT. OF REGULATORY AGENCIES, 2000 supra note 19 (recommendation 6, referring to 12-37-109).

Correcting the misperception that medical birth is the natural state of things is a tremendous task. Understanding and disseminating the history in a way that crystallizes the timing of things without oversimplifying is a start. Promoting and publishing studies that have good data about childbirth, particularly about what makes childbirth better, what helps, and what hinders will be important. Having a global perspective and exploring childbirth in other countries will help too. And just recognizing that this challenges the firmly held assumptions of most people in a way that feels acutely threatening. Many people feel sensitive about their parenting and health care decisions and also feel a lack of agency when it comes to health care in general.

Which is why it is also so important to capitalize on the changing health care landscape and the diversity of the health care profession. With the health care reform efforts of the past year most people recognize that the health care delivery system in this country does not work. Regardless of whether people support public options of prefer to keep health care private there are certain structural problems and economic realities that can no longer be denied. This makes for a much different landscape than in the 80's and 90's. Structurally, there are simply not enough doctors to meet the demand, and as a result the structure of medicine has slowly been shifting: like certified nurse midwives who formerly practiced under strict doctor supervision, more and more "physician extenders" and advance practice nurses are being licensed with greater autonomy. Leading the compact of the state, and the citizenry. When it comes to childbirth in particular, "Mothers' pregnancy and delivery' is the most costly hospital condition for both Medicaid and private insurers, followed by 'newborn infants,'" and when compared with other countries the United States pays more than twice as much for maternity care without improving birth outcomes as much as countries who do more with much less. Less that the least the state of the past of the p

Furthermore, doctors, nurses, public health officials and hospital leaders are not a homogenous group. They are as diverse as the people they serve and their professional organizations do not always represent their interests. Though the medical lobby has been successful in constraining midwifery, not all medical care providers are opposed to midwives, homebirth or natural birth; and even those who are may change their minds when presented with good information. Nurse-midwives have been particularly good at doing research on natural birth issues otherwise ignored, and nurse-midwives have a lot to offer as a bridge: understanding midwifery and medicine. Medical care providers are particularly well positioned to push back against their professional organizations that oppose midwifery and homebirth. To resuscitate natural birth in Colorado it is essential to include medical professionals and help build avenues for their engagement.

Maternity care impacts over 68,000 Colorado families every year and is a uniquely family-oriented kind of care. <sup>126</sup> It doesn't just impact the pregnant woman, it impacts grandmothers, sisters, fathers, brothers and friends, as well as future generations. The scope of the impact on families is one thing, but there is more to it than that. When midwifery was

<sup>124</sup> See for example Colo. Rev. Stat. § 12-43.2-101-107.

<sup>125</sup> SAKALA AND CORRY supra note 2, at 2 and 20.

<sup>126</sup> COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT, Colorado Births and Deaths 2009.

subsumed under medicine at the turn of the century it didn't just change the power relationship between midwives and doctors, it also changed the power relationship between families and their maternity care providers. Maternity care became less and less of a family matter and more of a medical one.

While this may have provided a measure of liberation, women could be free from the superstitions and biases of their families, it also displaced an important purpose to maternity care: the support and development of families. 127 It's important to learn how different kinds of maternity care impacts families, and not just bodies: for example, how do c-section births impact families differently from natural births? How do homebirths impact families differently from hospital births? And it is also necessary to have families participate in the legislative debates that frame their decision making not only for the purpose of health and safety, but for the purpose of protecting the civil rights and autonomy of parents.

Finally, to resuscitate natural birth in Colorado, the law has to change. The *Rosburg* decision and the way the law uses medicine as the defining basis for parental decision making combine to create a legal environment that makes natural birth vulnerable. Right now, the way the law is written, if medicine decided that surgical births were necessary it would be extremely hard for anyone to challenge that. This impacts the scope of practice of midwives, and it impacts the range of options for families. The distinction between medical and natural birth is not currently one that the law recognizes; there is nothing in the law that protects natural birth. The direct entry midwifery law isn't quite now, but could become, a place where the law makes the distinction between medical and natural birth, and also protects it.

C. The Colorado Midwifery Law: Protecting Natural Birth

For the Colorado midwifery law to protect natural birth several changes need to be made. Changes should be made that achieve three main goals: increasing access, reinforcing the midwifery standard of care, and creating a collaborative maternity care environment. Increasing access is important so that natural birth is not just a fringe value, because then it can still be dismissed or overrun. Right now homebirth midwifery is not very accessible to potential practitioners or to potential consumers. "Midwives with social capital - formal education, upbringing, socioeconomic standing and financial resources - to subvert the dominant paradigm have less at stake and less to fear from operating outside the law. But not all homebirth midwives are equally empowered in this scenario, and as with most laws, it is the people without social capital that the law must protect. A law that reflects what midwives actually do would benefit

<sup>127</sup> See for example, Henrike Donner, Domestic Goddesses: Maternity, Globalization and Middle-class Identity in Contemporary India, Ashgate Publishing Ltd. (2008)

<sup>128</sup>While this example sounds extreme, it's unfortunately not that far fetched. There have been too many cases of c-sections being forced on women. *See generally* Pemberton v. Tallahassee Mem'l Reg'l Med. Ctr., 66 F. Supp.2d 1247 (1999). In re A.C., 573 A.2d 1235, 1253 (D.C. 1990); In re Fetus Brown, 689 N.E.2d 397, 400 (Ill. App. Ct. 1997); and In re Baby Boy Doe, 632 N.E.2d 326 (Ill. App. Ct. 1994); see also April L. Cherry, The Free Exercise Rights of Pregnant Women Who Refuse Medical Treatment 69 Tenn. L. Rev. 563 (2003); and Ehrenreich *supra* note 1.

<sup>129</sup> Even when there are governmental initiatives related to birth, like the healthy people 2010 goals, natural birth is not mentioned. Even as a potential solution to identified problems. But natural birth is also not mentioned as a civil right or cultural value.

these midwives the most." The same is true of the families who work with midwives.

Reinforcing the midwifery standard of care is vital. That standard is what distinguishes midwifery from medicine. As long as midwifery is measured by the medical standard it will fall short, midwives aren't doctors and they aren't trying to be doctors. It is essential that the midwifery standard of care be clearly identified and used within the law. So that midwives, their clients, and the medical care providers with whom they interface (recall that most complaints against midwives are made my medical professionals) all have the same expectations about what is expected of midwives. The standard of care is also a well developed area of the law that provides professions with the ability to govern themselves. This kind of autonomy has long been demanded by doctors and lawyers and midwives should be given the same respect. 131

Creating a collaborative maternity care environment is the final step necessary to protect natural birth. As long as the legal framework allows doctors to alienate, isolate, and minimize midwifery, natural birth will be vulnerable. The more collaboration that exists between health care providers, midwives included, the more options families will have, the more opportunities for cross pollination and education the providers will have, and the less likely the minority (providers or consumers) will be bullied. A collaborative maternity care environment is akin to the marketplace of ideas, where there is a strong circulation of new ideas, protected by the underlying belief that a wide range of options/ideas increases benefits for all.

The first step to increase access is to allow nurses to also be registered as midwives. This will increase the number of potential midwives, which increases access for citizens. This involves deleting part of 12-37-101(1):

(1) The provisions of this article shall apply only to direct-entry midwives, also known as "lay" midwives, and shall not apply to those persons who are otherwise licensed by the state of Colorado under this title if the practice of midwifery is within the scope of such licensure. Noperson who is a licensed professional or practical nurse as provided in article 38 of this title or a physician as provided in article 36 of this title shall simultaneously be so licensed and also be registered under this article. A licensed professional or practical nurse as provided in article 38 of this title or physician as provided in article 36 of this title who holds a license in good standing may relinquish said license and subsequently be registered under this article. It is the intent of the general assembly that health care be provided pursuant to this article as an alternative to traditional licensed health care and not for the purpose of enabling providers of traditional licensed health care to circumvent the regulatory oversight to which they are otherwise subject under any other article of this title.

This leave some problematic language in the law, like the reference to "lay" midwives. The distinction between traditional licensed health care and midwifery at the end could be a benefit

<sup>130</sup> Erikson supra note 60, at 306

<sup>131</sup> Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 Wis. L. Rev. 1193, 1196-1197 (1992).

or a detriment. But when coupled with other changes recommended below, this section is neutralized.

The first step to reinforcing the midwifery standard of care involves bringing the law into congruence with the education, training and philosophy of midwives. Midwives who register in Colorado are required to learn things as a matter of their standard of care that they are then prohibited from practicing in Colorado. There are seven gaps where the law falls below the educational requirements: suturing, prophylactic opthalmic medication, vitamin K, Rho(D) immune globulin, antihemorrhagics, local anesthetic, and IV fluids. There are also three places in the law where the stated standard of care is incorrect. This involves several changes to § 12-37-105 and one change to § 12-37-107(3)(c).

# § 12-37-105. Prohibited acts - practice standards - informed consent - emergency plan - risk assessment - referral

(1) A direct-entry midwife shall not dispense or administer any medication or drugs except for required eye prophylactic therapy

ADD: those authorized by this section.

(2) A direct-entry midwife shall not perform any operative or surgical procedure

ADD: Suturing necessary to repair first or second degree tears of the peritoneum is a part of the midwifery standard of care and not an operative or surgical procedure under this act.

(3) A direct-entry midwife shall not provide care to a pregnant woman who, according to generally accepted medical standards,

REPLACE WITH: the direct entry midwifery standard of care

(4) A direct-entry midwife shall not provide care to a pregnant woman who, according to generally accepted medical standards,

REPLACE WITH: the direct entry midwifery standard of care

(13) It shall be lawful for a registered direct-entry midwife to purchase, possess, carry, and administer <del>oxygen.</del> The department of regulatory agencies shall promulgate rules concerning minimum training

<sup>132</sup> Oxygen is already legal; prophylactic opthalmic administration is required by law, but midwives can't get it; vitamin K is for the newborn after birth, is given as one shot into muscle, it prevents newborns from excessive bleeding; Rho(D) prevents hemolytic disease of the newborn, is a shot given to the pregnant person at 28 weeks and within 72 hours post partum,if blood type shows need; antihemorrhagics - usually oxytocin - help manage post-partum hemorrhage combined with hospital transport, it is a shot given intramuscularly to person after they give birth only if they are showing signs of excessive bleeding to buy time while transported for emergency care; local anesthetics, for suturing of 1st or 2nd degree tears; IV fluids can prevent dehydration and exhaustion.

requirements for direct-entry midwives with respect to the safe administration of oxygen to patients. Each direct-entry midwife registered pursuant to this article shall complete the minimum training requirements and submit proof of having completed such requirements to the director before administering oxygen to any patient.

REPLACE WITH: medication and drugs within their standard of care

This will help bring the law in to line with the training and practice of midwives and will also begin to establish the midwifery standard of care. There is one other part of the law where the midwifery standard of care should be clarified. § 12-37-107(3)(c) allows disciplinary action for "engaging in any act or omission that does not meet generally accepted standards of safe care for women and infants, whether or not actual injury to a patient is established." "Generally accepted standards" should be changed to "direct entry midwifery standards."

Finally, there are three places where the law isolates registered midwives from other maternity care and fosters an environment of distrust and animosity. By eliminating those parts and making two additions the law would help create a more collaborative maternity care environment. These changes primarily have to do with section 109, which the 2000 DORA report recommended be eliminated because it was confusing and against public policy.

# § 12-37-109. Assumption of risk - no vicarious liability - legislative declaration

(a) The general assembly hereby finds, determines, and declares that the authority granted in this article for the provision of unlicensed midwiferyservices does not constitute an endorsement of such practices, and that it is incumbent upon the individual seeking such services to ascertain the <del>qualifications of the registrant direct-entry midwife. It is the policy of this</del> state that registrants shall be liable for their acts or omissions in the performance of the services that they provide, and that no licensed physician, nurse, prehospital emergency medical personnel, or health care institution shall be liable for any act or omission resulting from the administration of services by any registrant. The provisions of this subsection (1) shall not relieve any physician, nurse, prehospital emergency personnel, or health care institution from liability for any willful and wanton act or omission or any act or omission constituting gross negligence, or under circumstances where a registrant has a businessor supervised relationship with any such physician, nurse, prehospitalemergency personnel, or health care institution. A physician, nurse, prehospital emergency personnel, or health care institution may provide consultation or education to the registrant without establishing a business

or supervisory relationship,

ADD: and they have an affirmative duty to accept referrals for care from registered midwives who refer their clients pursuant to the rules and regulations under this act.

- (b) The general assembly further finds, determines, and declares that the limitation on liability provided in section 13-64-302, C.R.S., is predicated upon full licensure, discipline, and regulatory oversight and that the practice of unlicensed midwifery by registrants pursuant to this article is authorized as an alternative to such full licensure, discipline, and regulatory oversight and is therefore not subject to the limitations provided in section 13-64-302, C.R.S.
- (c) Nothing in this article shall be construed to indicate or imply that a registrant providing services under this article is a licensed health care provider for the purposes of reimbursement by any health insurer, third party payer, or governmental health care program.

This change would not only eliminate the sections most at odds with public policy, but it would also put pressure on the medical community to rethink their relationship to midwives, by creating an affirmative duty to accept referrals for care from midwives. In addition, I recommend one other affirmative change, empowering the Director to appoint a midwifery advisory board.

Many other professions, as mentioned previously, are self governed. They have boards of practitioners (and sometimes lay people) who determine things like educational requirements and standards of care. Often, these boards work in conjunction with administrative bodies like DORA. For example, there is a Board of Medicine, a Board of Nursing, a Board of Chiropractics. The size of the regulated population (fifty four) is not large enough to warrant a board, but instead, the Director could appoint an advisory board.

# § 12-37-106. Director - powers and duties

ADD: (f) To appoint a midwifery advisory board which shall consist of three members with staggered three year terms, two certified professional midwives and one medical professional who provides pregnancy and childbirth services.

- (f)(I) to consult with the advisory board regarding the promulgation of rules and regulations
- (II) to consult with the advisory board regarding the review of complaints

<sup>133</sup> See generally Colo. Rev. Stat. Title 12.

to determine whether disciplinary action is warranted.

This would be beneficial for several reasons: it would create a self-governing standard, increase confidence in the regulatory system, and ensure that a midwifery standard of care was applied in the complaint review process, ultimately providing better legal protection for natural birth. <sup>134</sup>

These changes would dramatically improve the law. From there, other improvements along these lines should be considered: adding well woman care to the scope of practice, creating a registry for intern midwives, replacing references to "registry" with "licensure," and replacing "direct entry midwife" with "certified professional midwife," and taking the necessary steps to have medicaid and insurance programs reimburse direct entry midwives for their care (this would include establishing liability insurance for midwives). To address the paternalistic informed consent provisions in the law, instead of eliminating them (because, it's the context not the words themselves that are problematic), perhaps they could be added to the laws regulating medical care so that the hospital would be required to get informed consent for each intervention at birth (electronic fetal monitoring, labor induction, inability to eat and drink, etc) and every family would be given notice of the availability of alternatives (homebirth and birth centers). These changes will help establish natural birth (a normal physiological process that happens spontaneously and effectively) as a social and legal fact.

# **IV. Conclusion**

In addition to protecting natural birth, these changes can also help improve medicine. So that the hegemonic discourse, the value choices and beliefs the underlie medicine's definitions of truth, nature, and biological fact, may be realigned with science and liberated from paternalism and professional protectionism. Medicine and the law developed together in ways that have negatively impacted maternity care. The United States has a failing system that spends twice as much as dozens of other countries who have better maternal and infant outcomes. <sup>136</sup> Maternal mortality in the United States is on the rise and remains in some places twice as high for women of color. Colorado is no different, where the maternal mortality rate is 11.4, well above the Healthy People 2010 goal of 3.3. <sup>137</sup> And it is three times higher for black women in the state. <sup>138</sup> Medicine itself is in need of a change. And the midwifery law can support that.

When the law allows dual licensure (of nurses and midwives), allows midwives to

<sup>134</sup> Recall that the majority of complaints are submitted by medical professionals who are often uninformed about the midwifery standard of care. These complaints are reviewed by the department, which does not include a direct entry midwife. While the department nonetheless consults with midwives to address this gap in knowledge, those consultations are not formal or transparent. Having an advisory board would lend additional credibility, transparency and trust to the process.

<sup>135</sup> Certified Professional Midwife is the credential that the Colorado law now requires (as of 2003), and it is a nationally recognized credential, whereas "direct entry midwife" is less precise.

<sup>136</sup>SAKALA AND CORRY supra note 2.

<sup>137</sup> Colorado Maternal Mortality Review Committee, *Maternal Mortality in Colorado 1990-1997*, 1 August 2000. 138 *Id.* 

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practice their standard of care (including suturing, and administering antihemorrhagics, vitamin K, Rhogam for example), and eliminates language that isolates and alienates midwives, it will be a better law for protecting natural birth. It will begin to create a distinction between medicine and midwifery so that medicine is no longer the defining basis for parental decision making. Increased access will ensure that natural birth is more than a fringe value that can be easily dismissed, and reinforcing the midwifery standard of care will bring the law in to line with the training and practice of midwives. Finally, a collaborative maternity care environment is something that citizens want and need; the average consumer is more concerned with their health and safety than the preservation of one profession over another. While not every family will choose or need midwifery care, it's preservation is a matter of civil rights, family responsibility and community health.



<u>APHA > Policy Statements and Advocacy > Policy Statements > Policy Statement Database ></u> Supporting Access to Midwifery Services in the United States Position Paper

# Supporting Access to Midwifery Services in the United States (Position Paper)

Date: Jan 01 2000 | Policy Number: 20004

Key Words: Midwives, Maternity Services, Nurse Midwifery, Maternal And Child Health

#### I. Goal

The American Public Health Association (APHA) takes a position in support of the expansion of midwifery as a key strategy to improving access to care for childbearing families for the purpose of increasing their health care options and thereby to the subsequent improvement of birth outcomes.

#### II. Statement of the Problem

The United States spends more per capita on health care than any other country, and yet substantial gaps in maternal and child health care access remain. Although a large majority of the nearly 4 million children born annually in the U.S. result from an uncomplicated vaginal delivery, childbirth is increasingly viewed as a medical event, with over 90% of all births attended by a physician trained to focus on the pathologic potential of pregnancy and birth. Childbirth is one of most common reasons to seek health care and the single most common cause for hospitalization. Even with advances in prenatal care technology, low birth weight and preterm birth rates fall short of the Healthy People 2010 goals. The APHA has publicly supported the use of innovative strategies to improve birth outcomes and decrease maternal and newborn morbidity and mortality. These documents do not, however, address access to midwifery services.

In summary, the World Health Organization (WHO) defines a midwife as a competent care giver in midwifery graduated from an education program recognized by the government that licenses the midwife to practice. As the standard of care for uncomplicated pregnancies throughout much of the world,14 midwives are the main providers of care in 75% of all European births. Conversely, in the U.S. midwives participate in fewer than 10% of all births. In terms of quali-ty, satisfaction, and costs, the midwifery model for pregnancy and maternity care has been found to be beneficial to women and families, resulting in good outcomes and cost savings. A collaborative approach between midwife and physician utilizes the expertise of both professions, which is key to ensuring optimal outcomes for women and infants. With its focus on pregnancy as a normal life event and health promotion for women of all ages, the midwifery model of care is an appropriate alternative or complement to the medical approach to childbirth.

In exploring the use of interrelated health providers within managed care and other staffing con-figurations, the Health Services Resource Administration (HRSA), Bureau of Health Professions' project, Use and Impact of Alternative or Complementary Providers, is developing methods designed to forecast the need for alternative and/or complementary providers and document their impact on physician supply and demand. <sup>19</sup> For example, the project examines the integrated use of obstetrician/gynecologists with certified nurse-midwives, anesthesiologists with nurse-anesthetists, and the use of non-traditional providers in managed care. Through the project, the National Center for Health Workforce Information & Analysis will develop recommendations for health professions' training that will reflect current and projected "real world" use of alternative and complementary providers to increase access to health care. <sup>20</sup>

# III. The Status of Midwifery in the United States;

Women comprise 52% of our nation's population and 46% of the workforce. In general, women live longer than men, suffer more from chronic illnesses, are more frequent users of health ser-vices, and account for nearly two of every three health care dollars spent. Additionally, women make three out of four of all household health care decisions. 19 It is well documented that midwives contribute substantially to the health care services of diverse populations of women and their babies. In particular, studies have demonstrated that 7 of 10 visits to certified nurse-midwives (CNMs) were by women vulnerable to poor outcomes. <sup>21</sup> CNMs attended 7% of the approximately 4 million births in 1997 and "other" midwives attended 0.4%. <sup>22</sup> However, during 1995 and 1996 respectively, in the U.S. only 6.7% of CNMs and 6% of homebirth midwives in the U.S. were non-white, indicating that

the racial and ethnic diversity of midwives does not reflect that of the nation's population.<sup>23</sup> Nationally, the midwifery profession has demonstrated an increased commitment for diversity within its ranks, especially given midwives' historic commitment to the care of vulnerable women, children, and families.<sup>24,25</sup>

Midwives in the United States with national certification generally fall into three categories: certified nurse-midwives (CNMs), who number over 7,000<sup>3</sup> and who meet the educational criteria of the American College of Nurse Midwives (ACNM), and are certified by the American College of Nurse-Midwives Certification Council (ACC); certified midwives (CMs), who number fewer than 20,<sup>2</sup> a relatively new category of 'direct-entry' midwives who are non-nurses educated within ACNM accredited educational programs and certified by the ACC; and certified professional midwives (CPMs), another category of direct-entry midwife who number approximately 1,000 and are certified by the North American Registry of Midwives (NARM).<sup>26</sup> (Note: direct-entry midwifery, which included CPMs and CMs, is a term used to refer to midwives whose education did not require a nursing back-ground). It should be noted that there is small number of other midwives who have not attained these credentials. Most though not all recognized midwifery educational pathways are accredited by agencies recognized by the U.S. Department of Education, which assures the quality and content of midwifery education programs.

CNMs are educated in the fields of nursing and midwifery. CMs are educated in midwifery alongside CNMs, and thus have comparable competencies and skills although they are not nurses. This training differs from the professional preparation of CPMs certified by NARM focuses on competent entry-level midwives who will practice in predominantly out-of-hospital settings.23 CNMs, CMs, and CPMs must pass a national certification examination to use their respective titles. These categories of midwives are not inter-changeable, and important differences exist in education and certification mechanisms, scope of practice authority, and practice settings. <sup>2,27,28</sup>;

State laws and national certification regulate the practice of midwifery and legislation differs from state to state relative to credentialing and scope of practice. Nurse-midwifery practice has been legal in all states for over 20 years.<sup>23</sup>

As of January 2000, 17 states regulated non-nurse midwifery practice and in 14 states, non-nurse midwifery is legal but unregulated. In nine states nonnurse midwifery practice is legally prohibited and in six states the practice is effectively prohibited, as there is no legal way to gain legal authority to practice. Regulatory provisions are unclear in five states. Of those states regulating non-nurse midwifery practice, 14 states have widely varying regulatory mechanisms regarding the scope, qual-ifications, and requirements for supervision, consultation, and referral. <sup>2,26</sup>Whichever professional entry is chosen, the common connection for all midwives is their philosophical adherence to the midwifery model of care. <sup>23</sup>

With the exception of birth registration which captures only a portion of midwifery practice and excludes ambulatory care entirely, <sup>29</sup> there is no current national or state process for collecting data on services provided by midwives. <sup>23</sup> Thus, documentation of the practice of midwifery in the U.S. is incomplete and varies widely between CNMs and direct-entry midwives. Since 1928, more than 20 peer-reviewed journals have reported outcome studies of care by CNM's.30 To date, nine peer-reviewed studies have been published addressing outcomes of care by direct-entry mid-wives. These studies have primarily reported homebirth outcomes with homebirth being the predominant site of birth for direct-entry mid-wives. <sup>30</sup> While a number of publications and reports exist about process and outcomes for all categories of midwives, this literature is difficult to compare to studies about other women's health providers (especially direct-entry midwives). This is due in part to the lack of inclusion of midwives in systematic national data collection. <sup>23,25,30</sup>

In 1998 the University of California at San Francisco Center for Health Professions charged a National Taskforce on Midwifery with examining the current status of midwifery in the United States. Participants of the Taskforce, who represented all levels of entry into the midwifery profession in terms of education, training, and prac-tice, generated a comprehensive report which is the most current description of midwifery in the United States. As charged, the Taskforce also made specific recommendations for practice, regulation, credentialing, education, research, and policy.<sup>23,25</sup> The Taskforce on Midwifery report, endorsed by the PEW Health Professions Com-mission, presents a multifaceted approach to improving access to health care for women, chil-dren, and their families as well as increasing the diversity of the health care work force. These recommendations provide for a grounded approach to examining the field of midwifery and increasing an accountable provider pool with quality, high standards and sensitivity to the cultural needs of the clientele (Appendix).

IV. Actions Desired and Methods The APHA should:

- Communicate in writing with the major professional organizations whose members provide health care to women encouraging them to recognize nationally certified midwives as independent and collaborative practitioners
- 2. Recommend through correspondence to and meetings with members of the health care systems that enrollees be assured access to midwives and the midwifery model of care.
- 3. Urge all state legislatures to legalize the practice of midwifery and promulgate regulations, including specification of minimal educational standards and assurance to access to appropriate liability insurance in order to assure the safety of the public's health as it relates to midwifery practice.
- 4. Recommend that states consider in their regulations regarding midwives that the basis for entry-to-practice standards should include: successful completion of a recognized midwifery education process, and successful completion of the appropriate national midwifery certifying examination.
- 5. Recommend that federal and state agencies broaden systematic data collection in birth cer-tificates, death certificates, out patient data sets, the National Ambulatory Medical Care Survey, and other data collection activities that include visits or contacts made by midwives for the care of women or newborns, to include midwifery and midwives.
- 6. Recommend that the Bureau of Health Professions strengthen federal grants and traineeships to minority midwifery students.
- 7. Encourage entities including the Institute of Medicine, National Institutes of Health, Centers for Disease Control and Prevention, and the Health Resources and Services Administration to develop a research agenda addressing midwifery practice, outcomes and cost-effectiveness.

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Appendix: Recommendations for "The Future of Midwifery"

# Practice

Midwives should be recognized as independent and collaborative practitioners with the rights and responsibilities regarding scope of practice authority and accountability that all independent professionals share.

Every health care system should integrate midwifery services into the continuum of care for women by contracting with or employing midwives and informing women of their options.

When integrating midwifery services, health care organizations should use productivity standards based on the midwifery model of care and measure the overall financial benefits of such care.

Midwives and physicians should ensure that their systems of consultation, collaboration and referral provide integrated and uninterrupted care to women. This requires active engagement and participation by members of both professions.

#### Regulation and Credentialing

State legislatures should enact laws that base entry-to-practice standards on successful completion of accredited education programs, or the equivalent, and national certification; do not require midwives to be directed or supervised by other health care practitioners; and allow midwives to own or co-own health care practices. Hospitals, health systems, and public pro-grams, including Medicare and Medicaid, should ensure that enrollees have access to midwives and the midwifery model of care by eliminating barriers to access and inequitable reimbursement rates that discriminate against midwives. Health care systems should develop hospital privileging and credentialing mechanisms for midwives that are consistent with the profession's stan-dards, recognize midwifery as distinct from other professions, and recognize established processes that permit midwives to build upon their entrylevel competencies within their statutory scope of practice.

#### Education

Education programs should provide opportunities for inter-professional education and training experiences and allow for multiple points at which midwifery education can be entered. This requires proactive intra- and interprofessional collaboration between colleges, universities and education programs to develop affiliations and complementary curriculum pathways.

Midwifery education programs should include training in practice management and the impact of health care policy on midwifery practice, with special attention to managed care.

The profession should recognize and acknowledge the benefits of teaching the midwifery model of care in a variety of education programs and affirm the value of competency-based education in all midwifery programs.

The midwifery profession should identify, develop and implement mechanisms to recruit student populations that more closely reflect the US population and include cultural competence concepts in basic and continuing education pro-grams.

#### Research

Midwifery research should be strengthened and funded in the following areas:

- Demand for maternity care, demand for midwifery care, and numbers and distribution of midwives;
- Analyses of how midwives complement and broaden the woman's choice of provider, set-ting, and model of care;
- Cost benefit, cost-effectiveness, and costutility analyses, including the relationship between knowledge of economic/cost analyses and provider practices;
- Midwifery practice and benchmarking data (among midwives) with a goal of developing appropriate productivity standards;
  - Descriptions and outcome analyses of midwifery methods and processes;
- Analysis of midwifery practice outcomes, from pre-conception through infancy, using an evidence-based perspective;
- Normal pregnancy, normal labor and birth, healthy parent-infant relationships, and breastfeeding; and
  - · Satisfaction with maternity and midwifery care.

Federal and state agencies should broaden systematic data collection, which has traditionally focused on medicine and physicians, to include midwifery and midwives.

# Policy

A research and policy body, such as the Institute of Medicine, should be requested to study and offer guidance on significant aspects of the midwifery profession including:

· Workforce supply and demand;

- Coordination of regulation by the states;
- Funding of research, education and training; and
- Coordination among the federal agencies whose policies affect affect the practice of midwifery.

Source: Dower CM, Miller JE, O'Neil EH and the Taskforce on Midwifery. Charting A Course for the 21st Century: The Future of Midwifery. San Francisco, CA: Pew Health Professions Commission and the UCSF Center for the Health Pro-fessions; April 1999.

Back to Top

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**Certified Professional Midwives NOW** 

In 2019, add KY & HI In 2017, add SD & AL In 2016, add ME & MI In 2015, add MD In 2014, add RI In 2013, add IN

TN, UT, VA, WI, MO, ME, ID, WY By 2010, add VT, NJ,

1 other\* authorizes CPM

through licensure.

CPMs, most

34 states regulate practice by statute

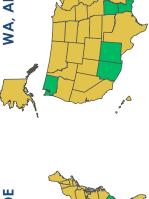
By 1990, add By 1980, add AZ, NM, SC, DE

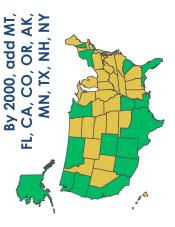
In 1970 there were

IIIIII New York CPMs would qualify for licenses if the state midwifery board had implemented properly the licensing statute.









# Midwifery Regulation

In October 2015 a consensus document was created called "Principles for Model U.S. Midwifery Legislation and Regulation." (This report is included in Section II on Regulation). The associations involved in the accreditation, credentialing and advocacy for every midwifery credential in the United States came together and agreed on principles for state authority to regulate, register, and license midwives, including the establishment of education qualifications, setting standards for practice and conduct, management of complaints, and issues pertaining to liability insurance and reimbursement.

The goal is to unify state laws and regulations which vary greatly across the country. To that end we hope that Colorado will take direction from the included report.

Colorado is aligned with the model (referenced above) in terms of education, qualifications and some elements of regulation, but falls short of the model in several ways:

- There is a lack of a midwifery-specific regulatory authority with adequate statutory powers to effectively regulate midwives and support autonomous midwifery practice.
- The regulatory authority does not work in collaboration with state, national, and international midwifery professional association(s).
- There is not a transparent process for nomination, selection, and appointment of members to the regulatory authority, which identifies roles and terms of appointment, nor are midwives represented by midwives.
- The regulatory authority does not work in collaboration with indigenous or other unique communities to consider licensure requirements or exemptions that encompass religious or cultural needs.
- Penalties, sanctions and conditions on practice are dubiou.
- The regulatory authority does not contribute to workforce planning and research.
- The scope of practice is more narrow than the definition and scope of practice established by the professional midwifery associations and the national certifying bodies.
- There is a lack of mechanisms to ensure that the regulator acts fairly, without bias or that complaints are unbiased and led by members of the profession.
- There is a lack of separation between investigation and determinations of misconduct.
- The law does not require third party payment for direct-entry midwives.

# PRINCIPLES for MODEL U.S. MIDWIFERY LEGISLATION & REGULATION

# Approved October 12, 2015 by US MERA ACME, ACNM, AMCB, MANA, MEAC, NACPM, NARM















# **Table of Contents**

Introduction	3
Glossary	
Midwifery Regulatory Authority	6
Education and Qualifications	6
Regulation, Registration and Licensure	7
Scope and Conduct of Practice	7
Complaints	8
Malpractice and Liability Insurance	8
Third Party Payment for Services	
Appendix A	g
Annendix R	10

# Introduction

The purpose of this consensus document is to foster communication and collaboration for future efforts in the development of U.S. midwifery legislation and regulation. The goal is to promote regulatory mechanisms that protect the public by ensuring that competent midwives provide high quality midwifery care. Midwifery is a profession that is autonomous, separate, and distinct from nursing and medicine. Only midwives can exercise the full scope of midwifery practice and provide all the competencies within this scope.

This document outlines the principles of model midwifery legislation to support and regulate practice. These principles address state authority to regulate, register, and license midwives, including the establishment of education qualifications, setting standards for practice and conduct, management of complaints, and issues pertaining to liability insurance and reimbursement. Recognizing that current state laws regarding midwifery vary widely, this document is intended to serve as a guide to those engaged in the revision of existing or the development of new laws. A glossary is provided to define the terms used in the document.

The document has been collaboratively produced by seven organizations that comprise US MERA (Midwifery Education, Regulation, & Association), with input from other health professional and advocacy organizations, researchers, midwives, legislative advocates, and consumer advocates. The document was drawn from the International Confederation of Midwives (ICM) *Global Standards for Regulation* and founding values and principles, which were adapted for the United States context (Appendix A). The national midwifery certifying and accrediting agencies referred to in this document have also incorporated the <u>ICM Global Standards for Education</u> and <u>Essential Competencies</u> for Basic Midwifery Practice for which are relevant to the United States context.

US MERA supports ICM's position that midwives work in partnership with women to promote self-care and the health of mothers, infants, and families; respect human dignity and women as persons with full human rights; and advocate for women so that their voices are heard and their health care choices are respected.

The organizations represented in US MERA include:

Accreditation Commission for Midwifery Education
American College of Nurse-Midwives
American Midwifery Certification Board
Midwives Alliance of North America
Midwifery Education Accreditation Council
National Association of Certified Professional Midwives
North American Registry of Midwives

**Glossary** (all terms are specific to the United States and its territories)

Accreditation – a process by which a credentialing or educational program is evaluated against defined standards by a third party. When in compliance with these standards, it is awarded recognition. As the term relates to midwifery education, accreditation is an official assessment that an educational program or institution has met standards established by an accrediting agency recognized by the U.S. Department of Education (USDE). As the term relates to credentialing or certifying agencies, accreditation is assurance that the agency has met standards established by the National Commission for Certifying Agencies (NCCA).

<u>Accrediting agency</u> – as the term relates to midwifery education, an organization charged with oversight of the accrediting process and authorized to issue certificate of assurance.

- Accreditation Commission for Midwifery Education (<u>ACME</u>) accrediting agency
  of nurse-midwifery and midwifery education programs whose graduates are
  eligible for certification by examination through the American Midwifery
  Certification Board (AMCB). ACME is recognized by the U.S. Department of
  Education.
- Midwifery Education & Accreditation Council (<u>MEAC</u>) accrediting agency of direct-entry midwifery institutions and programs whose graduates are eligible for certification by examination through the North American Registry of Midwives (NARM). MEAC is recognized by the U.S. Department of Education.

<u>Certification</u> – the recognition of an individual who has demonstrated through a standardized assessment that they meet the defined qualifications within the profession.

<u>Certifying agency</u> – an organization charged with oversight of the certification process, authorized to administer examination of knowledge and issue certificate of assurance.

- American Midwifery Certification Board (<u>AMCB</u>) certifying agency for certified nurse-midwives and certified midwives. AMCB's CNM and CM credentials are accredited by the National Commission for Certifying Agencies.
- North American Registry of Midwives (<u>NARM</u>) certifying agency for certified professional midwives. NARM's CPM credential is accredited by the National Commission for Certifying Agencies.

<u>Certificate</u> – an official document that attests to a certain fact (i.e., midwifery knowledge and competency).

<u>International Confederation of Midwives</u> (<u>ICM</u>) – a non-governmental organization that represents midwives and midwifery to organizations worldwide to achieve common goals in the care of mothers and newborns; they define midwifery and establish global standards for education, regulation, and association for country-specific adaptation.

Legislation – the creation or enactment of laws.

<u>License</u> – Licenses are issued by state authority and may be mandated by regulatory and government agencies. Licenses define the title and scope of practice, which may vary across states.

Midwifery credentials at the national level – the titles bestowed by the certifying agency.

- Certified Midwife (CM) conferred by AMCB
- Certified Nurse-Midwife (CNM) conferred by AMCB
- Certified Professional Midwife (CPM) conferred by NARM

<u>Midwifery Professional Association</u> – organization that represents the interests of midwives in service to women and their families. In general, these organizations in the United States contribute to the development of standards of education and practice.

- American College of Nurse-Midwives (ACNM)
- Midwives Alliance of North America (MANA)
- National Association of Certified Professional Midwives (NACPM)

<u>National Commission for Certifying Agencies</u> (<u>NCCA</u>) – works to ensure the health, welfare, and safety of the public through the accreditation of a variety of individual certification programs that assess professional competency.

<u>Regulation</u> – a rule or directive made and maintained by a regulatory authority.

Regulatory authority – a body with power to enforce rules or directives.

<u>Separation of powers</u> – divides investigatory procedures from administrative regulation.

Statute – a written law passed by a legislative body.

<u>U.S. Department of Education</u> – a department of the federal government concerned with education law, data collection and research, and student financial aid. The Secretary of Education also publishes a list of nationally recognized accrediting agencies determined to be reliable authorities as to the quality of education or training provided by the institutions of higher education and the higher education programs they accredit.

# **Midwifery Regulatory Authority**

There is a midwifery-specific regulatory authority with adequate statutory powers to effectively regulate midwives and support autonomous midwifery practice. If the midwifery-specific regulatory authority is administratively connected to another or broader authority (e.g., board of health professionals or nursing) the midwifery-specific authority must retain final authority over midwifery regulation.

The governance structures of the midwifery regulatory authority are set out by the legislation and include, but are not limited to, roles and responsibilities of board members, powers of the board, and process of appointment of board members and the chairperson.

Regulatory processes are transparent to the public through publication of an annual report and other mechanisms for publicly reporting on activities and decisions.

The midwifery regulatory authority is funded through licensing fees paid by members of the profession. When there are too few midwives to generate sufficient fee income, a mechanism should be provided to underwrite the regulatory authority. Since government funding has the potential to limit the autonomy of the midwifery regulatory authority, mechanisms should be designed to minimize such a consequence.

The midwifery regulatory authority works in collaboration with state, national, and international midwifery professional association(s) and relevant regulatory authorities.

Membership of the regulatory authority:

- There is a transparent process for nomination, selection, and appointment of members to the regulatory authority, which identifies roles and terms of appointment. The majority of members of the midwifery regulatory authority are midwives.
- Midwife members of the midwifery regulatory authority reflect the diversity of midwives and midwifery practice in the state.
- There is a provision for public members of the midwifery regulatory authority who ideally represent the diversity, interests and diverse perspectives of childbearing women.
- The chairperson of the midwifery regulatory authority must be a midwife, chosen by members of the group.

# **Education and Qualifications**

The midwifery regulatory authority:

- Adopts standards for midwifery education and accreditation of midwifery education programs and institutions. These are consistent with the education standards adopted by the national certifying bodies (AMCB, NARM), which are accredited by NCCA, and accrediting agencies (ACME, MEAC), which are recognized by the U.S. Department of Education.
- Recognizes midwifery education programs and institutions leading to the qualification prescribed for midwifery licensure when accredited by nationally recognized accrediting agencies (ACME, MEAC).

- Relies on national certifying agencies (AMCB and NARM) to establish criteria and processes to assess midwives educated in other countries.
- Relies on the national certifying (AMCB and NARM) and accrediting agencies (ACME and MEAC) to develop criteria and processes to assess equivalence of applicants who do not meet the requirements of a U.S. accredited midwifery education.
- Relies on national certifying agencies (AMCB and NARM) to identify criteria and processes to assess readiness for return to practice for midwives who have been out of practice for a defined period.
- Relies on the nationally recognized accrediting agencies to audit midwifery education programs and midwifery education institutions.

# Regulation, Registration and Licensure

Regulation occurs at the state level. It is based on completion of an accredited education program accredited by an agency recognized by the U.S. Department of Education and passage of a national certification exam administered by a certifying agency and accredited by NCCA. This enables uniformity of practice standards and facilitates freedom of movement of midwives across state jurisdictions.

Only those authorized under the relevant legislation may use the midwifery title endowed by that legislation. Midwives holding more than one national midwifery credential will be authorized to practice, as permitted by state law.

The legislation sets the criteria, standards, and processes for initial midwifery licensure and/or licensure renewal.

The midwifery regulatory authority:

- Maintains a register of midwives and makes it publicly available.
- Maintains mechanisms for a range of licensure status, such as provisional, temporary, conditional, suspended and full licensure.
- Works in collaboration with indigenous or other unique communities to consider licensure requirements or exemptions that encompass religious or cultural needs.<sup>i</sup>
- Relies on the national certifying agencies to maintain a mechanism through which midwives regularly demonstrate their continuing competence to practice.
- Defines expected standards of conduct and what constitutes unprofessional conduct or professional misconduct.
- Imposes, reviews, and removes penalties, sanctions, and conditions on practice.
- Collects information about midwives and their practice to contribute to workforce planning and research.

# **Scope and Conduct of Practice**

The midwifery regulatory authority:

 Defines the scope of practice of the midwife based upon the definition and scope of practice established by the professional midwifery associations and the national certifying bodies.  Defines the standards of practice and ethical conduct based upon those established by the professional midwifery associations and national certifying bodies.

# **Complaints**

The legislation sets out the powers and processes for receipt, investigation, determination and resolution of complaints.

Mechanisms must be in place to ensure that the regulatory authority has a duty to act fairly, including treatment without bias and a fair hearing.

The midwifery regulatory body has policy and processes to manage complaints in relation to competence, conduct or health impairment in a timely manner.

The legislation should provide for the separation of powers between the investigation of complaints and the hearing and determining of charges of professional misconduct.

Management processes for complaints are transparent, unbiased, include the right to a fair hearing, and are led by a team of members of the profession.

# **Malpractice and Liability Insurance**

Midwifery regulation does not require licensed midwives to purchase professional liability insurance. However, a licensed midwife who does not carry professional liability insurance will be required to inform clients of this and obtain written informed acknowledgement.

# **Third Party Payment for Services**

Midwifery or insurance regulation should mandate third party payment, including Medicaid payment, for licensed midwives.

# Appendix A

The document draws upon the <u>ICM Global Standards for Midwifery Regulation</u> and the ICM founding values and principles, which recognize that:

- Regulation is a mechanism by which the social contract between the midwifery
  profession and society is expressed. Society grants the midwifery profession
  authority and autonomy to regulate itself. In return, society expects the midwifery
  profession to act responsibly, ensure high standards of midwifery care, and maintain
  the trust of the public.
- Each woman has the right to receive care in childbirth from an educated and competent midwife authorized to practice midwifery.
- Midwives are autonomous practitioners; they practice in their own right and are responsible and accountable for their own clinical decision-making.
- Midwifery is a profession that is autonomous, separate and distinct from nursing and medicine. What sets midwives apart from nurses and doctors is that only midwives can exercise the full scope of midwifery practice and provide all the competencies within this scope.

The ICM identifies the following <u>principles of good regulation</u> to provide a benchmark against which regulatory processes can be assessed.

- Necessity is the regulation necessary? Are current rules and structures that govern this area still valid? Is the legislation purposeful?
- Effectiveness is the regulation properly targeted? Can it be properly enforced and complied with? Is it flexible and enabling?
- Flexibility is the legislation sufficiently flexible to be enabling rather than too prescriptive?
- *Proportionality* do the advantages outweigh the disadvantages? Can the same goal be achieved better in another way?
- *Transparency* is the regulation clear and accessible to all? Have stakeholders been involved in development?
- Accountability is it clear who is responsible to whom and for what? Is there an effective appeals process?
- Consistency will the regulation give rise to anomalies and inconsistencies given the other regulations already in place for this area? Are best practice principles being applied?

# Appendix B

# **Background**

In 2011 the International Confederation of Midwives (ICM) released Global Standards for Midwifery Education, Regulation, and Association (MERA) providing for the first time guidance for international midwifery. Inspired by the ICM's global vision for strengthening midwifery, seven U.S. midwifery organizations representing professional associations, education/accreditation, and certification (US MERA) began working together in 2012 to achieve common goals in midwifery that align with the ICM Global Standards. One of the first projects identified as a priority by the US MERA coalition was building consensus on the legal recognition of all nationally-certified midwives.

While midwifery is defined and regulated across all 50 states, the legal status, definitions, regulations, and scopes of practice vary markedly. This creates confusion for policymakers, consumers and insurance companies, and can actually limit services to women. In 2014, the US MERA coalition created a legislative task force to develop a consensus statement on model midwifery legislation and regulation using the Delphi research method, which is designed to help a diverse group of stakeholders gain consensus about a complex problem.

# Method

The Delphi method is an iterative process beginning with a panel of experts or stakeholders who anonymously respond to statements about the topic of interest. The process was facilitated by the legislative task force, a working group with representatives from each of the seven US MERA organizations. Three of the organizations had used the method previously to gain consensus on a clinical practice document (Kennedy et. al., 2015).

# **Steps in the Process**

Step 1: Identification of stakeholders/experts. The US MERA constituents anonymously identified key stakeholders for the Delphi study with the goal of including a wide range of perspectives and experience. These were anonymously ranked and retained if 75% of the group ranked ≥5 on a 1-7 Likert scale. Fifty-one stakeholders were retained:

- Midwifery professional organizations = 15
- Midwifery accreditation organizations = 10
- Midwifery certification organizations = 10
- Health professionals/organizations = 5
- Consumer/childbirth advocacy groups = 5
- Midwifery legislative advocates = 5
- Epidemiologist = 1

Step 2: Identification of Delphi Statements. The US MERA constituents anonymously identified key content areas to be addressed in the document. The working group

composed these into 42 initial statements in alignment with the ICM Global Standards for Regulation as applied in U.S. regulatory context.

Step 3: Round I Survey. The first survey contained the 42 initial statements and was sent to the 51 stakeholders who were asked to rank the importance of each statement on a 1-7 Likert scale to be included in the consensus document. Stakeholders could also comment on the statements. Statements were retained if 75% of the sample ranked ≥5. Forty statements were retained.

Step 4: Development of Consensus Statement. The working group clustered the 40 retained statements into thematic areas and drafted a working consensus statement. This was carefully constructed to also address the comments provided in Round I. The working group shared the first draft of the consensus statement with their US MERA constituents, soliciting comments, which were addressed in the next draft.

Step 5: Round II Survey. The revised draft consensus statement was sent to the 47 stakeholders that completed Round I. They were asked to note agreement on whether the statement reflected critical issues for midwifery regulation, whether any critical elements were missing and invited to make any other comments. The working group carefully evaluated all of the comments and responded in the revisions. Some minor changes were made for clarity and an additional paragraph was added in the introduction about midwives partnership with women – this is drawn directly from the ICM competencies. Some suggestions were simply not applicable to the document or the context of regulation.

Step 6: Endorsement and Dissemination. The final document was endorsed by the seven US MERA organizations in October 2015. US MERA may seek endorsements from other organizations. The document will be disseminated to all 50 state midwifery regulatory authorities and midwifery legislative advocates.

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ICM Global Standards for Midwifery Education, Regulation, and Association. (2013). The Hague: International Confederation of Midwives. http://internationalmidwives.org/what-we-do/education-regulation-association/

UN Declaration on the Rights of Indigenous Peoples: Article 24

- 1. Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals. Indigenous individuals also have the right to access, without any discrimination, all social and health services.
- 2. Indigenous individuals have an equal right to the enjoyment of the highest attainable standard of physical and mental health. States shall take the necessary steps with a view to achieving progressively the full realization of this right. http://www.un.org/esa/socdev/unpfii/documents/DRIPS en.pdf

i Explanatory Note: Models for this exist in certain Canadian provinces. In Nunavut and British Columbia, the exemption is only available for midwives who practiced Aboriginal midwifery prior to the coming into force of the Act. In Ontario, Aboriginal midwives providing care to Aboriginal communities are exempt from the Regulated Health Professions Act. The Ontario Midwifery Act allows Aboriginal midwives who provide traditional midwife services to use the title "Aboriginal midwife". The Quebec statute allows Aboriginal midwives to practice without being registered members, provided that the nation, group or community has entered into an agreement with the government. From <a href="http://www.aboriginalmidwives.ca/node/2270">http://www.aboriginalmidwives.ca/node/2270</a>.

# Health, Safety and Welfare

The application of the midwifery model of care has been proven to reduce incidents of birth injury, trauma, and cesarean section. This care is based on continuity of care, individualized education and counseling creating a foundation of trust. Direct-entry midwives (DEM) take client concerns and safety seriously. DEM's are trained to identify and respond to emergencies in birth and transfer care to doctors when needed. Birth in the U.S. is safe in general, but there is nowhere on earth where birth is 100% risk-free.

In 2014, the largest ever U.S. study of planned home-birth was completed. It examined nearly 17,000 families over a five-year period (2004-2009) (some Colorado midwives were part of this study) and found that the outcomes were comparable to hospital birth outcomes, much better in some respects, and slightly worse in others. The important question is whether birth with a DEM is safer than birth at home without a DEM – not whether birth with a DEM is safer than a hospital birth. The people who choose to give birth at home are specifically opting out of the medical-model of birth. Without the DEM program in Colorado, families will still give birth outside the hospital, and it's safer to have trained and regulated professionals there.

Furthermore, people are choosing to give birth away from hospitals and doctors for valid reasons, including the fact that hospital birth and doctor-led care in the United States is subpar. Maternal mortality rates are rising, and those rates are even worse for African-American and Indigenous women due to racism. Recent survey data also indicates that some women experience mistreatment during birth, and that mistreatment is worse in hospitals, for people of color, and for those who do not have a midwife.

When there are health and safety concerns related to midwifery or community birth, often the lack of midwifery integration in the overall system plays a role. Transfer between home and hospital for example, can be problematic, not because community birth is fundamentally less safe, but because of problems with the system.

We are providing several documents along these lines:

- The 2014 Planned Home Birth study
- Slides from the webinar of the Committee on Assessing Health Outcomes by Birth Settings, February 6, 2020
- Infographic on the impact of place of birth on mistreatment
- Best practice guidelines for transfer from planned home birth to hospital
- The 2008 report on evidence-based maternity care
- This link to the important USA Today coverage on how hospitals are failing new moms:

https://www.usatoday.com/deadly-deliveries/interactive/how-hospitals-are-failing-new-moms-in-graphics/

# **Original Research**

# Outcomes of Care for 16,924 Planned Home Births in the United States: The Midwives Alliance of North America Statistics Project, 2004 to 2009

Melissa Cheyney, PhD, CPM, LDM, Marit Bovbjerg, PhD, MS, Courtney Everson, MA, Wendy Gordon, MPH, CPM, LM, Darcy Hannibal, PhD, Saraswathi Vedam, CNM, MSN, RM

**Introduction:** Between 2004 and 2010, the number of home births in the United States rose by 41%, increasing the need for accurate assessment of the safety of planned home birth. This study examines outcomes of planned home births in the United States between 2004 and 2009.

Methods: We calculated descriptive statistics for maternal demographics, antenatal risk profiles, procedures, and outcomes of planned home births in the Midwives Alliance of North American Statistics Project (MANA Stats) 2.0 data registry. Data were analyzed according to intended and actual place of birth.

Results: Among 16,924 women who planned home births at the onset of labor, 89.1% gave birth at home. The majority of intrapartum transfers were for failure to progress, and only 4.5% of the total sample required oxytocin augmentation and/or epidural analgesia. The rates of spontaneous vaginal birth, assisted vaginal birth, and cesarean were 93.6%, 1.2%, and 5.2%, respectively. Of the 1054 women who attempted a vaginal birth after cesarean, 87% were successful. Low Apgar scores (<7) occurred in 1.5% of newborns. Postpartum maternal (1.5%) and neonatal (0.9%) transfers were infrequent. The majority (86%) of newborns were exclusively breastfeeding at 6 weeks of age. Excluding lethal anomalies, the intrapartum, early neonatal, and late neonatal mortality rates were 1.30, 0.41, and 0.35 per 1000, respectively.

Discussion: For this large cohort of women who planned midwife-led home births in the United States, outcomes are congruent with the best available data from population-based, observational studies that evaluated outcomes by intended place of birth and perinatal risk factors. Low-risk women in this cohort experienced high rates of physiologic birth and low rates of intervention without an increase in adverse outcomes.

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Keywords: birth place, home childbirth, midwifer, midwifery, perinatal outcome, pregnancy outcomes

# **INTRODUCTION**

In the United States, approximately 1% of all births occur in homes and birth centers, and these births are attended primarily by direct-entry midwives (DEMs), including certified professional midwives (CPMs). Of the 1.18% of US births occurring outside of the hospital in 2010, approximately 66% (31,500) were home births. Although a small proportion of total births in the United States, home births are on the rise. After a steady decline between 1990 and 2004, home births increased by 41% between 2004 and 2010, up from 0.56% to 0.79%, with 10% of this increase occurring between 2009 and 2010. By comparison, in Great Britain and the Netherlands 8% and 29% of women, respectively, give birth outside of an obstetric unit. 2.3

Data on outcomes from planned home births in the United States have not been reported in the peer-reviewed literature since 2005,<sup>4</sup> when Johnson and Daviss described outcomes for 5418 home births attended by CPMs in 2000. In 2004, the Midwives Alliance of North American (MANA) division of research developed a Web-based data collection system (the MANA Statistics Project [MANA Stats]) for the purpose of collecting information on a large, multiyear, voluntary sample of midwife-led births occurring primarily at home and

Address correspondence to Melissa Cheyney, PhD, CPM, LDM, Department of Anthropology, Oregon State University, Waldo Hall 238, Corvallis, OR 97331. E-mail: melissa.cheyney@oregonstate.edu

in birth centers within the United States.<sup>5</sup> This study describes outcomes from planned home births recorded in the MANA Stats database (version 2.0) from 2004 to 2009.

# BACKGROUND

A complete understanding of the safety of planned home and birth center birth is difficult to achieve. To date, universal perinatal data are only available in the United States through birth certificates, which are unreliable with respect to information on the intended and the actual place of birth. <sup>6–8</sup> Until recently, high-quality data comparing outcomes by birth setting were not available because many published studies failed to reliably distinguish among intended and actual place of birth, type of attendant, and maternal risk profiles. Despite attempts to design a randomized controlled trial, sufficient numbers of women have not consented to be randomized according to birth site. <sup>9</sup>

In 2009, 3 well-designed, population-based cohort studies were published comparing planned home births to planned hospital births with professional midwives as attendants. In the first study, de Jonge and colleagues  $^{10}$  used a national dataset (N = 529,688) of low-risk pregnancies in the Netherlands to compare perinatal mortality and morbidity outcomes for planned home (60.7%) and hospital births (30.8%) between 2000 and 2006. There were no significant differences in intrapartum death, neonatal death within 24 hours or 7 days

# Quick Points

- This study reports maternal and neonatal outcomes for women planning to give birth at home under midwife-led care, as recorded in the Midwives Alliance of North America Statistics Project dataset (version 2.0, birth years 2004-2009).
- ♦ Among 16,924 women planning a home birth at the onset of labor, 94% had a vaginal birth, and fewer than 5% required oxytocin augmentation or epidural analgesia.
- Eleven percent of women who went into labor intending to give birth at home transferred to the hospital during labor; failure to progress was the primary reason for intrapartum transfer.
- Nearly 1100 women attempted a vaginal birth after cesarean (VBAC) in this sample, with a total VBAC success rate of 87%.
- ◆ Rates of cesarean, low 5-minute Apgar score (< 7), intact perineum, breastfeeding, and intrapartum and early neonatal mortality for this sample are all consistent with reported outcomes from the best available population-based, observational studies of planned home births.</p>

after birth, or rates of neonatal intensive care unit (NICU) admissions.

The second study, a prospective, 5-year (2000-2004) matched cohort study in British Columbia, compared outcomes for low-risk women in a midwife-attended planned home birth group (n = 2889), a physician-attended hospital birth group (n = 5331), and a midwife-attended planned hospital birth group (n = 4752). In this intention-to-treat analysis, women in the planned home birth group had significantly fewer intrapartum interventions, including narcotic or epidural analgesia, augmentation or induction of labor, and assisted vaginal or caesarean birth—as well as significantly fewer adverse outcomes, including postpartum hemorrhage, and third- or fourth-degree lacerations. No significant differences were found between the home birth group and either comparison group with respect to the diagnosis of asphyxia at birth, seizures, need for assisted ventilation beyond the first 24 hours of life, or low 5-minute Appar scores (< 7).

The third study analyzed data from the Ontario Ministry of Health Midwifery Program database to compare outcomes of all women planning home births between 2003 and 2006 (n = 6692) with a matched sample of women planning a hospital birth (n = 6692). The primary outcome reported was a composite measure of perinatal and neonatal mortality or serious morbidity that included stillbirth or neonatal death at 0 to 27 days (excluding lethal anomalies), very low Apgar score (<4) at 5 minutes, neonatal resuscitation requiring both positive pressure ventilations and cardiac compressions, birth weight less than 2500 g, or admission to a neonatal or pediatric intensive care unit with a length of stay greater than 4 days. No differences were found between groups for perinatal and neonatal composite outcome measures (2.4% vs 2.8%; relative risk [RR] 0.84; 95% confidence interval [CI], 0.68-1.03). All measures of maternal morbidity were lower in the planned home birth group, as were rates for all obstetric interventions including cesarean (5.2% vs 8.1%; RR 0.64; 95% CI, 0.56-0.73).

Subsequently, in 2011 the Birthplace in England Collaborative Group reported findings from a prospective study of 64,538 births among low-risk women in England.<sup>2,13</sup> Investigators concluded that for healthy women, adverse maternal and newborn outcomes were extremely rare, regardless of birth setting. Planned home birth was associated with significantly fewer interventions, higher maternal satisfaction, and

increased cost-effectiveness compared to birth in a hospital obstetric unit. <sup>13</sup> Most recently, Stapleton and colleagues <sup>14</sup> described outcomes from births attended by certified nurse-midwives (CNMs), licensed midwives (LMs), and CPMs that occurred in birth centers in the United States. These data were collected through the Uniform Data Set (UDS), a Web-based tool developed by the American Association of Birth Centers (AABC) for use in member centers. This National Birth Center Study II reported excellent outcomes and reduced interventions as a result of midwifery-led care in birth centers.

Olsen and Clausen, 15 in their 2012 Cochrane systematic review, suggest that while evidence from randomized controlled trials sufficiently powered to assess differences in perinatal mortality by birth site may never be available, the balance of evidence from large well-designed observational studies supports informed choice of birth place in jurisdictions where integrated maternity systems exist. However, some have suggested that these outcomes are not generalizable to the United States because there currently is no integrated maternity care system with clear communication between birth settings and across provider types. 16,17 Rising rates of home and birth center births, in the absence of a unified, national policy on choice and interprofessional collaboration across birth settings, are a major concern. 18 In addition, without established systems for universal maternity care data collection, it is difficult to evaluate the quality and safety of care across birth settings and by multiple provider types. The establishment of reliable and inclusive tools for USbased perinatal data collection has become a priority.

### **METHODS**

#### **Data Collection**

Data were collected between 2004 and 2009 using the MANA Stats 2.0 Web-based data collection tool, which was developed by the MANA Division of Research in 2004 in accordance with the Agency for Healthcare Research and Quality guidelines. Participation in the project was voluntary, with an estimated 20% to 30% of active CPMs and a substantially lower proportion of CNMs contributing. Midwife participants obtained written informed consent from all clients at the onset of care, and only data from women who consented were included in the research dataset. More than 95% of women

consented to be included,<sup>5</sup> a high rate of participation that has been observed in other studies involving this population.<sup>4,14</sup> All analyses presented here were approved by the institutional review board at Oregon State University.

The MANA Stats 2.0 online form collected data on nearly 200 variables, including demographic characteristics of participating women and families; pregnancy history as well as general health and social histories; antepartum, intrapartum, neonatal, and postpartum events and procedures; and maternal and newborn outcomes. Data were also collected on antepartum, intrapartum, and postpartum maternal and neonatal transfers, as well as on intended and actual place of birth. The data collection design for MANA Stats includes preregistration, or prospective logging, of all clients at the start of care, before outcomes are known. Midwife contributors complete the Web-based form over the course of care through the 6-week postpartum visit, or the final visit if earlier. Data are stored on a secure server with encryption software congruent with privacy and security measures for protected health information, as defined by the United States Department of Health and Human Services. 20,21 Upon enrollment in the project, midwife contributors are provided with detailed instructions on the use of the online data collection tool; and data collection support team members, known as data doulas, provide e-mail and phone support to all contributors.

All courses of care reported here were submitted by midwives using the 2.0 form. These records were subjected to 3 postsubmission review processes, described in detail elsewhere.<sup>5</sup> All data forms indicating maternal, fetal, or newborn deaths also underwent detailed case review using a modified fetal-infant mortality review approach.<sup>22,23</sup> Analysis of pre- and postreviewed variables during quality testing evidenced near perfect agreement, suggesting that MANA Stats 2.0 data were entered with a high degree of accuracy by midwives.<sup>5</sup> Thus, any errors in the dataset are likely random rather than systematic. For a detailed analysis of the history, methodology, and validity of the MANA Stats 2.0 data collection tool, see Cheyney et al.<sup>5</sup>

# **Inclusion Criteria**

The complete November 2004 through December 2009 MANA Stats 2.0 dataset (N=24,848) includes records from all women receiving at least some prenatal care from contributor midwives. For the purposes of this analysis, we excluded women who transferred care to another provider prior to the onset of labor, women who at the onset of labor had a planned birth location other than home, and women who did not live in the United States. Thus, our final sample for this analysis consisted of all planned home births (N=16,924).

# **Data Export and Analysis**

All data from the 2.0 dataset were exported from the structured query language-based online data collection system as a comma-separated value (\*.csv) file and then imported into SPSS Statistics<sup>24</sup> for analysis. Our main analyses, in keeping with the descriptive objective of this study, consisted of calcu-

lating basic frequencies, measures of central tendency, measures of variance, and confidence intervals as indicated.

Throughout the analyses, we were careful to limit the denominators to those women and newborns at risk for the outcome. For instance, for all demographic characteristics, obstetric history, and pregnancy complication data, as well as the intrapartum transfers, the denominator is women who went into labor intending to give birth at home. For most perinatal outcomes, the denominator is newborns—removing those no longer at risk. For instance, the denominator for low Apgar score (< 7) is liveborn newborns. There are 2 exceptions: neonatal transfers and postpartum transfers are reported among the entire sample of neonates/women, as well as among only those who gave birth at home, thus excluding intrapartum transfers. The second method is technically correct. Mother-newborn dyads transferred during the intrapartum period are not at risk of postpartum or neonatal transfer. However, because the reporting of these variables is not consistent in the literature, <sup>14,25</sup> we report both values to allow for comparison with as many other studies as possible. In addition, in keeping with standards for reporting results from observational studies, 26 we have included the actual denominators (ie, the theoretical denominator of women, or liveborn newborns, minus participants missing data for that variable) as well as 95% CIs, as relevant.

#### **RESULTS**

## **Contributing Midwives**

Data were contributed by 432 different midwives, including CPMs/LMs/LDMs, CNMs/CMs, naturopathic midwives, unlicensed direct-entry midwives, and others (Table 1). The majority of births in the sample were attended by CPMs (79.2%).

# **Demographic Characteristics**

The final sample included 16,924 women and 16,984 newborns (Figure 1). Complete demographic characteristics for the sample are reported in Table 2. Briefly, most women in this sample were white, college-educated, and married. Of note, greater than 6% of the sample was identified by their midwife as Amish or Mennonite. Although midwives in all states are eligible to contribute data to MANA Stats, the 2.0 home birth cohort comes disproportionately from the Western United States. Almost two-thirds of the women in this sample paid for midwifery care out-of-pocket, either because their insurance did not cover home birth, their midwife did not provide insurance billing, or because they were uninsured.

# **Antenatal Risk Status**

Antenatal risk profiles of the women are presented in Table 2. Twenty-two percent of the sample was nulliparous, and 9.2% of multiparous women were grand multiparas ( $\geq$  5 previous births after 20 weeks' gestation). Of the parous women, 8.0% had a history of previous cesarean. Most women began their pregnancies with a normal (18.5-25 kg/m²) body mass index (BMI).

Very few of the pregnancies in our sample were complicated by maternal comorbidities, including hypertensive

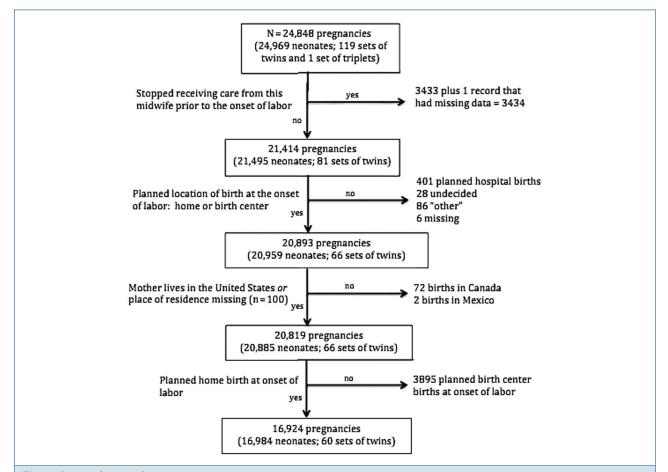
			Median (range) Number of Births
	Number of	<b>Total Number of Births</b>	Contributed by Individual Midwives
	Midwives With	Attended by This	of This Type During the Entire
Category	This Credential	Type of Midwife	62-month Study Period
CPM/LM/LDM	320	13,400	239 (4-880)
CNM/CM	44	1595	457 (108-800)
Both <sup>a</sup> CPM and CNM	16	1018	260 (7-721)
Neither <sup>b</sup>	52	971	287 (18-884)

Abbreviations: CM, certified midwife; CNM, certified nurse-midwife; CPM, certified professional midwife; LDM, licensed direct-entry midwife; LM, licensed midwife.

a These 16 practitioners held both a CPM and CNM credential

<sup>&</sup>lt;sup>a</sup>These 16 practitioners held both a CPM and CNM credential.

<sup>b</sup>Neither a CPM, LM, LDM, CNM, and/or CM. This category includes direct-entry midwives without licensure or certification; "other" providers, which is a heterogeneous category containing students, naturopathic doctors, and doctors of osteopathy; and "missing," where the credential is unknown.



**Figure 1.** Sample Size Delimitation

Delimitation begins with all records entered into the Midwives Alliance of North America Statistics Project (MANA Stats) using the 2.0 data form (birth years 2004- 2009). Final analyses are limited to women who planned home birth at onset of labor (N=16,924).

disorders, gestational diabetes mellitus (GDM), persistent anemia (defined as hematocrit <30 or hemoglobin <10 g/dL), or Rh sensitization. Because the 2.0 version form was not designed to collect data on collaborative care, it is impossible to determine exactly when these complications developed or how many women were co-managed with a physician. Of the 168 women with GDM, preeclampsia, eclampsia, or Rh sensitization, 74 had at least one prenatal visit with an obstetrician, and 47 had at least 3 prenatal visits with an obstetrician (an additional 33 women did not have data on obstetrician visits). In addition, of the 50 women with mul-

tiple gestations who had complete data on visits with other providers, 22 saw an obstetrician prenatally at least once, and 13 saw an obstetrician at least 3 times.

### **Mode of Birth**

The spontaneous vaginal birth rate for the sample was 93.6%. The rate of vacuum or forceps-assisted vaginal birth was 1.2%. The overall cesarean rate was 5.2%, and most of these were primary cesareans (84.4%). Our sample included 1054 women with a history of cesarean, and these women had a vaginal

Table 2. Demographic Characteristics, Obstetric History, and Pregnancy Complications for 16,924 Women in the MANA Stats 2.0 Sample who Planned Home Births

Characteristics	
Race/Ethnicity, a,b n (%)	
White	15,614 (92.3)
Black	361 (2.1)
Latina	714 (4.2)
Asian/Pacific Islander	760 (4.5)
Native American	163 (1.0)
Other	145 (0.9)
Belongs to Amish, Mennonite, or other Plain	1098 (6.5)
church, n (%)	
Age at first prenatal visit, mean (SD), y	30.3 (5.3)
Education, n (%)	
High school graduate <sup>c</sup>	15,283 (92.4)
Completed $\geq$ 4 years of college <sup>d</sup>	8300 (58.0)
Marital status, <sup>e</sup> n (%)	
Married	14,961 (88.4)
Unmarried with a partner	1579 (9.3)
Single (includes separated, divorced)	331 (2.0)
Other	51 (0.3)
MANA region of residence, n (%)	
Region 1: New England (CT, MA, ME, NH,	873 (5.2)
RI, VT)	
Region 2: North Atlantic (DC, DE, NJ, NY,	1992 (11.8)
MD, PA)	
Region 3: Southeast (AL, AR, FL, GA, LA, MS,	2054 (12.2)
NC, KY, SC, TN, VA, WV)	
Region 4: Midwest (IA, IL, IN, KS, MI, MN,	2646 (15.6)
MO, ND, NE, OH, SD, WI)	
Region 5: West (AZ, CO, ID, MT, NM, NV,	3949 (23.4)
OK, TX, UT, WY)	
Region 6: Pacific (AK, CA, HI, OR, WA)	5364 (31.8)
Method of payment, <sup>g</sup> n (%)	
Self-pay (does not necessarily mean	10,888 (64.4)
uninsured)	
Private insurance	4092 (24.2)
Government insurance (includes Medicaid,	1361 (8.0)
CHAMPUS)	
Other	576 (3.4)
Parity, n (%)	` /
Nulliparous	3773 (22.3)
Multiparous	13,150 (77.7)
Grand multiparous ( $\geq$ 5 pregnancies) <sup>h</sup>	1150 (9.2)
Trial of labor after cesareani	1052 (8.0)
Normal BMI prepregnancy, n (%)	11,144 (66.9)
1 11 10 3	, .()

Continued

Table 2. Demographic Characteristics, Obstetric History, and Pregnancy Complications for 16,924 Women in the MANA Stats 2.0 Sample who Planned Home Births

Characteristics	
Mother's pregravid BMI (kg/m²), k median	22.5 (20.6-25.7)
(IQR)	
Complications/comorbid conditions affecting	
this pregnancy, <sup>1</sup> n (%)	
Chronic hypertension	59 (0.3)
Pregnancy-induced hypertension	243 (1.4)
Preeclampsia	29 (0.2)
Eclampsia	10 (0.1)
Gestational diabetes mellitus	132 (0.8)
Persistent anemia	146 (0.9)
Rh sensitization	41 (0.2)
Multiple gestation, n (%)	60 (0.4)
Breech presentation, $^{\mathrm{m}}$ n (%)	222 (1.3)

Abbreviations: BMI, body mass index; CHAMPUS, Civilian Health and Medical Program of the Uniformed Services; IQR, interquartile range; MANA, Midwives Alliance of North America; SD, standard deviation.

birth after cesarean (VBAC) success rate of 87.0%. Of the 915 successful VBACs, 94% were completed at home. A total of 222 newborns in a breech presentation were born vaginally (57.2%) or by cesarean (42.8%) (Table 3). Of the 127 breech neonates born vaginally, 92% were born at home.

### **Gestational Age and Birth Weight**

Ninety-two percent of newborns were full-term, 2.5% were preterm, and 5.1% were postterm based on the midwife's clinical gestational age assessment following birth. The sample mean (SD) for live birth weight was 3651 g (488 g). The median birth weight was 3629 g (interquartile range, 3317 g-3969 g). Fewer than 1% of newborns were low birth weight (<2500 g), although almost one-quarter were macrosomic (> 4000 g) (Table 3).

### **Transfers**

### Intrapartum Transfers

Of the 16,924 women who began labor at home, 89.1% completed a home birth for an intrapartum transfer rate of 10.9%. Nulliparous women required transfer during labor 3 times as frequently as multiparous women (Table 4). The most common reason for transfer was failure to progress (n = 752, 40.7% of intrapartum transfers). Other reported reasons for

<sup>&</sup>lt;sup>a</sup>Midwife identified, categories are not mutually exclusive.

<sup>&</sup>lt;sup>b</sup>Missing data for 14 women. <sup>c</sup>Missing data for 390 women.

<sup>&</sup>lt;sup>d</sup>Missing data for 970 women.

<sup>&</sup>lt;sup>e</sup>Missing data for 2 women. <sup>f</sup>Missing data for 46 women.

gMissing data for 7 women.

<sup>&</sup>lt;sup>h</sup>Missing data for 606 women; percent calculated using multiparous women as the denominator.

Missing data for 6 women.

Missing data for 273 women.

Missing data for 273 women.

<sup>&</sup>lt;sup>1</sup>Missing data for one woman. <sup>m</sup>Denominator is 16,984 neonates.

Table 3.	Birth Outcomes for 16,984 Neonates with Planned	
Home Birt	ths in the MANA Stats 2.0 Sample	

Outcome	n (%)
Mode of Birth <sup>a</sup>	
Spontaneous vaginal	15,876 (93.6)
Assisted vaginal (166 vacuum, 35 forceps)	201 (1.2)
Cesarean	887 (5.2)
If cesarean, was this birth a primary cesarean? $\!\!^{b}$	
Yes	743 (84.4)
No	137 (15.6)
If this birth included a TOLAC, did mother have	
a vaginal birth?	
Yes	915 (87.0)
No	137 (13)
Breech presentation	
Vaginal birth	127 (57.2)
Cesarean	95 (42.8)
Gestational age of neonate <sup>c</sup>	
$Preterm^d$	423 (2.5)
Postterm <sup>e</sup>	862 (5.1)
Birth weight <sup>f</sup>	
Low birth weight (<2500 g)	142 (0.8)
Macrosomic (> 4000g)	3817 (22.6)
5-minute Apgar score < 7g	245 (1.5)
Any NICU admissions in the first 6 weeks $^{\rm h}$	479 (2.8)

Abbreviations: MANA, Midwives Alliance of North America: NICU, neonatal intensive care unit; TOLAC, trial of labor after cesarean.

intrapartum transfer included desire for pain relief (n = 281, 15.2%), fetal distress or meconium (n = 185, 10.0%), malpresentation (n = 118, 6.4%), and maternal exhaustion (n = 98, 5.3%). When entering data, midwives could select more than one reason. Of the 1856 women who transferred to the hospital during labor, more than half gave birth vaginally (Table 4).

### Postpartum Maternal Transfers

Postpartum maternal transfer occurred for 1.5% of women who went into labor intending to give birth at home and occurred for 1.7% of women who gave birth at home. Of the 251 women who were transferred after giving birth at home, 177 (70.5%) were transferred for complications related to hemorrhage and/or retained placenta, and 41 (16.3%) were transferred for a laceration repair. The remaining postpartum transfers were for a variety of reasons including abnormal maternal vital signs, hematoma, unassisted precipitous labor

**Table 4.** Intrapartum, Postpartum Maternal, and Neonatal Transfers with Key Outcomes Following Transfer<sup>a</sup>

Variable	n (%)	(95% CI)
Intrapartum transfer <sup>b</sup>	1850 (10.9)	(10.4-11.4)
Primiparous women ( $n = 3770$ )	864 (22.9)	(21.6-24.2)
Multiparous women ( $n = 13,143$ )	986 (7.5)	(7.0-8.0)
If intrapartum transfer		
Epidural analgesia <sup>c</sup>	1028 (56.1)	(53.8-58.4)
Oxytocin augmentation <sup>d</sup>	408 (22.0)	(20.1-23.9)
Vaginal birth <sup>e</sup>	984 (53.2)	(50.9-55.5)
5-minute Apgar score $<$ $7^{\rm f}$	69 (4.5)	(3.5-5.5)
NICU admission in the first 6	167 (9.5)	(8.1-10.9)
weeks <sup>g</sup>		
Postpartum maternal transfer $^{\rm h}$	251 (1.5)	(1.3-1.7)
Neonatal transfer <sup>i</sup>	149 (0.9)	(0.7-1.1)
If neonatal transfer		
5-minute Apgar score < 7	66 (44.3)	(36.3-52.3)
NICU admission in the first 6	109 (75.2)	(68.2-82.2)
weeks <sup>j</sup>		

Abbreviations: CI, confidence interval; NICU, neonatal intensive care unit. <sup>a</sup>Denominators are 16,984 neonates or 16,924 mothers, unless otherwise indicated. Proportions are calculated for postpartum maternal and neonatal transfers using the entire sample (less missing) for the denominator, rather than limiting to mother/newborn dyads still at risk for transfer after birth, in order to be consistent with other literature in this field. bMissing data for 11 women.

when parents called emergency medical services, or mother unable to void.

### **Neonatal Transfers**

Neonatal transfer occurred for 0.9% (149/16,984) of all newborns whose mothers went into labor intending to give birth at home and occurred for 1.0% (149/15,134) of the newborns born at home. The majority of these 149 newborn transfers were for respiratory distress and/or Apgar scores below 7 (n = 116, 77.9%); an additional 9 newborns (6.0%) were transferred for evaluation of congenital anomalies.

### **Maternal Morbidity and Mortality**

Of the 16,039 women who gave birth vaginally, 49.2% did so over an intact perineum; 1.4% had an episiotomy; 40.9% sustained a first- or second-degree perineal laceration; and 1.2% had a third- or fourth-degree perineal laceration. Labial lacerations or skin splits that did not require suturing occurred in 12.8% of the women, and 4.8% had more substantial labial lacerations that required suturing. Midwives could indicate more than one type or location of laceration. Of women who gave birth vaginally, 15.5% (n = 2426) lost greater than 500 mL of blood following birth, and 4.8% (n = 318) lost 1000 mL or greater. Of the women who lost greater than 500 mL of blood

<sup>&</sup>lt;sup>a</sup>Missing data for 20 women.

<sup>b</sup>Missing data for 7 women.

<sup>c</sup>These data come from 2 questions on the 2.0 data entry form. The exact wording of the questions are: "Any clinical evidence that baby is preterm?" and "Any clinical evidence that baby is postterm?" Further instructions were not given to midwives.  $^{\rm d}$  Missing data for 33 neonates.

<sup>&</sup>lt;sup>e</sup>Missing data for 43 neonates.

fMissing data for 66 neonates.

gMissing data for 401 neonates.

hMissing data for 130 neonates.

<sup>&</sup>lt;sup>c</sup>Missing data for 18 women. <sup>d</sup>Missing data for 1 woman.

<sup>&</sup>lt;sup>e</sup>Missing data for 1 woman. <sup>f</sup>Missing data for 329 women.

gMissing data for 93 women.

hMissing data for 91 women. Missing data for 128 newborns.

<sup>&</sup>lt;sup>j</sup>Missing data for 4 neonates

after a vaginal birth, 51.4% were given oxytocin (n = 797), methergine (n = 132), or both (n = 317) to control bleeding.

There was one pregnancy-related maternal death in the sample. This multiparous mother had no antenatal or intrapartum risk factors. The newborn was born vaginally at home with Apgar scores of 8 and 9 at 5 and 10 minutes, respectively, and the postpartum course for mother and newborn was normal through the first 3 postpartum days. Death occurred at the mother's home on the third day postpartum in the afternoon, following a morning visit by the midwife during which all vital signs had been normal. A blood clot was found in the mother's heart during autopsy; the death was attributed to the pregnancy by the medical examiner.

### **Fetal and Neonatal Morbidity and Mortality**

For all newborns in the sample (including those with congenital anomalies and regardless of actual location of birth), 1.5% (n = 245) had 5-minute Apgar scores below 7, and 0.6% (n = 97) had Apgar scores below 4. Of the 1850 newborns born in the hospital following an intrapartum transfer, 3.7% (n = 69) had a 5-minute Apgar score below 7. During the first 6 weeks postpartum, 479 (2.8%) newborns were admitted to the NICU (Tables 3 and 4).

The rate of intrapartum fetal death (occurring after the onset of labor, but prior to birth) was 1.30 per 1000. The rate of early neonatal death (death occurring after a live birth, but before 7 completed days of life) was 0.88 per 1000; and the rate of late neonatal death (death occurring at 7 to 27 completed days of life) was 0.41 per 1000. When lethal congenital anomaly-related deaths were excluded (n=0 intrapartum, n=8 early neonatal, n=1 late neonatal), the rates of intrapartum death, early neonatal death, and late neonatal death were 1.30 per 1000 (n=22), 0.41 per 1000 (n=7), and 0.35 per 1000 (n=6), respectively (Table 5).

Of the 22 fetuses who died after the onset of labor but prior to birth, 2 were attributed to intrauterine infections, 2 were attributed to placental abruption, 3 were attributed to cord accidents, 2 were attributed to complications from maternal GDM, one was attributed to meconium aspiration, one was attributed secondary to shoulder dystocia, one was attributed to preeclampsia-related complications, and one was attributed to autopsy-confirmed liver rupture and hypoxia. The causes of the remaining 9 intrapartum deaths were unknown. For the 7 newborns who died during the early neonatal period, 2 were secondary to cord accidents during birth (one with shoulder dystocia), and the remaining 5 were attributed to hypoxia or ischemia of unknown origin. Of the 6 newborns that died in the late neonatal period, 2 were secondary to cord accidents during birth, and the causes of the remaining 4 deaths were unknown.

When examining perinatal death rates among higher-risk women, the data suggest that compared to neonates born in vertex presentation, neonates born in breech presentations were at increased risk of intrapartum death (1.09/1000 vertex vs 13.51/1000 breech, P < 0.01), early neonatal death (0.36/1000 vertex vs 4.57/1000 breech, P = 0.09), and late neonatal death (0.30/1000 vertex vs 4.59/1000 breech, P = 0.08). In this sample, primiparous women were at increased risk of having an intrapartum fetal death compared to mul-

tiparous women (2.92/1000 primiparous vs 0.84/1000 multiparous, P < 0.01). Newborns born to primiparas were not, however, at increased risk of either early or late neonatal death. The same pattern was seen for multiparous women with a history of cesarean undergoing a trial of labor after cesarean (TOLAC): an increased risk of intrapartum fetal death, when compared to multiparous women with no prior cesarean (2.85/1000 TOLAC vs 0.66/1000 multiparas without a history of cesarean, P = 0.05; Table 5), but no increase in neonatal death. There was no evidence of increased risk of death among multiple births. When higher-risk women (those with multiple gestations, breech presentation, TOLAC, GDM, or preeclampsia) were removed from the sample, the intrapartum death rate was 0.85 per 1000 (95% CI, 0.39-1.31).

### **Breastfeeding**

At 6 weeks postpartum, 97.7% (n=16,338) of newborns were at least partially breastfed. Only 0.4% (n=70) were never breastfed, and 86.0% (n=14,344) were exclusively breastfed through at least 6 weeks postpartum.

### **DISCUSSION**

In this large national sample of midwife-led, planned home births in the United States, the majority of women and newborns experienced excellent outcomes and very low rates of intervention relative to other national datasets of US women.<sup>27-29</sup> Rates of spontaneous vaginal birth, cesarean, low 5-minute Apgar score (<7), intact perineum, breastfeeding, and intrapartum and early neonatal mortality are all consistent with reported outcomes from the best available population-based observational studies of planned home and birth center births. 2, 10-12, 14, 30 Rates of successful VBAC are higher than reported elsewhere (87% vs 60-80%),<sup>31-33</sup> with no significant increase in early or overall neonatal mortality. There is some evidence of increased intrapartum fetal death associated with TOLAC; however, the total number of events was too low for reliable analysis. Only 4.5% of the total MANA Stats sample required oxytocin augmentation and/or epidural analgesia, which is notably lower than rates of these interventions reported more broadly in the United States (26% for oxytocin augmentation and 67% for epidural analgesia).<sup>27</sup> Rates of operative vaginal birth and cesarean are also substantially lower than those reported for hospital-based US samples (1.2% vs 3.5% and 5.2% vs 32.8%, respectively). 27,29,34 Such reduced rates of obstetric procedures and interventions may result in significant cost savings and increased health benefits for low-risk women who give birth outside of the hospital. 13,35 In addition, fewer than 5% of the newborns born in the hospital after an intrapartum transfer had a 5-minute Apgar score below 7, and 2.1% had a score below 4, indicating relatively low morbidity even among the transferred subsample. These findings are consistent with outcomes reported in the National Birth Center Study II. 14

The reported rate of postpartum hemorrhage (>500 mL for vaginal births) is higher in this sample relative to the rates reported by others (15.4% vs 1.4%-3.7%). However, only 51.4% of women with postpartum hemorrhage received an antihemorrhagic agent. In addition, the frequency of

Table 5. Death Rates for the Entire Sample and for Selected Subgroups* Excluding Lethal Congenital Anomalies	for the Entir	e Sample and for S	elected Subgroups <sup>a</sup> E	xcluding Le	thal Conge	nital Anomalies						
		Intraț	Intrapartum			Early N	Early Neonatal			Late N	Late Neonatal	
			Rate/1000	P			Rate/1000	Ь			Rate/1000	Р
	Deaths	Denominator	(95% CI)	Value <sup>b</sup>	Deaths	Denominator	(95% CI)	Value <sup>b</sup>	Deaths	Denominator	(95% CI)	Value <sup>b</sup>
Overall	22	16,980	1.30 (0.75-1.84)		7	16,950	0.41 (0.11-0.72)		9	16,942	0.35 (0.07-0.64)	
Presentation												
Vertex	18	16,575	1.09 (0.58-1.59)	0.003	9	16,549	0.36 (0.07-0.65)	0.088	5	16,542	0.30 (0.04-0.57)	0.076
Breech	3	222	13.51 (0-28.70)		1	219	4.57 (0-13.50)		1	218	4.59 (0-13.56)	
Parity												
Multiparous	11	13,146	0.84 (0.34-1.33)	0.004	9	13,132	0.27 (0-0.79)	1.0	3	13,126	0.23 (0-0.49)	0.13
Primiparous	11	3773	2.92 (1.20-4.64)		1	3757	0.46 (0.09-0.82)		3	3755	0.80 (0-1.70)	
Trial of Labor After												
Cesarean <sup>c</sup>												
No	<b>%</b>	12,088	0.66 (0.20-1.12)	0.052	5	12,077	0.41 (0.05-0.78)	0.39	7	12,072	0.17(0-0.40)	0.22
Yes	3	1052	2.85 (0-6.07)		1	1049	0.95 (0-2.82)		1	1048	0.95 (0-2.82)	
Multiple Gestation												
Singleton	21	16,914	1.24 (0.71-1.77)	0.14	7	16,831	0.42 (0.11-0.72)	ΡĮ	9	16,823	0.36 (0.07-0.64)	I
Twins	1	120	8.33 (0-24.6)		0	119	1		0	119	I	
Gestational												
Diabetes Mellitus												
No	20	16,787	1.19 (0.67-1.71)	0.013	7	16,759	0.42 (0.11-0.73)	ı	9	16,751	0.36 (0.07-0.64)	ı
Yes	2	132	15.15 (0-35.99)		0	130	1		0	130	I	
Preeclampsia												
No	21	16,880	1.24 (0.71-1.77)	0.037	7	16,862	0.42 (0.11-0.72)	I	9	16,854	0.36 (0.07-0.64)	I
Yes	1	29	34.48 (0-100.89)		0	27 <sup>e</sup>	I		0	27	ı	

Abbreviations: CJ, confidence interval.

<sup>a</sup> There are 4 singleton pregnancies, 3 of which were breech presentations, for which all birth outcomes data are unavailable. These women began labor at home and then transferred to the hospital prior to birth. The midwives of record were contacted, and in each case the midwife did not accompany the mother, nor did the mother return to the midwife for postpartum care.

Fishers exact test where were midwife did not accompany the mother return to the midwife for postpartum care.

Among parous women only.

<sup>d</sup> Dashes indicate value cannot be calculated because there were no events in this subgroup.

<sup>e</sup>One newborn of a mother with preeclampsia died during the early neonatal period of a lethal congenital anomaly and was therefore excluded from all calculations for the neonatal period.

postpartum maternal transfer for excessive bleeding was low overall, suggesting that midwife contributors to MANA Stats did not deem all cases of blood loss greater than 500 mL to require pharmacologic intervention or transfer. We interpret these findings in 2 ways. First, we suspect that the MANA Stats rates for postpartum hemorrhage may be unreliable because they are dependent on visual estimation of blood loss, which has been shown to be highly inaccurate across provider types and birth setting. <sup>39,40</sup> Second, because active management of third stage is less frequent in this sample, and because so few of the women in MANA Stats had intravenous oxytocin administered at the time of birth, our findings call into question, as have other studies, <sup>36,41–43</sup> whether 500 mL is an appropriate benchmark for the diagnosis of postpartum hemorrhage in a physiologic birth population.

It is difficult to compare birth-related mortality statistics across studies; there are so few death outcomes that statistical power is quite low. This is not unexpected: The intrapartum, maternal, and neonatal death rates in high-resource countries are remarkably low overall. The lack of power is further compounded in studies of planned home and birth center births because cohorts from these birth locations are commonly comprised of relatively low-risk women, thus fewer deaths are expected. Furthermore, when examining the home and birth center birth literature to date, there is little consistency in the way that mortality data are defined and reported, and few authors provide confidence intervals or sufficient raw data to allow for comparison. Nonetheless, it is useful to compare death rates associated with planned home and birth center births, as reported across a variety of geographic settings (although confidence intervals around the rates are large) because any potential differences observed can serve to generate hypotheses for future work.

The intrapartum fetal death rate among women planning a home birth in our sample was 1.3 per 1000 (95% CI, 0.75-1.84). This observed rate and CI are statistically congruent with rates reported by Johnson and Daviss<sup>4</sup> and Kennare et al<sup>30</sup> but are higher than the intrapartum death rates reported by de Jonge et al,<sup>10</sup> Hutton et al,<sup>12</sup> and Stapleton et al.<sup>14</sup> While the absolute risk<sup>44</sup> is still quite low, the relatively elevated intrapartum mortality rate in our sample may be partially a function of the higher risk profile of the MANA Stats sample relative to de Jonge et al,10 Hutton et al,12 and Stapleton et al14 whose samples contain primarily low-risk, singleton, vertex births. When women who are at higher risk for adverse outcomes (ie, women with multiple gestations, breech presentation, TOLAC, GDM, or preeclampsia) are removed from our sample, the intrapartum death rate (0.85 per 1000; 95% CI, 0.39-1.31) is statistically congruent with rates reported by Hutton et al.12 and Stapleton et al,14 although still higher than that reported by de Jonge et al.<sup>10</sup> It is also possible that the unique health care system found in the United States-and particularly the lack of integration across birth settings, combined with elevated rates of obstetric intervention—contributes to intrapartum mortality due to delays in timely transfer related to fear of reprisal and/or because some women with higher-risk pregnancies still choose home birth because there are fewer options that support normal physiologic birth available in their local hospitals. 18, 30, 45-48

The early neonatal death rate in our home birth sample was 0.41 per 1000, which is statistically congruent with rates reported by de Jonge et al<sup>10</sup> and the Birthplace in England Collaborative Group.<sup>2</sup> Our combined early and late neonatal death rates, or total neonatal death rate, of 0.77 per 1000 is statistically congruent with the rate reported by Hutton et al.12 Other studies of planned home or planned birth center birth either define neonatal mortality differently or do not define it at all, making comparisons difficult. In addition, some of the intrapartum fetal deaths, as well as some additional neonatal deaths, reported in MANA Stats may have been congenital anomaly-related. There were several incidences when the midwife or receiving physician suspected congenital defect based on visual assessment, but an autopsy or other testing was declined and no official cause of death was assigned. The number of unknown causes of death in our sample is also at least partially attributable to parents declining autopsies<sup>49</sup>; of the 35 intrapartum and neonatal deaths not attributed to congenital anomaly, only 6 received an autopsy.

Collectively, our findings are consistent with the body of literature that shows that for healthy, low-risk women, a planned home birth attended by a midwife can result in positive outcomes and benefits for both mother and newborn. However, the safety of home birth for higher-risk pregnancies, particularly with regard to breech presentation (5 fetal/neonatal deaths in 222 breech presentations), TOLAC (5 out of 1052), multiple gestation (one out of 120), and maternal pregnancy-induced comorbidities (GDM: 2 out of 131; preeclampsia: one out of 28) requires closer examination because the small number of events in any one subgroup limited the effective sample size to the point that multivariable analyses to explore these associations further were not possible. It is unclear whether the increased mortality associated with higher-risk women who plan home births is causally linked to birth setting or is simply consistent with the expected increase in rates of adverse outcomes associated with these complica-

### Limitations

The main limitation of this study is that the sample is not population-based. There is currently no mandatory, reliable data collection system designed to capture and describe outcomes for all planned home births in the United States. We are also unable, for a number of reasons detailed elsewhere,<sup>5</sup> to quantify precisely what proportion of practicing midwives of various credentials contributed data to MANA Stats between 2004 and 2009. In addition, the data entered into the MANA Stats system come from medical records. Because medical records are kept primarily for patient care purposes with secondary uses for billing, research, and legal documentation, researchers using data derived from medical records must be cognizant of these limitations. 50-53 However, we expect that the outcomes reported here were likely to be recorded in the medical record with a reasonably high degree of accuracy because of their importance to clinical care. Furthermore, our pre-/postdata review analysis indicated that data were initially entered with a high degree of accuracy.<sup>5</sup> Finally, we cannot confirm with 100% certainty that participating midwives entered data from all of their clients. However, because the MANA Stats system requires that clients be logged early in prenatal care, any such exclusions would have occurred prior to the outcome of the birth being known.<sup>5</sup>

### CONCLUSION

Descriptive data from the first 6 years (2004-2009) of the MANA Statistics Project demonstrate that for this large, national cohort of women who planned home births under the care of a midwife, perinatal outcomes are congruent with the best available data from population-based observational studies that have evaluated outcomes by intended place of birth and by pregnancy risk profiles. Low-risk women in this sample experienced high rates of normal physiologic birth and very low rates of operative birth and interventions, with no concomitant increase in adverse events. Conclusions are less clear for higher-risk women. Given the low absolute number of events and the lack of a matched comparison group, we were unable to discern whether poorer outcomes among higher-risk women were associated with place of birth or related to risks inherent to their conditions.

Prospective cohort studies with matched comparison groups that utilize the large datasets collected by MANA Stats and AABC's UDS have the potential to address critical gaps in our understanding of birth settings and providers in the United States. We recommend that future research focus on 3 critical questions: 1) What place of birth is most likely to lead to optimal maternal and newborn health, given specific risk profiles and regionally available birth options? 2) What are the characteristics of midwife-led care that contribute to safe physiologic birth? and 3) Regardless of where a woman chooses to give birth, how can clinicians most effectively collaborate across birth settings and provider types to achieve the best possible outcomes for women and newborns?

### **AUTHORS**

Melissa Cheyney, PhD, CPM, LDM, is an Associate Professor of medical anthropology and reproductive biology in the Department of Anthropology at Oregon State University in Corvallis, Oregon. She is also a certified professional midwife, licensed in the State of Oregon, and the Chair of the Division of Research for the Midwives Alliance of North America (MANA).

Marit Bovbjerg, PhD, MS, is a Research Associate (postdoctoral) in the College of Public Health and Human Sciences at Oregon State University in Corvallis, Oregon. She is also the Director of Data Quality for the MANA Division of Research.

Courtney Everson, MA, is a Doctoral Candidate in medical anthropology in the Department of Anthropology at Oregon State University in Corvallis, Oregon. She is also the Director of Research Education for the MANA Division of Research and faculty at the Midwives College of Utah.

Wendy Gordon, MPH, CPM, LM, is a midwife and Assistant Professor in the Department of Midwifery at Bastyr University in Seattle, Washington. She is also a board member and Director of Equity Initiatives for the Association of Midwifery Educators.

Darcy Hannibal, PhD, is a primatologist conducting research on welfare improvement for the Behavioral Management Program at the California National Primate Research Center at the University of California (UC) Davis. She is also Laboratory Manager for the McCowan Animal Behavior Laboratory for Welfare and Conservation in the Department of Population Health and Reproduction at UC Davis.

Saraswathi Vedam, CNM, RM, MSN, FACNM, SciD(hc), is an Associate Professor in the Faculty of Medicine at the University of British Columbia. She serves as Senior Advisor to the MANA Division of Research and practices as a registered midwife in Vancouver, British Columbia.

### **CONFLICT OF INTEREST**

The authors have no conflicts of interest to disclose.

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### Committee on Assessing Health Outcomes by Birth Settings

**February 6, 2020** 

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WENDY GORDON Bastyr University

MARIAN FRANCES MACDORMAN Maryland Population Research Center

M. KATHRYN MENARD University of North Carolina

**KAREN MILGATE** Karen Milgate Health Policy Consulting

JOCHEN PROFIT Stanford University

**CAROL SAKALA** National Partnership for Women & Families

**NEEL SHAH** Harvard Medical School and Ariadne Labs KATHLEEN SIMPSON Mercy Hospital Saint Louis

**RUTH E. ZAMBRANA** University of Maryland

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### Study Staff

**EMILY P. BACKES** 

Study Director

**ELIZABETH S. HOWE-HUIST** 

Associate Program Officer

**DARA SHEFSKA** 

Associate Program Officer

**MARY GHITELMAN** 

Senior Program Assistant

**LESLEY WEBB** 

Senior Program Assistant (through October 2019)

**LORI TREGO** 

NAM Distinguished Nurse Scholar-in-Residence (through August 2019)

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### Statement of Task

An ad hoc committee will provide an evidence-based analysis of the complex findings in the research on birth settings, focusing particularly on health outcomes experienced by subpopulations of women. It will bring together key stakeholders in a public workshop to further inform this analysis, including representatives from government, academia, healthcare provider organizations, third party payers, and women's health

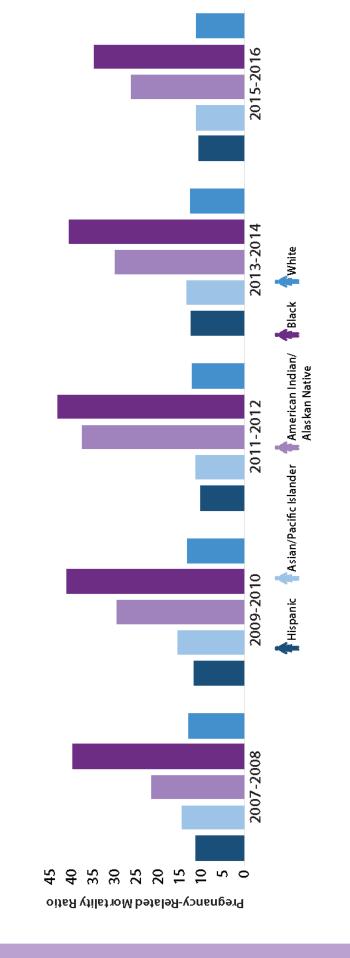
The ad hoc committee will explore and analyze the current state of science on the following topics, identifying those questions that cannot be answered given available

i. Risk factors that affect maternal mortality and morbidity
ii. Access to and choice in birth settings
iii. Social determinants that influence risk and outcomes in varying birth settings
iii. Social determinants that influence risk and outcomes in varying birth settings
iv. Financing models for childbirth across settings
v. Licensing, training, and accreditation issues pertaining to professionals providing maternity care across all settings
v. Learning from international experiences

### Main Messages

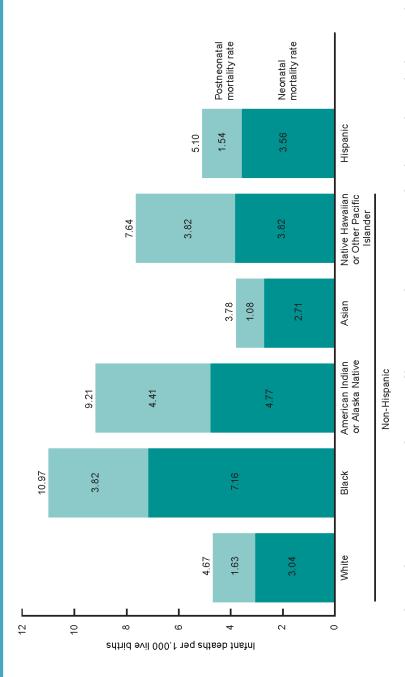
- United States has among the highest rates of maternal and neonatal mortality and morbidity of any high-resource country, particularly among Black and Native American individuals. There is also growing recognition of a mismatch between the collective expectations of the care and exorbitant costs, particularly in comparison with other peer countries. At the same time, the The U.S. maternity system is fraught with uneven access and quality, stark inequities, and support pregnant people deserve and what they actually receive.
- These challenges, while urgent, are not insurmountable, and opportunities for improving the systems that support childbirth exist.
- respectful treatment; to ensure informed choices about medical interventions when appropriate for risk status in all birth settings; and to facilitate integrated and coordinated care across all maternity care providers and all birth settings. economic and geographic access to maternity care in all settings; to provide high-quality and To improve maternal and infant outcomes in the United States, it is necessary to provide
- accreditation bodies, among others—to ensure system-wide improvements for the betterment of Achieving these objectives will require coordination and collaboration among multiple actors– professional organizations, third-party payers, governments at all levels, educators, and all women, newborns, and families.

- and neonatal mortality and morbidity of any high-resource The United States has among the highest rates of maternal country, particularly among Black and Native American women
- discrimination underlie large and persistent racial and ethnic disparities in the quality of care received by Structural racism, implicit and explicit bias, and childbearing women and infants



Trends in pregnancy-related mortality ratio: United States, 2005-2016

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Infant, neonatal, and postneonatal mortality rates, by race and Hispanic origin: United States, 2017

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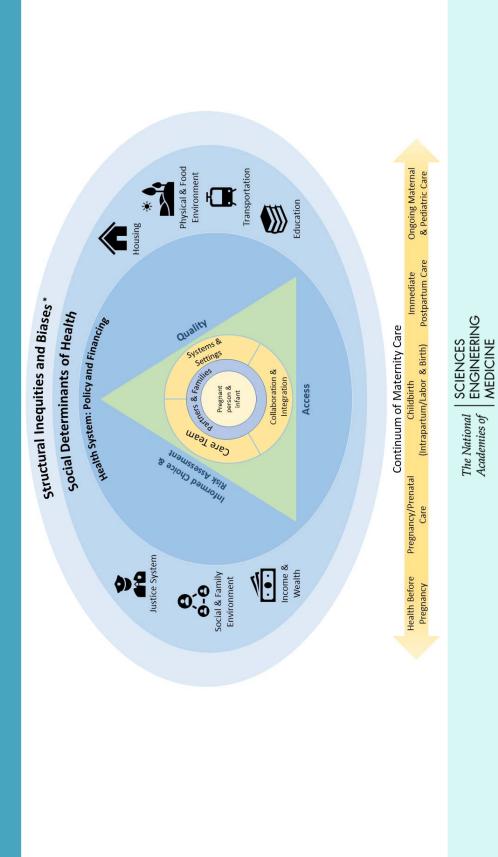
- location. In 2016, more than 5 million women lived in counties (rural or urban) Disparities also exist in maternal and infant mortality rates by geographic with neither an OB/GYN, CNM, nor a hospital with a maternity unit
- The maternal mortality rate in large metropolitan areas was 18.2 per 100,000 live births, but in the most rural areas it was 29.4 per 100,000 (in 2015).
- Infant mortality in rural counties was 6.55 deaths per 1,000 births, 20 percent higher than in large urban counties (in 2014).
- mothers, mortality was 16 percent higher in rural counties (12.08) and 15 percent 1,000) was 41 percent higher than in large urban counties and 13 percent higher Mortality for infants of non-Hispanic White mothers in rural counties (5.95 per than in small and medium urban counties. For infants of non-Hispanic Black higher in small and medium urban counties than in large urban counties.

- Some childbearing women and newborns do not reliably receive quality care that is safe, evidence-based, and appropriate for their health needs and preterences.
- variations in practice, with considerable overuse of non-medically indicated care, Maternal and newborn care in the United States is characterized by broad underuse of beneficial care, and gaps between practice and evidence
- For example, the United States has one of the highest rates of caesarean birth among high-resource countries—31.9 percent of all births.
- The United States continues to outpace its peer countries in the costs of maternity care.

Two urgent questions for women, families, policy makers, and researchers arise:

- designed that allows multiple safe and supportive options for How can an evidence-informed maternity care system be childbearing families?
- How can birth outcomes be improved across and within all birth settings?

# Interactive Continuum of Maternity Care: A Conceptual Framework



# Understanding Birth Settings

### **Definitions**

Birth Center Birth: occur in a freestanding health facility not attached to or inside a hospital Home Birth: occur at a person's residence and can be either planned or unplanned

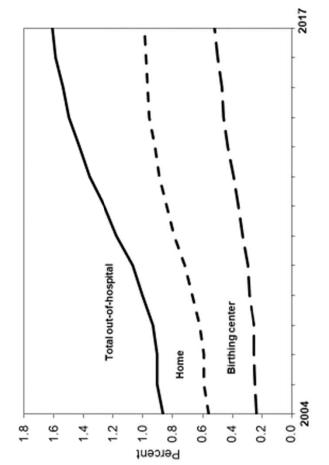
Hospital Birth: those births occurring in a hospital, whether a Level 1 community hospital or a Level 4 maternity unit.

# Understanding Birth Settings

### Settings and Providers

- In the United States, the vast majority (98.4 percent) of women give birth in hospitals, with 0.99 percent giving birth at home and 0.52 percent giving birth in freestanding birth centers
- Nurses, physicians, and midwives provide the majority of maternal and newborn care across birth settings.
- The United States is unique among nations in that it has three types of midwives with nationally recognized credentials: certified nurse midwives (CNMs), certified midwives (CMs), and certified professional midwives (CPMs)

Trends in home and birth center births in the United States, 2004–2017



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# Understanding Birth Settings

### Policy and Financing

- Federal and state laws and regulations help determine which settings and providers are legally able to provide maternity care, and set rules about Medicaid eligibility
- Insurance coverage for home and birth center births varies by state and coverage type.
- where they can practice, what services they can provide, and whether they are States are responsible for licensing health care professionals and for dictating required to be supervised.
- Currently, CNMs are licensed in all 50 states, CPMs are licensed in 33 states, and CMs are licensed in only 6 states

# Risk in Pregnancy and Childbirth

- Risk is defined by the committee as the increased likelihood of an adverse maternal, fetal, or neonatal outcome.
- Risk is conferred by four main sources:
- 1) individual medical and obstetrical factors;
- 2) health system related factors, such as policy and financing decisions;
- 3) the social determinants of health;
- 4) and structural inequities and biases in the health system and in society at large.
- event, or poor outcomes occurring during or after the pregnancy or birth as compared to an The term "high-risk pregnancy" typically describes a situation in which the pregnant woman, fetus, or both have an increased likelihood or odds of a pregnancy complication, adverse uncomplicated or "low-risk" pregnancy.
- The majority of U.S. pregnancies are not high-risk, but rates of conditions that warrant additional monitoring are on the rise.

## **Epidemiology of Clinical Risks**

- At the individual level, a variety of medical and obstetric factors can contribute to elevated risk during pregnancy and birth. Many of these risk factors are increasing in prevalence in the U.S.
- Hypertensive disorders were the cause of 6.8% of maternal deaths from 2011 2015
- Between 6 9% of women develop gestational diabetes during pregnancy
- Rates of first births to women ages 35 and above increased by 23% between 2000 2013
- These individual risk factors can influence women's choices in maternity care. Appropriate risk assessment by qualified providers is needed to match pregnant people with the most appropriate setting and provider for their care during pregnancy and birth.

# Choice, Risk, and Decision Making

- Given the prevalence of medical risk factors in the U.S. population, risk assessment and selection in birth settings is critical to decision making and choice.
- Ongoing risk assessment is needed to determine if maternal or fetal risk factors are present that would place a woman at increased risk of requiring care accessible to her or her newborn only in the inpatient setting.
- Women with decisional capacity have the right to refuse medically recommended care, and may do so for any number of reasons. Maternity care providers have a responsibility to ensure that these are informed refusals, offering resources and information to support informed choice and mitigate bias and misinformation where possible.
- Providers have a responsibility to accurately and transparently inform women about the risks and benefits of their options, and do so in a way that is culturally concordant, easily understandable, and respectful—a process known as **risk communication**.

## Systems-Level Risk Factors

- Systems-level factors can contribute to existing risk factors or create new ones, shaping quality, access, choice, and outcomes in birth settings. Systems-level factors include:
- laws, governance, and culture. They include inequitable treatment in the health care system, the Structural inequalities and biases that are historically rooted and deeply embedded in policies, health effects of racism, and inequitable distribution of resources in society
- The social determinants of health, which are mutable upstream factors that influence health, such as housing instability, transportation, and employment.
- ervices across the country, financing for maternity care, and access to prenatal and birth care. Policy and financing aspects of the health system, including the distribution of maternity care
- higher risk for poor pregnancy outcomes and inequity in care and outcomes. These systems-level factors and social determinants are correlated with
- Understanding the role that non-clinical factors play in determining clinical risk is essential for developing risk-appropriate models of care.

# Challenges Studying Outcomes by Birth Settings

- Data and methodological limitations
- Finding 5-7: Vital statistics and birth registry data each have limitations for evaluating birth outcomes by setting, provider types, and intentionality
- Differing definitions, terminology, and reports of outcomes
- Small number of women giving birth in home and birth center settings
- exploration of the relationship of maternal mortality and severe maternal morbidity to birth A lack of data and the relatively small number of home and birth center births prevent an settings. (Conclusion 6-2).
- Lack of data on differences by race/ethnicity or other subpopulations in comparisons across birth settings
- Modifications to the birth certificate that allow inquiry into birth settings based on models indicating intended setting of birth, including planned attended and planned unassisted home births in the United States and intended birth attendants, and development of best practices for use of these expanded data in birth settings research are needed to better understand and assess outcomes by birth settings. (Conclusion 5-1).

# Maternal and Newborn Outcomes by Birth Setting

- In the United States, home, birth center, and hospital birth settings each offer risks and benefits to the childbearing individual and the newborn. These risks may be modifiable within each setting and across settings. (Conclusion 6-1)
- Finding 6-7: Statistically significant increases in the relative risk of neonatal death in the home compared with the hospital setting have been reported in most U.S. studies of low-risk births using vital statistics data. However, the precise magnitude of the difference is difficult to assess given flaws in the underlying data. Regarding serious neonatal morbidity, studies report a wide range of risk in low-risk home versus hospital birth and by provider type. Given the importance of understanding these severe morbidities, the differing results among studies are of concern and require further study.
- Finding 6-2: Vital statistics studies of low-risk births in freestanding birth centers show an increased risk of poor neonatal outcomes, while studies conducted in the United States using models indicating intended place of birth have demonstrated that low-risk births in birth centers and hospitals have similar to slightly elevated rates of neonatal and perinatal mortality. Studies of the comparative risk of neonatal morbidity between low-risk birth center and hospital births were mixed with variation across studies by outcome and provider

# Maternal and Newborn Outcomes by Birth Setting (cont.)

- fact that women choosing home and birth center births tend to select these settings delivery, induction of labor, augmentation of labor, and episotiomy, and lower rates hemorrhage, and genital tract tearing among low-risk women compared with women choosing hospital birth. These findings are consistent across studies. The birth have lower rates of intervention, including cesarean birth, operative vaginal Finding 6-3: In the United States, low-risk women choosing home or birth center because of their desire for fewer interventions contributes to these lower rates. of intervention-related maternal morbidity, such as infection, postpartum
- caregiver-patient relationship, and involvement in decision making appear to be the Finding 6-4: Some women experience a gap between the care they expect and want and the care they receive. Women want safety, freedom of choice in birth setting expectations, the amount of support received from caregivers, the quality of the and provider, choice among care practices, and respectful treatment. Individual greatest influences on women's satisfaction with the experience of childbirth.

### International Perspective

- Finding 6-5: International studies suggest that home and birth center births may be as safe as hospital births for low-risk women and infants when:
- (1) they are part of an integrated, regulated system;
- (2) multiple provider options across the continuum of care are covered;
- (3) providers are well-qualified and have the knowledge and training to manage first-line complications;
- (4) transfer is seamless across settings;
- (5) appropriate risk assessment and risk selection occur across settings and throughout pregnancy
- Such systems are currently not widespread in the United States.
- across birth settings and maternity care providers is associated with poor birth Finding 6-6: Lack of integration and coordination and unreliable collaboration outcomes for women and infants in the United States.



### Framework for Maternal and Newborn Care in the **United States**

### Culture of Health Equity:

- availability of transportation, housing instability, lack of social support, stress, limited availability of healthy and nutritious foods, lower level of education, and lack of access to health care, including mental health care, are System-level factors and social determinants of health such as structural racism, lack of financial resources, correlated with higher risk for poor pregnancy outcomes and inequity in care and outcomes.
- These system-level factors are modifiable and improving maternal and newborn care in the United States will require interventions outside of the health care system.

## "Right Amount of Care at the Right Time":

- "Too little, too late" and "too much, too soon" patterns in the provision of maternity care contribute to excesses of morbidity and mortality.
- Available care is matched to the preferences, needs, and life circumstances of the woman and her fetus/infant. The woman and infant are matched to a risk appropriate level of care. Rigorous attention to the best available evidence limits overuse of unneeded care and underuse of beneficial care.

### Respectful Treatment:

information in understandable terminology, providing culturally and linguistically appropriate care, providing Need for respectful care for all women by listening to them and responding appropriately, providing risk informed choices around care and interventions, and providing clear and supportive communication for



## Improving Hospital Settings

- guidelines for care in hospital settings have been shown to improve outcomes for pregnant Conclusion 7-1: Quality improvement initiatives...and adoption of national standards and people and newborns in hospital settings.
- (including midwives, physicians, and nurses), and ensuring cultivation of skills in obstetrical some women have difficulty obtaining...according to the best evidence available, can help Conclusion 7-2: Providing currently underutilized nonsurgical maternity care services that residency and Maternal Fetal Medicine fellowship programs can help support such care. existing maternity units, enabling greater collaboration among maternity care providers hospitals and hospital systems ensure that every pregnant person receives care that is respectful, appropriate for their condition, timely, and responsive to individual choices. Developing in-hospital low-risk midwifery-led units or adopting these practices within
- Conclusion 7-3: Efforts are needed to pilot and evaluate high value payment models in maternity care and identify and develop effective strategies for value-based care.

# Improving Home and Birth Center Settings

- assessment and risk selection across settings and throughout the episode of care; and well-qualified Conclusion 7-4: Integrating home and birth center settings into a regulated maternity and newborn care system that provides shared care, and access to safe and timely consultation; written plans for discussion, consultation, and referral that ensure seamless transfer across settings; appropriate risk maternity care providers with the knowledge and training to manage first-line complications may improve maternal and neonatal outcomes in these settings.
- and quality of care in these settings. Additional research is needed to understand variation in outcomes Conclusion 7-5: The availability of mechanisms for all freestanding birth centers to access licensure at the state level and requirements for obtaining and maintaining accreditation could improve access to for birth centers that follow accreditation standards and those that do not.
- practice to the full extent of their scope and areas of competence in all jurisdictions in the United States accredited midwifery education program, and who are nationally certified to access licensure and professional midwives whose education meets ICM Global Standards, who have completed an Conclusion 7-6: The inability of all certified nurse midwives, certified midwives, and certified is an impediment to access across all birth settings

# Improving Informed Choice and Risk Selection

- Conclusion 7-7: Ongoing risk assessment to ensure that a pregnant person is an appropriate candidate for home or birth center birth is integral to safety and optimal outcomes. Mechanisms for monitoring adherence to best-practice guidelines for risk assessment and associated birth outcomes by provider type and settings is needed to improve birth outcomes and inform policy.
- Conclusion 7-8: To foster informed decision making in choice of birth settings, high-quality, evidence-based online decision aids and risk-assessment tools that incorporate medical, risk preferences and tolerance and enable pregnant people, in concert with their providers, obstetrical, and social factors that influence birth outcomes are needed. Effective aids and tools incorporate clinical risk assessment as well as a culturally appropriate assessment of to make decisions related to risk, settings, providers, and specific care practices.

# Improving Access to Care and Birth Settings

- is needed to inform consideration of nation-wide expansion, particularly with regard to effects on reduction Additional research, demonstration, and evaluation to determine the potential impact of state-level models Conclusion 7-9: Access to choice in birth settings is curtailed by a pregnant person's ability to pay. Models for increasing access to birth settings for low-risk women that have been implemented at the state level... of racial/ethnic disparities in access, quality, and outcomes of care.
- Conclusion 7-10: Ensuring that levels of payment for maternity and newborn care across birth settings are adequate to support maternity care options across the nation is critical to improving access.
- to maternal and newborn care, including prenatal and postpartum care. These programs would need to be sustainably financed demonstration model birth centers and hospital services. Such research could explore options for using a variety of maternity care professionals...in underserved communities to increase access adequately resourced maternity care in underserved rural and urban areas, including establishment of adequately funded for evaluation, particularly with regard to effects on reduction of racial/ethnic and Conclusion 7-11: Research is needed to study and develop sustainable models for safe, effective, and geographic disparities in access, quality, and outcomes of care.
- goal of increasing its diversity, distribution, and size. Greater opportunities for interprofessional education, investments are needed to increase the pipeline for the maternity and newborn care workforce...with the Conclusion 7-12: To improve access and reduce racial/ethnic disparities in quality of care and treatment, collaboration, and research across all birth settings are also critical to improving quality of care.



# Future research

Future research is needed:

- 1) To understand safety, quality, and outcomes of each birth setting by type of provider and the profiles of pregnant people such as race/ethnicity, socioeconomic status, gender identity and sexual orientation, and immigrant status as well as risk factors.
- 2) On how to improve the quality of care and outcomes in each setting.
- 3) To understand the impacts of policy and practice changes on racial/ethnic inequities in outcomes.

# Final Thoughts

- System-wide improvements for the betterment of all pregnant people, newborns, and families organizations, third-party payers, governments at all levels, educators, and accreditation are possible with coordination and collaboration from multiple actors: professional bodies, among others.
- Key areas for improving the knowledge base around birth settings and levers for improving policy and practice across settings include:
- providing economic and geographic access to maternity care options in all settings;
- providing high-quality and respectful treatment;
- ensuring informed choices about medical interventions when appropriate for risk status in all birth
- facilitating integrated and coordinated care across all maternity care providers and all birth settings.
- maternity care and build a high-functioning, integrated, regulated, and collaborative maternity care system, a system that fosters respect for all pregnant people, newborns, and While change will take time, there is an urgent need for all to come together to improve families, regardless of their circumstances or birth or health choices.

# Thank you!

To read or download a copy of the report, please visit: www.nationalacademies.org/birthsettings

For more information about the study or dissemination activities, please contact:

Emily P. Backes, JD, MA

Study Director

ebackes@nas.edu

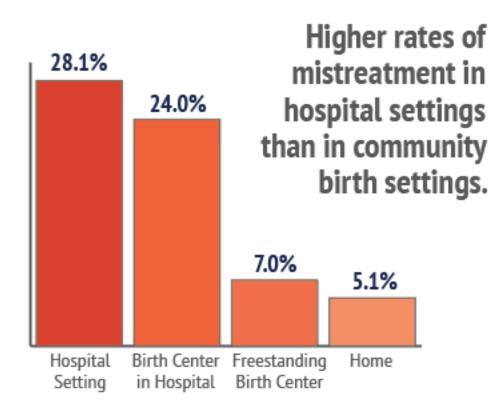


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# Impact of Place of Birth on Mistreatment

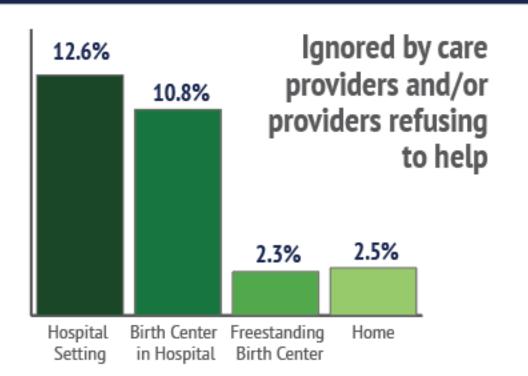
Global health experts agree that how people are treated during childbirth can affect the health and well-being of mother, child, and family. How does the place of birth - hospital or community - affect rates of mistreatment?

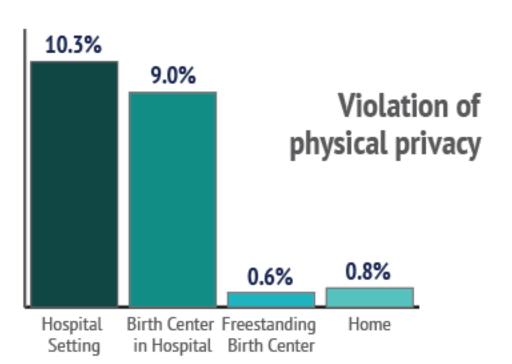
# Place of Birth Impacts Rate of Mistreatment

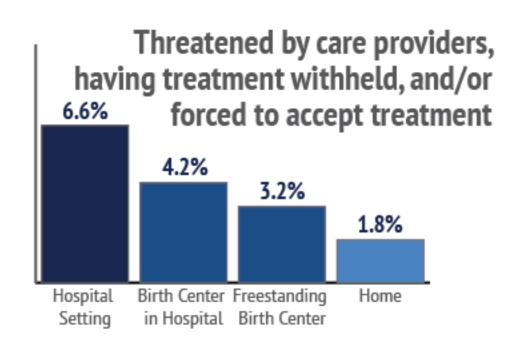


# Place of Birth Impacts Mistreatment for Women of Color 33.9% Women of color who give birth in the hospital 6.6% Women of color who give birth in the community

# Types of Mistreatment by Place of Birth









## Find the full study and learn more at www.birthplacelab.org/mistreatment

Vedam, S., Stoll, K., Khemet Taiwo, T., Rubashkin, N., Cheyney, M., Strauss, N. . . . & the GVtM-US Steering Council. (2019). "The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States". *Reproductive Health*, 16. DOI: 10.1186/s12978-019-0729-2

### **Home Birth Summit**



The Future of Home Birth in the United States: Addressing Shared Responsibility

## Best Practice Guidelines: Transfer from Planned Home Birth to Hospital

"We believe that collaboration within an integrated maternity care system is essential for optimal mother-baby outcomes. All women and families planning a home or birth center birth have a right to respectful, safe, and seamless consultation, referral, transport and transfer of care when necessary. When ongoing inter-professional dialogue and cooperation occur, everyone benefits."

The statement above from the Home Birth Consensus Summit serves as the foundation for the following guidelines on transfer from planned home birth to hospital. These guidelines were developed by a multidisciplinary group of home and hospital based providers and stakeholders who were delegates at the national Home Birth Consensus Summits in 2011 and 2013. These guidelines are informed by the best available evidence on risk reduction and quality improvement and by existing regional policy and practice documents addressing transfer from home to hospital. <sup>2-19</sup>

The purpose of these guidelines is twofold:

- 1. To highlight core elements to be included when developing documents and policies related to transfer from home to hospital.
- 2. To promote the highest quality of care for women and families across birth settings via respectful inter-professional collaboration, ongoing communication, and the provision of compassionate family-centered care.

Collaborative care throughout the antepartum, intrapartum, and postpartum periods is crucial to safety whenever birth is planned outside the hospital setting. Coordination of care and communication of expectations during transfer of care between settings improve health outcomes and consumer satisfaction. <sup>20-34</sup>

State-specific hospital regulations and the Emergency Medical Treatment and Labor Act (EMTALA)<sup>35</sup> establish the legal framework for requiring access to hospital care in the United States. The legal recognition of providers of maternity care services varies between states. However, each woman seeking care at any point during the maternity cycle has the right to optimal and respectful care regardless of her planned birth setting, the persons she selects to be part of the process, or state provider regulations.

These guidelines are appropriate for births planned at home or in a freestanding birth center. Furthermore, we recognize not all providers of home birth or birth center services are midwives. However, we use the term midwife herein because the vast majority of providers of home birth or birth center services identify as midwives.

### Model practices for the midwife

- In the prenatal period, the midwife provides information to the woman about hospital care and procedures that may be necessary and documents that a plan has been developed with the woman for hospital transfer should the need arise. <sup>15</sup>
- The midwife assesses the status of the woman, fetus, and newborn throughout the maternity care cycle to determine if a transfer will be necessary.
- The midwife notifies the receiving provider or hospital of the incoming transfer, reason for transfer, brief relevant clinical history, planned mode of transport, and expected time of arrival. 11,13-16,19
- The midwife continues to provide routine or urgent care en route in coordination with any emergency services personnel and addresses the psychosocial needs of the woman during the change of birth setting.
- Upon arrival at the hospital, the midwife provides a verbal report, including details on current health status and need for urgent care. The midwife also provides a legible copy of relevant prenatal and labor medical records. 11,12,15,16,19
- The midwife may continue in a primary role as appropriate to her scope of practice and privileges at the hospital. Otherwise the midwife transfers clinical responsibility to the hospital provider. <sup>13</sup>
- The midwife promotes good communication by ensuring that the woman understands the hospital provider's plan of care and the hospital provider understands the woman's need for information regarding care options.
- If the woman chooses, the midwife may remain to provide continuity and support.

### Model practices for the hospital provider and staff

- Hospital providers and staff are sensitive to the psychosocial needs of the woman that result from the change of birth setting. <sup>11</sup>
- Hospital providers and staff communicate directly with the midwife to obtain clinical information in addition to the information provided by the woman. <sup>12</sup>
- Timely access to maternity and newborn care providers may be best accomplished by direct admission to the labor and delivery or pediatric unit. 11-15
- Whenever possible, the woman and her newborn are kept together during the transfer and after admission to the hospital.
- Hospital providers and staff participate in a shared decision-making process with the woman to create an ongoing plan of care that incorporates the values, beliefs, and preferences of the woman.
- If the woman chooses, hospital personnel will accommodate the presence of the midwife as well as the woman's primary support person during assessments and procedures.
- The hospital provider and the midwife coordinate follow up care for the woman and newborn, and care may revert to the midwife upon discharge.
- Relevant medical records, such as a discharge summary, are sent to the referring midwife.

### Quality improvement and policy development

All stakeholders involved in the transfer and/or transport process, including midwives based at home or in the hospital, obstetricians, pediatricians, family medicine physicians, nurses, emergency medical services personnel, and home birth consumer representatives, should participate in the policy development process. Policies and quality improvement processes should incorporate the model practices above and delineate at a minimum the following:

- Communication channels and information needed to alert the hospital to an incoming transfer.
- Provision for notification and assembly of staff rapidly in case of emergency transfer.
- Opportunities to debrief the case with providers and with the woman prior to hospital discharge.
- Documentation of the woman's perspective regarding her care during transfer.
- A defined process to regularly review transfers that includes all stakeholders with a shared goal of quality improvement and safety. This process should be protected without risk of discovery.
- Opportunities for education regarding home birth practice, shared continuing medical education, and relationship building that are incorporated into medical, midwifery and nursing education programs. Multi-disciplinary sessions to address system issues may enhance relationship building and the work culture.

Quality of care is improved when policies and procedures are in place to govern best practices for coordination and communication during the process of transfer or transport from a home or birth center to a hospital.<sup>2-10</sup>

### Home Birth Summit, Collaboration Task Force

- Diane Holzer, LM, CPM, PA-C, Fairfax California (Chair)
- Jill Breen, CPM, CLC, Midwife, St. Albans Maine
- Kate T. Finn, MS, CM, CPM, Licensed Midwife, Ithaca New York
- Timothy J. Fisher, MD, MS, FACOG, Chair Department of Surgical Services, Cheshire Medical Center/Dartmouth-Hitchcock Keene, Keene New Hampshire
- Lawrence Leeman, MD, MPH, Professor, Family and Community Medicine,
   Obstetrics and Gynecology, University of New Mexico, Albuquerque New Mexico
- Audrey Levine, LM, CPM, Licensed Midwife, Olympia Washington
- Ali Lewis, MD, FACOG, OB/GYN, Seattle Washington
- Lisa Kane Low, CNM, PhD, FACNM, Associate Professor, Director Midwifery Education, University of Michigan, Ann Arbor Michigan
- Tami J. Michele, DO, FACOOG, OB/GYN, Fremont Michigan
- Judy Norsigian, Executive Director, Our Bodies Ourselves, Cambridge Massachusetts
- Saraswathi Vedam, RM, MSN, FACNM Sci D(hc), Professor, Division of Midwifery, University of British Columbia, Vancouver British Columbia

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### Best Practice Guidelines for Interprofessional Collaboration: Community Midwives and Specialist Providers

### **Background and Context**

Collaborative care throughout the antepartum, intrapartum\*, and postpartum periods is crucial to safety in all birth settings, including hospital, birth center, and home. Collaboration improves health outcomes, as well as quality and experience of care  $(\underline{1,2,3,4})$ . Collaboration between health providers also meets the diverse needs and preferences of families  $(\underline{5})$ .

Optimal care during the childbearing year depends upon both effective interprofessional collaboration and systems-level support for community based providers (1,4,6). Obstetricians, family physicians, nurse-practitioners, and midwives provide care consistent with their education, expertise, and scope of practice. When they work together they can establish systems to enhance effective communication, role clarity, access to services, and coordination of care across settings (1). Best Practice Guidelines for Transfer from Planned Home Birth to Hospital as well as Implementation Tools (https://www.birthplacelab.org/best-practice-guidelines-for-transfer-and-collaboration/) are available and delineate consultation, collaboration, and referral during the intrapartum period. However, most available evidence based guidelines do not specifically delineate the nature of collaboration and coordination of care between community based midwives and physicians during the antepartum, postpartum, and newborn phases. Hence, this document, prepared by the multi-disciplinary Home Birth Summit Collaboration Task Force, describes best practices for promoting interprofessional collaboration across community-based and institutional settings for care during the childbearing year.

### **Ethics**

Ethical practice honors each person's fundamental rights to access appropriate health education, care and consultation. Ethics statements, as established by all health professions, provide guidance for professional conduct and decision making. Ethical treatment respects a person's autonomy to make informed decisions for themselves and their family, without judgement and in consideration of their belief system and values, including the right to accept or decline treatment options without coercion, threat or fear of abandonment.

In a best practice model, the midwife, physician, family, and family participate in a person-centered decision making process, and each provider acts in accordance with ethical standards for all health professions. Coordination of care between healthcare professionals will reflect fairness, honesty, and integrity, and demonstrate mutual respect and concern for the patient/client (7).

### **Equity and Access**

The first step toward achieving health equity in childbirth is to ensure that all patients/clients have access to timely and appropriate care at all stages throughout their pregnancy, birth, and postpartum period (8).

Equity is the quality of being fair, just and impartial without discrimination in regards to race, ethnicity, cultural background, national origin or immigration status, religion, language, sexual orientation or gender expression, health insurance, socio-economic status or difference of belief system or opinion. Putting a focus on reducing barriers to access to care sets an example of health equity that benefits all childbearing families.



For families planning childbirth in a community setting, access to collaboration, consultation and transfer of care is essential to quality, safety, and improved outcomes (4,5). Strengthening collaborative referral networks also addresses rural maternity care workforce shortages, and improves maternal and newborn health disparities common in rural communities throughout the United States (9,10). Emerging evidence suggests that disparities in health outcomes within communities of color can also be improved through intensive, culturally-competent care in homes, and population-specific community clinics and birth centers (11).

### PROVIDER ROLES AND RELATIONSHIPS

### **Vicarious Liability**

The assignment of vicarious liability generally requires a formalized supervisory or employment relationship where a supervising person is held liable for the actionable conduct of a subordinate or agent. This does not generally apply to independent health care providers who engage in collaborative care relationships. As explained by the American College of Obstetricians and Gynecologists document on collaboration and team based care, "Health care providers, including physicians, working in teambased care settings may not always be found to have the requisite principal-agent relationship with other health care team members to be vicariously liable for their actions. In determining legal imputation of vicarious liability, courts will consider the facts of each case, and factors such as statutory and regulatory language in the specific jurisdiction; creation of an agency or employment relationship; and the contractual language in the employment, supervisory, of consultative agreement". (3)

### **Primary Provider in the Childbearing Year**

In North America, the primary provider during the childbearing year may be a midwife, family physician, nurse-practitioner, or obstetrician/gynecologist. Primary providers offer preventive and routine care, including assessment, health promotion and education. If the care needs of the patient/client extend beyond the area of expertise of the primary provider, they will refer and coordinate care with other specialty providers. The accompanying graphic illustrates the intersection between midwives, when they are the primary providers, and need to interact with specialists as needs of the patient/client evolve through the childbearing year.

### **Professional Dialogue (Discussion)**

Professional dialogue refers to an informal conversation between providers, a sharing of opinions and knowledge about management of a specific condition or clinical scenario. Generally this pertains to a clinical question without referencing a particular patient/client. For example, a community midwife may seek input from another midwife or from a specialist physician, by phone or in person. The colleague providing input has not examined or talked with the patient/client or reviewed any medical record. Neither provider formally documents this conversation. Professional dialogue does not constitute a formal consultation or establish a patient-consultant relationship (6).

### Antepartum, Postpartum, and Newborn Consultation

With the agreement of the patient/client, the midwife, as a primary provider, initiates a consultation upon assessment and identification of need for evaluation by another health care professional. Relevant history, reason for consultation, and medical records accompany the request for consultation. The patient/client has a face-to-face appointment with the specialty provider, although it is also possible to have technology-assisted remote consultation. The consultant may provide a diagnostic evaluation, information, recommendations, therapeutic interventions, or other services. The consultant sends a written summary of their assessment and any recommendations to the midwife. Typically, the outcome



of a consultation will be that the patient/client remains in the care of the midwife.

### Collaboration

Collaboration has been defined as "a process involving mutually beneficial active participation between autonomous individuals whose relationships are governed by negotiated shared norms and visions." Collaborative care is a complementary approach to care when medically indicated or requested by the patient/client. In this model, a midwife and physician coordinate their care for a patient/client or newborn according to scope of practice, skills, and established relationships (3). Clear and effective communication between the providers about their respective roles and the care plan is essential, and is documented in the medical record. One health professional takes primary responsibility for ongoing coordination of the collaborative care plan. The plan occurs in the context of a person-centered decision making process that includes the patient/client, midwife, and physician.

### **Transfer of Care**

Transfer of care can happen at any time during the prenatally, intrapartum,\* postpartum, or newborn phase. The transfer is typically initiated by the midwife, after a shared decision making process with the patient/client that addresses the reason(s) for transfer. A transfer can also be at the request of the patient/client. If the transfer requires hospitalization, and community midwife has admitting privileges at the receiving hospital she may continue in a clinical care role, or transfer care to another provider as indicated. Best practices for intrapartum transfer from planned community birth to a hospital are published elsewhere (13) and implementation tools are available at www.birthplacelab.org.

When care is transferred from a community midwife to a physician or hospital affiliated midwife during the antepartum or postpartum periods, the referring midwife remains responsible for the patient/client's care, within their own scope of practice, until the receiving provider has seen the patient/client and agreed to assume responsibility for care. If requested by the patient/client and to facilitate continuity, a referring midwife may participate in communication about the new care plan and continue in a supportive role (12, 13). Care may be transferred back to the referring midwife, when clinically appropriate. In this situation, the physician or hospital affiliated midwife remains responsible until the return transfer of care to the midwife has been confirmed by all parties.

### **Best Practices for the Community Midwife**

- Assesses the status of the patient/client, fetus, or newborn and uses clinical judgment to determine whether discussion, consultation, collaboration, or transfer is indicated.
- Engages with the patient/client in a process of <u>person-centered decision making</u> to explain the assessment and reasons for recommendation that consultation, collaboration, or transfer of care.
- Communicates with the consulting provider, gives a concise verbal and/or written summary of the clinical situation, including indication for consultation, request for collaboration, or transfer, an assessment of specific care needed, and the degree of urgency.
- Provides contact information and patient/client records to the office of the consulting provider along with the patient/client's HIPAA release.
- Documents consultation, collaboration and transfer in the patient/client's record.
- Works with the consulting provider and patient/client to develop a new care plan, including clarifying the continuing role of the midwife.
- Follows up with the patient/client on any recommendations from the consulting provider and continues to assess status and whether a different level of care is appropriate.



- Provides a summary of the clinical outcome to the consulting provider.
- Maintains confidentiality in communications and when discussing the case with other providers in compliance with relevant HIPAA regulations.

### **Best Practices for the Collaborating Provider**

- Responds to the request for consultation, collaboration, or transfer in a timely manner.
- Receives clinical report, verbal or written, from the midwife and reviews the medical record.
- Agrees to make timely appointment with the patient/client in the office or at the hospital, as appropriate to assess the clinical situation.
- Recommends, orders or performs any necessary diagnostic testing or therapeutic intervention, with patient/client consent.
- Provides access to routine labs, tests, and ultrasound evaluation if not available through the midwife's practice.
- Discusses any test results, their assessment, and care recommendations with the patient/client.
- Respects patient/client's autonomy in decision making related to recommendations.
- Respects the relationship between the patient/client and the midwife as the referring provider.
- Sends a written summary of their assessment, copies of diagnostic tests, and any recommendations to the primary provider.
- Maintains confidentiality in communications and when discussing the case with other providers in compliance with relevant HIPAA regulations.

### **Best Practices for Health Systems**

When the organization of care ensures integration of midwives across the health system there are demonstrable improvements in maternal, fetal, and newborn health, quality, and safety. (5,6,14-18). Actionable guidelines and policies for collaboration that are developed by health systems lay a foundation for promoting mutual trust between providers. They also facilitate the patient/client's acceptance of medical services when consultation, collaboration, or transfer is necessary.

### Person-centered, well-integrated health systems:

- 1. Facilitate licensure, regulatory, and institutional credentialing frameworks that support integration of midwives across community and institutional settings.
- 2. Promote and establish systems that support communication, consultation, collaboration, and referral relationships between midwives and other providers.
- 3. Support midwives to provide community based care within a team-based model during antepartum period. Facilitate the midwife's prompt access to result of procedures and assessments such as ultrasound, labs, genetic screening or fetal surveillance results.
- 4. Support presence of midwife during ambulatory encounters if requested by patient/client.
- 5. Offer patients/clients planning a community based birth the opportunity to participate in prenatal/postpartum educational services offered by the system.
- 6. Ensure access for all providers to participate in interdisciplinary protected case reviews.
- 7. Provide opportunities for interprofessional emergency skills training and education that includes midwives, nurses, physicians, and EMS.
- 8. Engage community based midwives and patients/clients in quality assurance and improvement initiatives, including development, implementation and evaluation.
- 9. Facilitate equitable reimbursement for maternal and newborn services by Medicaid and private insurance companies for all providers, in all settings, including home and birth center.



10. Recognize that all primary providers, including midwives, function within their own regulatory frameworks and scopes of practice, and do not require or need supervision by another profession.



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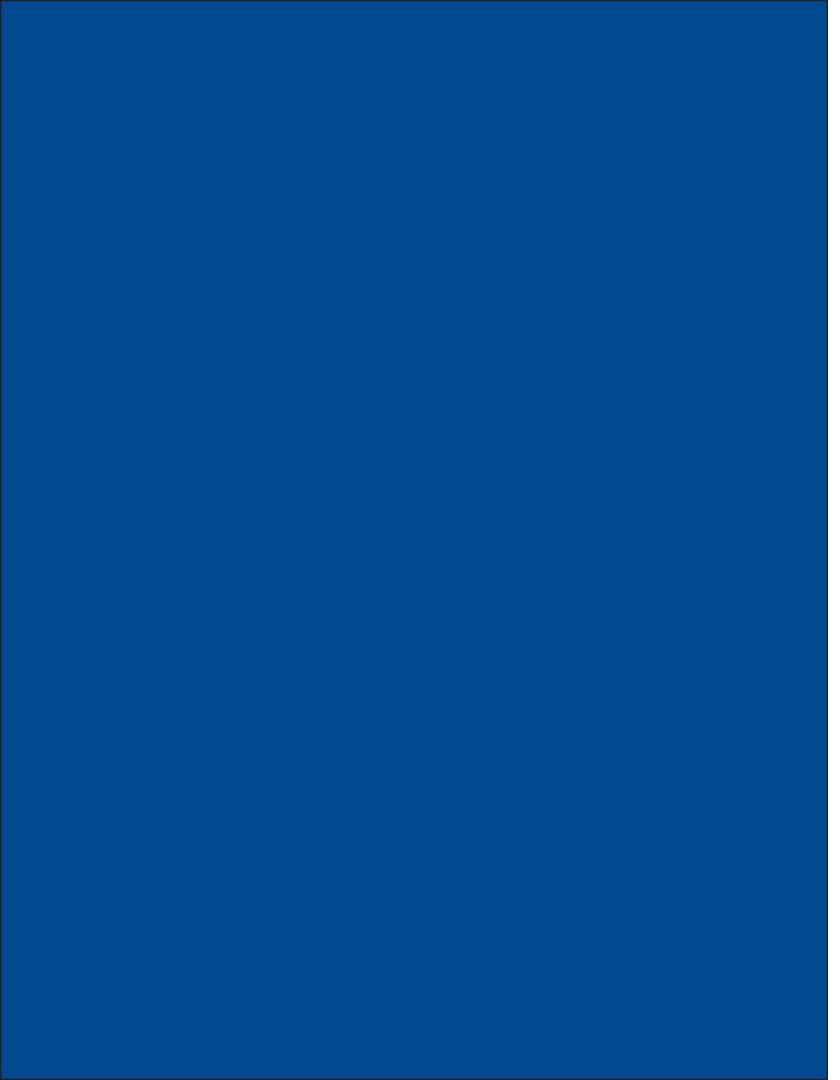






# Evidence-Based Maternity Care: What It Is and What It Can Achieve

by Carol Sakala and Maureen P. Corry



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**Childbirth Connection** 

Reforming States Group

Milbank Memorial Fund

Milbank Memorial Fund 645 Madison Avenue New York, NY 10022

The Milbank Memorial Fund is an endowed operating foundation that engages in nonpartisan analysis, study, research, and communication on significant issues in health policy. In the Fund's own publications, in reports, films, or books it publishes with other organizations, and in articles it commissions for publication by other organizations, the Fund endeavors to maintain the highest standards for accuracy and fairness.

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### TABLE OF CONTENTS

List of Tables, Figures, and Sidebars
Foreword v
Acknowledgmentsvii
Executive Summary
Introduction
Maternity Care in the U.S. Health Care System: Prominent Position, Large Expenditures,  Troubling Performance
Evidence-Based Maternity Care: Effective Care with Least Harm
The Physiologic Foundation of Evidence-Based Maternity Care
Overused Interventions: Examples of Practices to Use Judiciously and with  Careful Attention to Informed Consent
Underused Interventions: Examples of Practices to Use Whenever Possible and Appropriate
Challenges to Closing Evidence-Practice Gaps in Maternity Care in the United States
Policy Recommendations Developed in Collaboration with Members of the
Reforming States Group
Appendix: Leading Resources and Tools for Evidence-Based Maternity Care
References
The Authors
Selected Publications of the Milbank Memorial Fund
Selected Publications of Childbirth Connection

### LIST OF TABLES, FIGURES, AND SIDEBARS

TABLES		
1	Leading Procedures Billed to Medicaid and Private Insurance Payers, United States, 2005	
2	Performance on Selected Indicators of Maternal and Newborn Health, United States, Each State, and District of Columbia	
3	Childbirth in U.S. Hospitals, 2005: Listening to Mothers II Survey	
4	Intervention Rates for Low-Risk Women in the United States and among Births Attended by Certified Professional Midwives, 2000	
FIGURES		
1	Leading Major Diagnostic Categories by Number of Hospital Discharges, United States, 2005	
2	Percentage of Pregnancy, Childbirth, and Puerperium and All-Condition Hospital  Discharges by Payer, United States, 2005	
3	Total Hospital Charges by Payer, United States, 2005	
4	Average Facility Labor and Birth Charge by Site and Mode of Birth, United States, 2003–2005	
5	Preterm Birth Rate and Low Birthweight Rate, United States, 1981–2006 16	
6	Total Cesarean, Primary Cesarean, and Vaginal Birth after Cesarean (VBAC) Rates, United States, 1989–2006	
SIDEBARS		
What Is the "Gold Standard" for Knowledge about Effects of Maternity Care?		
National U.S. Midwifery Credentials: Certified Nurse-Midwife, Certified Midwife, and Certified Professional Midwife		
Diethylstilbestrol (DES) Clarifies Importance of Caution with Perinatal Exposures 33		
Is the Most Resource-Intensive Care the Best Care?		
The Evidence about Vaginal Birth after Cesarean (VBAC) 57		

### FOREWORD

Evidence-based maternity care uses the best available research on the safety and effectiveness of specific practices to help guide maternity care decisions and to facilitate optimal outcomes in mothers and newborns. Although the field of pregnancy and childbirth pioneered evidence-based practice, resulting in a wealth of clear guidance for evidence-based maternity care, there remains a widespread and continuing underuse of beneficial practices, overuse of harmful or ineffective practices, and uncertainty about effects of inadequately assessed practices.

In order to inform coverage and clinical policy decision making for maternity care, Childbirth Connection (CC), the Reforming States Group (RSG), and the Milbank Memorial Fund (MMF) collaborated to write, review, and publish this report. The report presents a discussion of current maternity care in the U.S. health care system and identifies key indicators that show the need for improvement. The report further summarizes results of the many systematic reviews that could be used to improve maternity care quality, identifies barriers to the use of evidence-based maternity care, and offers policy recommendations and other strategies that could lead to wider implementation of evidenced-based maternity care in the United States. These maternity care quality concerns and opportunities for improvement are not widely recognized at this time.

Organized in 1992, the RSG is a voluntary association of leaders in health policy in the legislative and executive branches of government, from all fifty states, Canada, England, Scotland, and Australia. The Milbank Memorial Fund is an endowed national foundation, established in 1905, that works with decision makers in the public and private sectors to carry out nonpartisan analysis, study, and research on significant issues in health policy. Established in 1918, Childbirth Connection (formerly Maternity Center Association) is a national not-for-profit voice for the needs and interests of childbearing families. Its mission is to improve the quality of maternity care through research, education, advocacy, and policy.

Many members of the RSG, as well as others knowledgeable in the field, reviewed successive drafts of this report. As a result of these reviews and the authors' subsequent revisions, we believe that the information in this report is timely and accurate. The matters that have been highlighted by the authors do not necessarily represent the policy preferences of all the members of the RSG or of the other individuals who reviewed drafts of this report.

We thank all who participated in this project.

Eileen Cody Chair, Health Care and Wellness Committee Washington House of Representatives Co-Chair, Reforming States Group Kevin Concannon
Former Director
Iowa Department of Human Services
Past Co-Chair, Reforming States Group

John Nilson Member of the Legislative Assembly Province of Saskatchewan Co-Chair, Reforming States Group

Maureen P. Corry Executive Director Childbirth Connection

Carmen Hooker Odom President Milbank Memorial Fund

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### **EXECUTIVE SUMMARY**

### SYNOPSIS

Effective maternity care with least harm is optimal for childbearing women and newborns. High-quality systematic reviews of the best available research provide the most trustworthy knowledge about beneficial and harmful effects of health interventions. A large, growing body of systematic reviews is available to help clarify effects of maternity practices, yet these valuable resources are grossly underutilized in policy, practice, education, and research in the United States. Practices that are disproved or appropriate for mothers and babies in limited circumstances are in wide use, and beneficial practices are underused. Rates of use of specific practices vary broadly across facilities, providers, and geographic areas, in large part because of differences in practice style and other extrinsic factors rather than differences in needs of women and newborns. These gaps between actual practice and lessons from the best evidence reveal tremendous opportunities to improve the structure, process, and outcomes of maternity care for women and babies and to obtain greater value for investments. This report points the way to achieving these gains for the large population of childbearing women and newborns and for those who pay for their care.

### REPORT AIMS

This report has several aims:

- to position maternity care within the U.S. health care system and to identify key indicators that clarify the need for improvement
- to present a framework for identifying the best available research, based on the principle of
  effective care with least harm, and to apply the framework to maternity care
- to summarize results of many systematic reviews that could be used to improve maternity care
  quality, with a focus on opportunities to increase benefit and/or reduce harm for large segments
  of the population of childbearing women and newborns
- to identify barriers to wider implementation of evidence-based maternity care in the United States
- to identify policy and other strategies that, if adopted, could lead to wider implementation of evidence-based maternity care in the United States

### REPORT AUDIENCES

This report is directed toward many stakeholder groups. It is a priority to communicate about these matters with policymakers who have legislative, executive, delivery system, purchasing, and other responsibilities for maternity care. Members of the Reforming States Group, a voluntary association of state-level health policymakers, have helped ensure that the strategies for quality improvement and other sections of this report can assist policymakers with efforts to improve maternity care. The report

is also directed to others who are involved with maternity care, including health professionals and health profession educators, hospital and health plan administrators, insurers, employers, researchers, childbearing women and their families, consumer advocates, and journalists.

### MATERNITY CARE IN THE U.S. HEALTH CARE SYSTEM

Childbearing is a major life passage for over 4.3 million mothers, newborns, and families annually in the United States. Within the U.S. health care system, childbirth is the leading reason for hospitalization. About 23 percent of all individuals discharged from hospitals are mothers or newborns. The current style of maternity care is procedure-intensive, and six of the fifteen most commonly performed hospital procedures in the entire population are associated with childbirth. Cesarean section is the most common operating room procedure in the country. Only three reasons for outpatient visits involve more visits annually than maternity care (prenatal and postpartum visits combined): general medical examination, progress visit, and cough.

### FINANCING MATERNITY CARE

Due to the large number of births per year and this technology-intensive style of care, hospital charges for birthing women and newborns far exceed those of any other condition. Costs of this care especially impact employers and private insurers, the primary payers for 51 percent of the births, and taxpayers and Medicaid programs, primary payers for 42 percent. "Mother's pregnancy and delivery" is the most costly hospital condition for both Medicaid and private insurers, followed by "newborn infants." These conditions are associated with 27 percent of hospital charges to Medicaid and 15 percent of hospital charges to private insurers.

Charges for childbirth vary considerably depending on the type and place of birth. The average hospital charge in 2005 ranged from about \$7,000 for an uncomplicated vaginal birth to about \$16,000 for a complicated cesarean section, and charges for newborn care, anesthesia services, and the maternity provider involved additional expense. By contrast, childbirth charges in a national survey of out-of-hospital birth centers were about one-quarter of the charges of uncomplicated vaginal birth in hospitals (\$1,624 in 2003, when the national average charge for uncomplicated vaginal birth in hospitals was \$6,239), in addition to charges for maternity provider services.

Actual payments tend to be lower than charges, but payment data are difficult to obtain. A recent analysis of a large database of payments for all maternity services (excluding newborn care) was weighted to reflect the national population of childbearing women with commercial insurance; the report concluded that average payments for cesarean births exceeded those for vaginal births by nearly 50 percent, adding several thousand dollars to insurers' expenditures. Another recent analysis estimated that the average total prenatal and intrapartum expenditure for women with a code for "normal pregnancy and delivery" was \$7,564 (2004 dollars), with over three-quarters of the expense

concentrated in the hospital stay. Although the cost of prenatal care for Medicaid and privately insured women was similar, the hospital component of care for privately insured women was about \$2,000 more than the hospital component for women with Medicaid coverage.

### PERFORMANCE OF THE U.S. MATERNITY CARE SYSTEM

Many performance indicators raise concern about U.S. maternity care. A mid-course review of national Healthy People 2010 objectives for the country found that we have been moving away from targets for many maternity objectives, including low birthweight and preterm birth measures, cerebral palsy, mental retardation, and cesarean measures. Changes in measurement make it difficult to understand trends in maternal mortality, which may be rising after stagnating with no improvement at the end of the past century. The national cesarean rate has increased annually from the mid-1990s and has reached a record level each successive year of the present century. Four percent of women lack access to insurance for childbirth, and a much larger proportion transitions from being uninsured to having insurance coverage during pregnancy. Rates of specific indicators vary widely across states. In comparison with white non-Hispanic and Hispanic mothers, black mothers experience a breadth and depth of disparity in maternity care delivery and outcomes. Cross-national comparisons from the World Health Organization and the Organisation for Economic Co-operation and Development clarify that many other nations are doing a better job with measures such as perinatal, neonatal, and maternal mortality, low birthweight, and cesarean rates. Nonetheless, per capita health expenditures for the United States far exceed those of all other nations. These outcomes, together with costly, procedure-intensive care, have been called the "perinatal paradox: doing more and accomplishing less."

### FRAMEWORK FOR EVIDENCE-BASED MATERNITY CARE

Evidence-based maternity care uses the best available research on the safety and effectiveness of specific practices to help guide maternity care decisions and to facilitate optimal outcomes in mothers and newborns. Various care paths that might be pursued in a specific situation can involve very different benefit/harm profiles. Evidence-based maternity care gives priority to effective care with least harm.

A rigorous, well-conducted systematic review of original studies yields the most trustworthy knowledge about beneficial and harmful effects of specific interventions. Randomized controlled trials are especially valuable original studies, but have some important limitations. Other types of study designs are often needed to help answer important questions. Many factors shape both views about suitable care and patterns of care, which often do not reflect the best current research. Thus, it is always important to ensure that policy and practice are in fact guided by the best available research. Informed decision making should consider safety and effectiveness as well as values and circumstances of individual women.

Although most childbearing women and newborns in the United States are healthy and at low risk for complications, national surveys reveal that essentially all women who give birth in U.S. hospitals experience high rates of interventions with risks of adverse effects. Optimal care avoids when possible interventions with increased risk for harm. This can be accomplished by supporting physiologic childbirth and the innate, hormonally driven processes that developed through human evolution to facilitate the period from the onset of labor through birth of the baby, the establishment of breastfeeding, and the development of attachment. With appropriate support and protection from interference, for example, laboring women can experience high levels of the endogenous pain-relieving opiate beta-endorphin and of endogenous oxytocin, which facilitates labor progress, initiates a pushing reflex, inhibits postpartum hemorrhage, and confers loving feelings. Large national prospective studies report that women receiving this type of care are much less likely to rely on pain medications, labor augmentation, forceps/vacuum extraction, episiotomy, cesarean section, and other interventions than similar women receiving usual care. Such physiologic care is also much less costly and thus provides outstanding value for those who pay for it. Burgeoning research on the developmental origins of health and disease clarifies that some early environmental and medical exposures are associated with adverse effects in childhood and in adulthood. Recognition of known harms and the possibility that many harms have not yet been clarified further underscores the importance of fostering optimal physiologic effects and limiting use of interventions whenever possible.

### OVERUSED MATERNITY PRACTICES

Many maternity practices that were originally developed to address specific problems have come to be used liberally and even routinely in healthy women. Examples include labor induction, epidural analgesia, and cesarean section. These interventions are experienced by a large and growing proportion of childbearing women; are often used without consideration of alternatives; involve numerous co-interventions to monitor, prevent, or treat side effects; are associated with risk of maternal and newborn harm; and greatly increase costs. Mothers, babies, and purchasers would benefit from giving priority to effective, safer care paths and using risky interventions for wellsupported indications only or when other measures are inadequate. The following practices would instead be consistent with the framework of this report: avoiding induction for convenience; using labor support, tubs, and other validated nonpharmacologic pain relief measures and stepping up to epidurals only if needed; and applying the many available measures for promoting labor progress before carrying out cesarean section for "failure to progress." Such protocols would require considerable change in many settings, but would lead to a notable reduction in the use of more consequential procedures and an increase in cost savings. Available systematic reviews also do not support the routine use of other common maternity practices, including numerous prenatal tests and treatments, continuous electronic fetal monitoring, rupturing membranes during labor, and episiotomy.

### UNDERUSED MATERNITY PRACTICES

Systematic reviews also clarify that many effective maternity practices with modest or no known adverse effects are underutilized. Greater fidelity in providing these forms of care would lead to improved outcomes for many mothers and babies. In pregnancy, such care includes prenatal vitamins, smoking cessation interventions, measures for preventing preterm birth, and hands-to-belly maneuvers to turn fetuses to a head-first position before birth. The many beneficial, underused practices around the time of birth include continuous labor support, numerous measures that increase comfort and facilitate labor progress, nonsupine positions for giving birth, delayed cord clamping, and early mother-baby skin-to-skin contact. Best available evidence also supports providing access to vaginal birth after cesarean (VBAC) for most women with a previous cesarean. Systematic reviews also identify many strategies for increasing both establishment and duration of breastfeeding and effective ways to treat postpartum depression.

### BARRIERS TO EVIDENCE-BASED MATERNITY CARE

Efforts to increase access to evidence-based maternity care should address barriers to quality improvement. Barriers to evidence-based maternity care include the following:

- lack of a set of robust maternity performance measures with buy-in of key stakeholders to use them for measuring, reporting, rewarding, and improving performance
- perverse incentives of payment systems
- adverse effects of the malpractice system
- primary reliance on specialists for providing maternity care to a predominantly healthy, low-risk population
- limited reliance on best evidence in leading guidelines for maternity care
- loss of core childbearing knowledge and skills among health professionals
- limited attention to harms and iatrogenesis
- challenge of translating research into practice
- adverse effects of pressure from industry
- inadequate informed consent processes and women's lack of preparation for making informed decisions
- limitations of views put forth in media and popular discourse

Efforts to improve payment systems, the liability system, consumer decision making processes, and other factors that impact clinical decisions should identify best evidence and develop policies, programs, and processes that align these systems with optimal care.

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### POLICY AND OTHER STRATEGIES TO HELP ALIGN PRACTICE WITH EVIDENCE

Members of the Reforming States Group have worked with the authors of this report to identify the following priority strategies to increase provision of evidence-based maternity care:

- increase awareness about concerns with the present maternity care system and knowledge of
  evidence-based maternity care by educating and advising the range of stakeholders
- support research to further evidence-based maternity care
- reform the current reimbursement system to promote evidence-based maternity care and involve federal and state payers and private insurers
- require performance measurement, reporting, and improvement.

The report provides specific recommendations for operationalizing these strategies.

### INTRODUCTION

This report addresses the scientific basis for maternity practice. It begins by positioning care for the large, distinctive population of childbearing women and newborns within the U.S. health care system and describing performance on several maternity care quality indicators. The report then provides a framework for understanding "evidence-based maternity care," including the relationship between evidence about human physiology and evidence about specific maternity practices. Evidence-based maternity care uses best available evidence to identify and provide optimal maternity care, defined as effective care with the least harm. The report then identifies a series of practices that are overused, as they have an unfavorable benefit/harm profile and good evidence points to the availability of effective, safer, and less costly options for most women. The next section identifies underused practices that offer established benefit with little or no identified risk. Mothers and babies would benefit from judicious, more restrictive use of the overused practices and more extensive use of underused practices. The examples identify important opportunities for improving the quality of maternity care for large proportions of mothers and babies through provision of effective care with minimal harm. While a comprehensive, up-to-date overview of best maternity evidence is needed, such an overview is beyond the scope of this technical report. Final sections of the report describe some of the greatest challenges to reducing the evidence-practice gaps and identify policy and practice strategies that might be used to narrow the gaps.

The Committee on Quality of Health Care in America and the Institute of Medicine's landmark 2001 report, Crossing the Quality Chasm: A New Health System for the 21st Century, outlined fundamental concerns with the quality of health care in the United States. The report identified six aims for improvement that have been widely adopted: health care should be safe, effective, patient-centered, timely, efficient, and equitable. A major theme of the report was the importance of providing care that is based on the best available scientific evidence. The report identified impediments to such care, including underuse of beneficial care, overuse of services unlikely to offer benefits, and illogical variation in care from provider to provider and place to place. The report found that these concerns have troubling implications for health outcomes and efficient use of resources.

As detailed in the following section, more than 4.3 million babies are born in the United States every year, a life passage with major consequences for mothers, newborns, and families. Within the health care system, childbirth is the leading reason for hospitalization, and charges for birthing women and newborns far exceed hospital charges for any other condition. Notably, a follow-up Institute of Medicine report, *Priority Areas for National Action: Transforming Health Care Quality*, identified pregnancy and childbirth as a national priority area for health care quality improvement (Adams, Corrigan, et al. 2003).

Maternity care has attributes that distinguish it from much other health care. The "Bridges to Health" model identified childbearing women and infants as one of eight population segments with distinct characteristics that must be addressed if the entire population is to achieve the Institute of Medicine's aims for improvement (Lynn et al. 2007). Another contribution points to numerous similarities between maternity care and end-of-life care, in contrast to the delivery of health care for

many other conditions (Clark 2008). Distinctive attributes of care for childbearing families include the following:

- the challenge of caring for a primarily healthy population within acute care facilities that focus
  on treatment of pathology
- the difficulty of predicting how childbirth will unfold and the individual nature of the experience
- the importance of the continuous attentive presence of caregivers and loved ones
- the importance of respectful care of women and families—including clear communication, high-quality information, and control over decision making—and of their positive memories of the experience
- incentives arising from service bundling and global fee payment systems that encourage use of
  interventions and measures to hasten and control childbirth even though such care generally is
  not optimal for mothers and babies
- missed opportunities to prepare women to make informed decisions during their pregnancy and well before labor
- the challenge for women of making informed decisions about many crucial care matters while in labor and constraints on their choice at that time
- the great extent to which services could be calibrated to provide more appropriate care and to increase benefit and reduce harm and waste
- concerns about the severe impact of the malpractice system on maternity services
- exclusion of this clinical area from many established quality initiatives due to their focus, for example, on Medicare beneficiaries or chronic conditions

The evidence base for care during pregnancy and childbirth has been progressively developed and refined over several decades. Three comprehensive overviews of best evidence in the field were published in 1989: Effective Care in Pregnancy and Childbirth (Chalmers, Enkin, and Keirse 1989), A Guide to Effective Care in Pregnancy and Childbirth (Enkin, Keirse, and Chalmers 1989), and Oxford Database of Perinatal Trials (Chalmers 1989–92). Through updating and further development of these or successor products, along with the work of many other organizations, agencies, and individuals, a large, growing body of systematic reviews is available to guide maternity policy, practice, education, and research.

However, comparing current maternity care practice and performance in the United States to lessons from the best available research and to performance benchmarks reveals large gaps. Consistent with common patterns of innovation in medicine (McKinlay 1981), obstetric practices such as episiotomy (Graham 1997) and electronic fetal monitoring (Graham et al. 2004; Hoerst and Fairman 2000) were adopted prior to adequate evaluation. Implementation of best evidence has proven to be extremely difficult following adequate evaluation. Therefore, many practices that are

disproved or appropriate for mothers and babies only in limited circumstances are in wide use. Conversely, numerous beneficial practices are underused because they offer limited scope for economic gain, are less compatible with predominant medical values and practices, have only recently been favorably evaluated, or due to other reasons. Beyond average overall gaps between evidence and practice, use of specific maternity practices varies broadly across facilities, providers, and geographic areas. This is primarily due to differences in practice style and other extrinsic factors rather than differences in needs of mothers and newborns. These gaps between where we are and what we could achieve present opportunities to improve the structure, process, and outcomes of care for mothers and babies and to obtain greater value for investments.

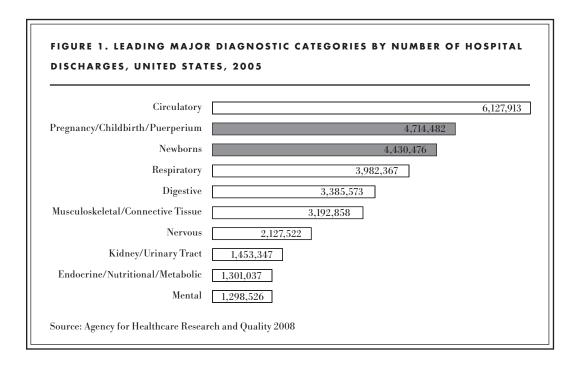
The discussion of overused and underused practices focuses on some of the greatest opportunities for increasing benefit and/or reducing harm for large segments of the population of childbearing women and newborns. It is not intended to be a comprehensive review of the evidence about maternity care. The Appendix points to many excellent resources for a more comprehensive understanding of evidence-based maternity care. Most are freely available to those with Internet access. Despite the abundance of resources, there are important areas where systematic evidence is not presently available and adequate to guide practice, such as evidence about effective pre- and interconceptional care, care for childbearing teenagers, and interventions to prevent and treat alcohol abuse and depression in pregnancy.

This report was developed to inform many stakeholder groups. It is a priority to communicate with policymakers who have legislative, executive, delivery system, purchasing, and other responsibilities about these matters. Sections on barriers to optimal care and on policy and other strategies for closing evidence-practice gaps are intended to assist policymakers with efforts to improve maternity care. The involvement of policymakers from the Reforming States Group has strengthened the entire report and these sections in particular. This report is also directed to many others who are involved with maternity care, including health professionals and health profession educators, hospital and health plan administrators, insurers, employers, researchers, childbearing women and their families, consumer advocates, and journalists.

## MATERNITY CARE IN THE U.S. HEALTH CARE SYSTEM: PROMINENT POSITION, LARGE EXPENDITURES, TROUBLING PERFORMANCE

### MATERNITY CARE LEADING REASON FOR HOSPITALIZATION/OFFICE VISITS

With over 4.3 million births every year, childbirth is the leading reason for hospitalization in the United States, exceeding such prevalent conditions as pneumonia, cancer, heart failure, bone fracture, and stroke (Kozak, DeFrances, and Hall 2006). Figure 1 lists leading major diagnostic categories by number of hospital discharges in 2005. Combined annual discharges for childbearing women and newborns greatly surpassed those for other major categories. In the 2005 Nationwide Inpatient Sample, 23 percent of all hospital discharges (9,144,958 among 39,163,834 total discharges) were for these two major diagnostic categories (Agency for Healthcare Research and Quality 2008).



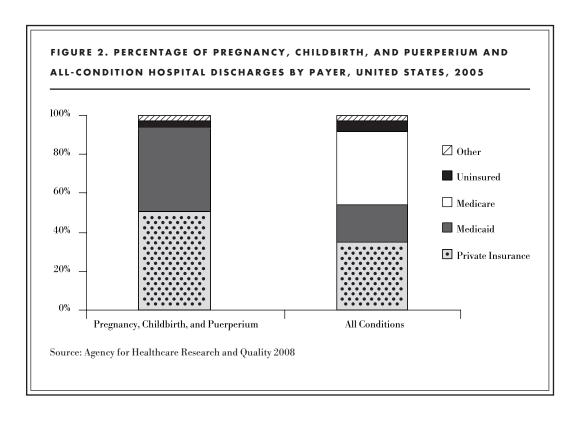
Maternity care is also a leading reason for ambulatory visits. Within the entire population in 2003–2004, maternity care (combined prenatal and postpartum visits) was the fourth most common reason for an outpatient visit, exceeded only by general medical examination, progress visit, and cough, and representing 2.8 percent of all outpatient visits (Hing 2007).

## HOSPITAL CHARGES FOR CURRENT STYLE OF MATERNITY CARE HIGHEST OF ALL HOSPITAL CONDITIONS

Hospitalization is by far the largest component of health care costs, and hospital charges for the current style of childbirth are considerable. Combined hospital charges for birthing women (about

\$44 billion) and newborns (about \$35 billion) totaled \$79,277,733,843 and far exceeded charges for any other condition in 2005 (Agency for Healthcare Research and Quality 2008).

In 2005, private insurers paid for 51 percent of hospital stays for childbirth in the United States, and Medicaid paid for 42 percent of these stays, with variation in these proportions across states. These payers were responsible for markedly greater proportions of childbirth payments than for all conditions combined (Figure 2) (Agency for Healthcare Research and Quality 2008).



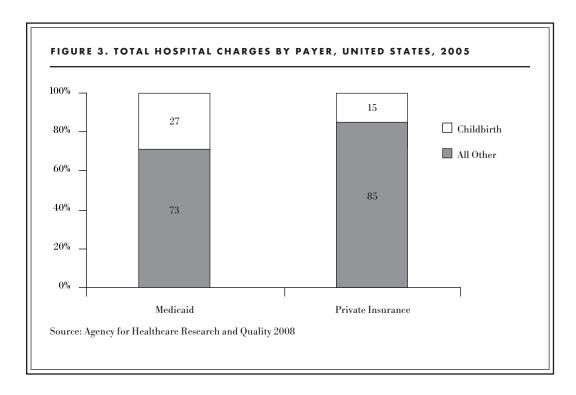
Thus, the financial toll of maternity care on private payers/employers and Medicaid/taxpayers is especially large. In 2005, fully 27 percent of hospital charges (or \$34,164,460,561) to Medicaid and 15 percent of hospital charges (or \$39,726,164,301) to private insurers were for birthing women and newborns (Figure 3). "Mother's pregnancy and delivery" was the most expensive condition for both payers, followed by "newborn infants" (Andrews and Elixhauser 2007).

The procedure-intensity of these hospital stays helps to explain the level of expense. In 2005, 49 percent of all hospital procedures performed on all individuals aged eighteen to forty-four were obstetric procedures, and six of the fifteen most commonly performed hospital procedures in the entire population involved childbirth (Agency for Healthcare Research and Quality 2008):

- medical induction, manually assisted delivery, and other procedures to assist delivery (number 2)
- repair of current obstetric laceration (number 6)

- cesarean section (number 7)
- circumcision (number 8)
- fetal monitoring (number 13)
- artificial rupture of membranes (number 14)

Six of the ten most common procedures billed to Medicaid and to private insurers in 2005 were maternity related (Table 1). Cesarean section was the most common operating room procedure for Medicaid, for private payers, and for all payers combined (Agency for Healthcare Research and Quality 2008).



Maternity care thus plays a considerable role in escalating health care costs, which increasingly threaten the financial stability of families, employers, and federal and state budgets (Blumenthal 2006; Cowan and Hartman 2005).

### GREAT VARIANCE IN CHARGES AND PAYMENTS BY TYPE AND PLACE OF BIRTH

In 2005, the national average hospital charge for childbirth ranged from about \$7,000 to nearly \$16,000, depending on whether the birth was vaginal or cesarean and, further, was coded as uncomplicated or complicated (Figure 4). A national 2003 survey puts hospital charges in further perspective. In eighty-six freestanding birth centers across the country, the average childbirth charge was about \$1,600, one-

TABLE 1. LEADING PROCEDURES BILLED TO MEDICAID AND PRIVATE INSURANCE PAYERS, UNITED STATES, 2005

Rank	Medicaid-Billed Procedure	Private Insurance-Billed Procedure
1	Medical induction, manually assisted	Medical induction, manually assisted
	delivery, and other procedures to	delivery, and other procedures to
	assist delivery	assist delivery
2	Cesarean section	Repair of current obstetric laceration
3	Repair of current obstetric laceration	Circumcision
4	Prophylactic vaccinations	Cesarean section
	and inoculations	
5	Circumcision	Other therapeutic procedures
6	Fetal monitoring	Diagnostic cardiac catheterization,
		coronary arteriography
7	Artificial rupture of membranes	Blood transfusion
8	Other therapeutic procedures	Fetal monitoring
9	Other vascular catheterization, not heart	Artificial rupture of membranes
10	Blood transfusion	Other vascular catheterization, not heart

Source: Agency for Healthcare Research and Quality 2008

quarter of the hospital charge for uncomplicated vaginal birth that year (Figure 4). These figures do not include additional hospital-only charges for newborn care and additional anesthesia services charges for most hospital births, as well as maternity provider fees for all births. The National Birth Center Study of nearly twelve thousand women found excellent outcomes and very high levels of satisfaction with birth center care (Rooks et al. 1989; Rooks, Weatherby, and Ernst 1992a, 1992b, 1992c); this comparison suggests that the level of resource use in hospitals for uncomplicated vaginal births could be much lower. At present, less than 1 percent of childbearing women in the United States experience the style of care and efficient use of resources of freestanding birth centers (Martin et al. 2007).

Actual payments for medical services are generally somewhat lower than charges; however, payment data are often not publicly available. A recently reported analysis of a database of employer-sponsored health insurance attempted to measure comprehensive payments (rather than charges) for having a baby, including hospitalization, ambulatory visits, outpatient medications, laboratory services, and radiology/imaging services. Newborn care was not included, and elimination of outliers led to further underestimation of average payments. The database included about 1 percent of U.S.

births in 2004, and was weighted to reflect the national population of childbearing women covered by commercial insurance. The study found that actual payments were well below charges. It also found a large differential between vaginal and cesarean births, with average payments for cesarean births (\$10,958) exceeding average payments for vaginal births (\$7,737) by nearly 50 percent. The average vaginal-cesarean differential was \$2,090 for hospital payments and \$723 for payment of professional fees (Thomson Healthcare 2007).

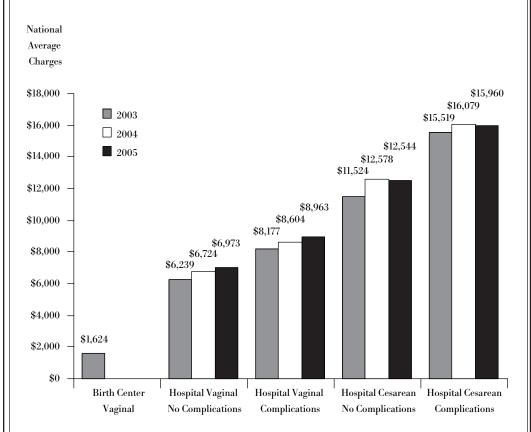
Another recent national analysis used federal Medical Expenditure Panel Survey results to estimate all prenatal and in-hospital childbirth expenditures in 2004 for women with a Clinical Classification Code of "normal pregnancy and delivery." The analysis considered all sources of payment and included all professional services, hospital charges, prescription medications, and other expenses. Expenses associated with newborns appear to have been excluded. The analysis pooled and did not distinguish vaginal and cesarean births. Investigators estimated that combined average prenatal and childbirth costs were \$7,564, with delivery expenses (\$5,850) involving about five times the expense of prenatal care (\$1,159). Expenditures for privately insured women were higher than average (\$8,366 total, \$6,520 delivery), and expenditures for women with Medicaid coverage were lower than average (\$6,540 total, \$4,577 delivery), with differences concentrated in the childbirth component. Privately insured women paid about 8 percent of the expenses out of pocket, and Medicaid-insured women were responsible for about 1 percent of expenses (Machlin and Rohde 2007).

### OVERALL PERFORMANCE A CONCERN AND MANY TRENDS HEADED IN WRONG DIRECTION

The U.S. Department of Health and Human Services established national Healthy People 2010 objectives for the first decade of this century. A midcourse review of progress found movement away from targets for low birthweight and very low birthweight, all preterm birth (live births before thirty-seven completed weeks of gestation), preterm births of thirty-two through thirty-six weeks of gestation, maternal labor and birth complications, initial ("primary") and repeat cesareans in low-risk women, cerebral palsy, and mental retardation. Numerous other maternity-related goals had not reached 15 percent of their targets at midcourse, including perinatal mortality—the child mortality measure most closely associated with the quality of maternity care (U.S. Department of Health and Human Services 2006).

In the quarter-century from 1981 to 2006, the national rate of preterm birth increased by 36 percent, and the proportion of low birthweight babies increased by 22 percent (Figure 5) (Hamilton, Martin, and Ventura 2007; Martin et al. 2007). Following a steady decrease through most of the twentieth century, maternal mortality stagnated from 1982 to 1998. Changes in the measurement of maternal mortality in the United States in 1999 (implementation of *International Classification of Diseases*, Tenth Revision) and in 2003 (new pregnancy status question on U.S. standard certificate of death) make it difficult to compare the most recent years with the period through 1998. The national maternal mortality rate was 8/100,000 live births in 1998 and 13/100,000 live births in 2003 (Centers for Disease Control and Prevention 1998; Hoyert 2007; Miniño et al. 2007).





Site and Mode of Birth

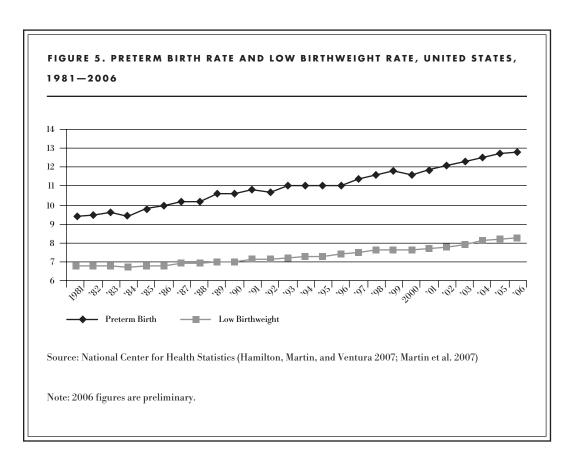
 $Sources: Agency for Healthcare \ Research \ and \ Quality \ 2008 \ (DRGs \ 370-373); \ National \ Association \ of Childbearing \ Centers \ 2004$ 

Notes: Figures in graph do not include additional anesthesia services charge associated with all cesarean and most vaginal births in hospitals, additional newborn care charge associated with all births in hospitals, and additional maternity provider charge associated with all births.

Payments of third-party payers typically reflect a discounting of charges.

 $Birth\ center\ figure\ is\ average\ charge\ reported\ by\ eighty-six\ out-of-hospital\ birth\ centers.$ 

Comparable birth center figure will next be available for 2008.



Following a period of modest decline, the national cesarean rate rose by 50 percent from 1996 to 2006, setting a new record each year from 2000 onward. The repeat cesarean rate rose by 28 percent from 1996 to 2005, when 92 percent of mothers with a previous cesarean had a repeat cesarean. From 1990 to 2005, the proportion of medically induced labors rose by 135 percent, from 9.5 percent to 22.3 percent (Hamilton, Martin, and Ventura 2007; Martin et al. 2006; Martin et al. 2007). Moreover, validation studies suggest that these official rates—derived from aggregate birth certificates—identify just 45 percent to 61 percent of actual instances of induced labor (Lydon-Rochelle et al. 2005; Parrish et al. 1993; Piper et al. 1993; Yasmeen et al. 2006). In just over ten years, from 1990 to 2002, with an increasing proportion of induced labors and planned cesarean sections, the most common gestational age among singleton births in the United States fell from forty to thirty-nine weeks (Davidoff et al. 2006), and current trends suggest continued foreshortening of gestational age.

In national surveys, women who gave birth in U.S. hospitals in 2005 reported high rates of numerous new-onset physical and mental health problems in the first two months after birth, with many problems persisting to six months or more postpartum (Declercq et al. 2008).

Table 2 clarifies that there is large variation in these performance indicators across states, including greater than sixfold for vaginal birth after cesarean and greater than threefold for labor induction.

In 2005, 4 percent of births were uninsured, an increase of 12 percent over the previous year (Agency for Healthcare Research and Quality 2008). Moreover, a much larger proportion of women lacks insurance prior to pregnancy than at the time of birth and transitions to insurance coverage during pregnancy. We were unable to find data describing conditions since 1999, when a study across nine states found that from 17 percent to 41 percent of childbearing women lacked insurance prior to pregnancy, with 1 percent to 4 percent remaining uninsured through to the time of birth. From 13 percent to 35 percent of mothers made the most common insurance status transition, from uninsured to Medicaid. Levels of prepregnancy uninsurance, continuous uninsurance, and transition from uninsurance to Medicaid were considerably higher for women with annual incomes below \$16,000 than for women with higher incomes (Adams, Gavin, et al. 2003). Current data, along with an understanding of the impact of insurance transitions in pregnancy on access to high-quality care and health outcomes, are needed. Uninsured childbearing women face bills for maternity services when they are adjusting physically and emotionally from pregnancy and childbirth and when their infants benefit from continuity of caregiver and breastfeeding.

When comparing experiences of childbearing women with private and public payment sources or across major race/ethnicity groupings, all segments of the population appear to experience problems with access to quality care. Where differences exist, there are greatest concerns about the quality of care received by black non-Hispanic women in comparison with both white non-Hispanic and Hispanic women (Sakala and Corry 2008). Similarly, black non-Hispanic mothers experience much higher rates of preterm birth, low birthweight, and fetal, perinatal, and maternal mortality than both other groupings (Martin et al. 2006). Moreover, the midcourse Healthy People 2010 review found that disparities for black non-Hispanic women were increasing for numerous indicators, including neonatal deaths, very low birthweight infants, mental retardation, and cerebral palsy (U.S. Department of Health and Human Services 2006).

Our national maternity care performance is also disappointing when compared with other nations. In *The World Health Report 2005: Make Every Mother and Child Count*, the World Health Organization identified twenty-nine nations with lower estimated maternal mortality rates than the United States (14/100,000 live births), thirty-five with lower early neonatal mortality rates (4/1,000 live births), and thirty-three with lower neonatal mortality rates (5/1,000 live births) in 2000 (2005). An analysis of maternal mortality rates for 2005 identified thirty-three countries with better performance than the United States (estimated at 11/100,000 live births, but perhaps as high as 21/100,000) (Hill et al. 2007). Among the thirty member nations of the Organisation for Economic Co-operation and Development (OECD), twenty-three reported a lower low birthweight rate than that of the United States (7.9 percent) for 2003, and six had higher rates. Fourteen OECD countries reported a lower perinatal mortality rate than that of the United States (6.9 percent) for 2003, and nine had higher rates. For the same year, nineteen members reported a lower cesarean rate than that of the United States (29.1 percent), and three reported higher rates (Organisation for Economic Cooperation and Development 2007).

TABLE 2. PERFORMANCE ON SELECTED INDICATORS OF MATERNAL AND NEWBORN HEALTH, UNITED STATES, EACH STATE, AND DISTRICT OF COLUMBIA

	2003	2005				
	Births Covered by Medicaid <sup>1</sup>	Low Birthweight <sup>2</sup>	Preterm Birth <sup>2</sup>	Cesarean Section <sup>2</sup>	Vaginal Birth after Cesarean	Induction of Labor <sup>2,</sup>
		_			$(VBAC)^2$	
STATE	PERCENT	PERCENT OF LIVE BIRTHS	PERCENT OF LIVE BIRTHS	PERCENT OF LIVE BIRTHS	RATE PER 100 WOMEN WITH A PREVIOUS C-SECTION	PERCENT OF LIVE BIRTHS
United States	_a	8.2	12.7	30.3	_c	22.3
Alabama	46	10.7	16.7	31.8	5.9	30.5
Alaska	55	6.1	10.6	21.9	18.6	20.2
Arizona	50	6.9	13.2	24.7	6.0	18.9
Arkansas	52	8.9	13.4	31.5	6.0	26.5
California	45	6.9	10.7	30.7	5.5	11.0
Colorado	37	9.2	12.3	24.6	11.7	19.6
Connecticut	28	8.0	10.4	32.4	6.7	20.1
Delaware	41	9.5	14.0	30.0	10.3	25.3
District of Columbia	34	11.2	15.9	30.5	7.0	26.1
Florida	50	8.7	13.8	34.9	$5.7^{d}$	24.2
Georgia	50	9.5	13.6	30.5	5.8	23.8
Hawaii	27	8.2	12.2	25.6	12.4	12.1
Idaho	40	6.7	11.4	22.6	17.3d	28.3
Illinois	40	8.5	13.1	28.8	9.5	25.2
Indiana	41	8.3	13.5	28.2	6.9	26.5
Iowa	28	7.2	11.8	26.7	8.4	27.0
Kansas	40	7.2	12.2	28.9	11.3 <sup>d</sup>	27.1
Kentucky	44	9.1	15.2	33.9	6.9 <sup>d</sup>	29.5
Louisiana	59	11.5	16.5	36.8	3.6	22.9
Maine	47	6.8	10.7	28.3	6.0	19.7
Maryland	34	9.1	13.3	31.1	9.8	22.4
Massachusetts	29	7.9	11.3	32.2	9.7	18.0
Michigan	35	8.3	12.5	28.8	8.3	18.7
Minnesota	37	6.5	10.7	25.3	10.6	21.2
Mississippi	60	11.8	18.8	35.1	3.8	20.1
Missouri	45	8.1	13.3	29.7	7.6	29.8
Montana	35	6.6	11.4	25.8	11.4	27.1
Nebraska	40	7.0	12.2	28.6	$9.5^{\mathrm{d}}$	33.0
Nevada	$32^{\rm b}$	8.3	13.9	31.0	4.9	19.4
New Hampshire	23	7.0	10.5	28.1	16.6 <sup>d</sup>	23.0
New Jersey	$26^{\rm b}$	8.2	12.5	36.3	9.6	20.1
New Mexico	67 <sup>b</sup>	8.5	13.1	22.2	13.0	14.9
New York	40	8.3	12.1	31.5	$10.8^{ m d,e}$	21.4
North Carolina	48	9.2	13.7	29.3	8.9	19.8

TABLE 2. (CONTINUED)

	Births Covered	2005				
		Low Birthweight <sup>2</sup>	Preterm Birth <sup>2</sup>	Cesarean Section <sup>2</sup>	Vaginal Birth after Cesarean (VBAC) <sup>2</sup>	Induction of Labor <sup>2, g</sup>
STATE	PERCENT	PERCENT OF LIVE BIRTHS	PERCENT OF LIVE BIRTHS	PERCENT OF LIVE BIRTHS		PERCENT OF LIVE BIRTHS
North Dakota	30	6.4	11.5	26.4	10.3	29.3
Ohio	32	8.7	13.0	28.1	8.9	30.4
Oklahoma	50	8.0	13.1	32.5	2.8	27.6
Oregon	43	6.1	10.2	27.6	10.3	26.9
Pennsylvania	31	8.4	11.9	28.9	15.2 <sup>d</sup>	21.9
Rhode Island	37	7.8	12.1	30.3	9.4	20.2
South Carolina	55	10.2	15.6	32.7	$10.0^{d}$	31.8
South Dakota	36	6.6	11.5	25.1	13.7	29.3
Tennessee	46	9.5	14.7	31.1	$11.1^{d}$	32.6
Texas	48	8.3	13.6	32.6	$10.0^{d}$	25.2
Utah	30	6.8	11.4	21.6	18.2	35.3
Vermont	48	6.2	9.0	25.9	_f	22.6
Virginia	28	8.2	12.3	31.4	6.6	17.9
Washington	46	6.1	10.6	27.8	$13.2^{d}$	22.2
West Virginia	50	9.6	14.4	34.2	4.8	33.9
Wisconsin	38	7.0	11.4	23.7	11.8	24.0
Wyoming	$46^{\rm b}$	8.6	13.1	24.6	8.0	25.3

### Notes:

- <sup>a</sup> U.S. rate not available for 2003.
- <sup>b</sup> Data from 2002; 2003 data is not available.
- c U.S. rate not available; the 2005 VBAC rate for thirty-seven states using unrevised birth certificates (69 percent of all births) was 7.9 percent, and for twelve states using revised certificates (31 percent of all births) was 10.1 percent. For more information, see www.marchofdimes.com/peristats/calc/dm.
- $^{
  m d}$  Data are based on the 2003 revised birth certificate; VBAC rates calculated based on the 2003 revision are slightly higher and should not be compared to those based on the 1989 revision.
- e New York City did not use the 2003 revised birth certificate and was excluded from state data. To access data for NYC, visit www.marchofdimes.com/peristats.
- $^{\rm f}\,$  Data not available due to midyear transition from the 1989 to 2003 revised birth certificate.
- ${\tt g}\ \ Validation\ studies\ and\ national\ surveys\ indicate\ that\ birth\ certificates\ underestimate\ actual\ rates\ of\ induced\ labor.$

### Sources:

- $^{\,1}\,$  Data collected by the National Governors Association, 2006 and 2007.
- $^{\rm 2}$  National Center for Health Statistics, 2005 final natality data.

Prepared by March of Dimes Perinatal Data Center, April 2008.

Although maternity-specific expenditure level data are not available across a large set of countries, the United States had by far the greatest overall health expenditure per capita across the thirty OECD countries in 2005, which was greater than twice the average expenditure of these nations. Similarly, the United States far exceeded all other OECD countries in health expenditure as a share of gross domestic product in 2005 (Organisation for Economic Co-operation and Development 2007).

These disappointing, often deteriorating outcomes in concert with procedure-intensive care and very large financial investments have been described as "the perinatal paradox: doing more and accomplishing less" (Rosenblatt 1989).

### EVIDENCE-BASED MATERNITY CARE: EFFECTIVE CARE WITH LEAST HARM

NOTE: REFERENCES TO SYSTEMATIC REVIEWS ARE IN ITALICS

"Evidence-based maternity care" uses the best available research on the safety and effectiveness of specific practices to help guide maternity care decisions and facilitate optimal outcomes in mothers and newborns. Various paths that might be pursued in a given situation often have very different benefit/harm profiles. Evidence-based maternity care gives priority to care paths and practices that are effective and least invasive, with limited or no known harms whenever possible. This framework is in the tradition enjoining practitioners to "first, do no harm" and consider undesirable consequences of good intentions.

The principle of effective care with least harm has two corollaries. First, practices with established or plausible adverse effects should be avoided when best available research identifies no clear anticipated benefit to justify their use. For example, mothers reported that a substantial proportion of labor inductions and cesarean sections in 2005 were carried out because of a caregiver's judgment and concern about a large fetus (Declercq et al. 2006; National Collaborating Centre for Women's and Children's Health 2008b), but a series of rigorous reviews have found that best research does not support this as a valid indication for either procedure (Chauhan, Grobman, et al. 2005; Coomarasamy et al. 2005; Pattinson and Farrell 1997; Rouse and Owen 1999). An evidence-based framework also questions the wisdom of using interventions with a marginal expected benefit that is overshadowed by greater risk of established harm. Examples of such a situation include inducing labor by various means or hastening it with synthetic oxytocin for convenience and in the absence of a clear medical rationale (Grobman 2007; Simpson and Thorman 2005).

These principles for evidence-based maternity care are especially important in consideration of the sensitive perinatal development period, the potential for long-term beneficial and adverse health effects, and the large scope for uncertainty about unintended consequences of many possible exposures, as discussed in the following section. These principles are also guides for helping purchasers obtain good value.

To implement these principles and to help guide maternity care decisions, decision makers need access to the highest quality of evidence about the safety and effectiveness of specific procedures, medications, and other interventions. They should require rigorous research results demonstrating that the care provided has been shown to work, may thus be expected to offer genuine benefit, and is a wise choice when considering associated harms and alternatives.

Basic principles for determining what constitutes best available evidence are as follows:

- Question common assumptions. Maternity care practices based on the opinions of experts or
  the general public or on tradition are unreliable guides for decision making. These views and
  patterns of care have been shaped by many factors and often do not reflect the best current
  research. They may lead to inadequate care, poor outcomes, and wasted resources. It is
  important to demand to be shown the best evidence.
- Know that many studies of interventions are unreliable guides for decision making. Careful
  evaluation of the quality of research using "critical appraisal" skills is essential. Many studies
  are flawed or limited in scope and do not provide valid answers to key questions. One newly

- reported study rarely offers the best, most definitive answer, and commercial interests influence many studies. It is important to ask what is already known about a particular question on the basis of the best available research, and what, if anything, a new study adds.
- Look for the "gold standard." When available, well-designed and well-conducted systematic reviews of research should inform maternity care decisions. If systematic reviews are not available, well-designed and well-conducted studies with randomized controlled trial designs can provide the most valid answers to many questions. For many reasons, it may be important to consider other types of studies as well. (See sidebar titled "What is the 'Gold Standard' for Knowledge about Effects of Maternity Care?" for more about systematic reviews and original studies.)
- Make informed decisions that consider evidence about safety and effectiveness and the values and
  circumstances of individual childbearing women. When making maternity care decisions, it is
  crucial to consider the best available evidence as well as values, preferences, and individual
  circumstances of childbearing women who have been supported to understand this evidence.
  It is also important to consider the options within specific care settings, such as the skills of
  caregivers and available forms of care.
- Beware of misleading claims. With growing recognition of the value of evidence-based policy and
  practice, it is important to be wary of bandwagon slogans describing "evidence-based" products
  and services and of deeply flawed execution that may not in fact reflect these principles.

### WHAT IS THE "GOLD STANDARD" FOR KNOWLEDGE ABOUT EFFECTS OF MATERNITY CARE?

A rigorous and transparent systematic review of original studies that has been conducted according to established guidelines and with discernment regarding both methodology and topic (Cochrane Methodology Register 2008; Moher et al. 2007; Sheikh et al. 2007) is a powerful tool for understanding the weight of the best available evidence. Such a review gives the most trustworthy knowledge about beneficial and harmful effects of specific health interventions. Systematic review procedures help limit investigator bias and error that can easily distort results of single studies and of more conventional and haphazard research reviews. A systematic review establishes the scope and other basic review parameters at the outset as a guide for conducting the review. It involves a thorough search for all the studies that meet explicit criteria for inclusion. Using criteria for assessing methodological rigor, researchers include only better quality studies in the review. When possible, researchers reach a conclusion by pooling data from the included studies using statistical techniques of

meta-analysis. Systematic reviews should be updated over time to incorporate new relevant high-quality research and to refine and strengthen the original analysis when possible. A recent Milbank Report describes the history, methodology, and uses of systematic reviews (Moynihan 2004), and another highlights the use of systematic reviews in policymaking (Sweet and Moynihan 2007).

The earliest systematic reviews were carried out more than twenty-five years ago to evaluate pregnancy and childbirth care. This pioneering work led to the formation of the Cochrane Collaboration to continue the pregnancy and childbirth research and to develop and update systematic reviews across all clinical and public health fields (Chalmers 1993). Many hundreds of systematic reviews are now available to guide maternity policy and practice from the highly regarded Cochrane Pregnancy and Childbirth Group and many other entities and individuals throughout the world. These invaluable tools for providing high-quality maternity care and obtaining good value have been grossly underutilized in the United States (see, for example, Chauhan et al. 2006).

Among individual studies, randomized controlled trials (or RCTs) can provide especially trustworthy results about many effects of specific interventions. In this type of research, participants are randomly assigned to receive one or another form of care. Those receiving usual care (or placebo treatment such as a sugar pill) are in the control group. Those receiving the type of care that is being studied are in the treatment or experimental group. Random assignment helps ensure that the groups being compared are truly similar and that any differences in outcomes are due to the treatment under study rather than some other difference between the groups.

RCTs are not the best study design for answering many important questions. For example, due to the great expense that would be required to enroll large numbers of participants and/or to follow participants over time, RCTs generally do not provide meaningful data about (1) less common but important outcomes (such as maternal mortality) and (2) outcomes that may occur far in the future (such as effects of cesarean section on mothers and babies in future pregnancies) or at earlier points when a high rate of follow-up may be difficult and expensive. Due to the expense, many pregnancy and childbirth RCTs do not collect any outcome data after postpartum hospital discharge—a serious limitation. For ethical reasons, it may not be possible to carry out RCTs (for example, researchers would not randomly assign babies to a non-breastfeeding group). RCTs can be misleading when they are not carried out according to plan. Notably, when large proportions of participants do not receive the care of the group to which they were assigned, the experience of the groups becomes more similar and RCTs lose power to detect true differences in effects. Thus, reports of "no difference" may be invalid

in the many RCTs where such group crossover occurred. Even if feasible and ethical, RCTs may not have been conducted to answer key questions. In general, we need to complement knowledge from RCTs with best options among other types of studies and carefully weigh the better studies (Jadad and Enkin 2007).

### THE PHYSIOLOGIC FOUNDATION OF EVIDENCE-BASED MATERNITY CARE

NOTE: REFERENCES TO SYSTEMATIC REVIEWS ARE IN ITALICS

#### SHORT-TERM HEALTH BENEFITS OF PHYSIOLOGIC MATERNITY CARE

In addition to evidence about interventions, an evidence-based maternity care framework must take into account evidence about the biological foundation of childbearing: how mothers' and babies' bodies work, and work in concert, from prenatal through postpartum periods, to accomplish growth, development, the childbirth process, the establishment of breastfeeding, and attachment as the basis of the mother-child relationship and other relationships.

The authors of A Guide to Effective Care in Pregnancy and Childbirth, the highly regarded manual on evidence-based maternity care, gave priority to the biological foundation and accorded fundamental respect to mothers and babies when they described their framework for interpreting evidence on interventions:

We worked from two basic principles: first, that the only justification for practices that restrict a woman's autonomy, her freedom of choice, and her access to her baby, would be clear evidence that these restrictive practices do more good than harm; and second, that any interference with the natural process of pregnancy and childbirth should also be shown to do more good than harm. We believe that the onus of proof rests on those who advocate any intervention that interferes with either of these principles (p. 486 Enkin et al. 2000).

This report affirms these principles. With appropriate support and protection from external interference, childbearing women and their fetuses/newborns experience innate, mutually regulating, hormonally driven processes that have developed during human evolution. These processes facilitate the period from the onset of labor through birth of the baby and placenta, as well as the establishment and continuation of breastfeeding and the development of mother-baby attachment. Examples of steps along this path include the following (Buckley 2004a; Winberg 2005):

- the mother's elevated levels of beta-endorphin, an endogenous opiate that relieves pain and facilitates an altered state of consciousness, similar to experiences of endurance athletes
- the mother's rhythmic involuntary expulsion efforts shortly before birth (Ferguson's reflex)
- the unmedicated and undisturbed infant's drive to crawl on its mother's chest, self-attach to the breast, and begin suckling shortly after birth
- the mother's surge of oxytocin at the time of birth, which stimulates loving feelings and inhibits hemorrhage by contracting the uterus
- the continuing oxytocic effects with breastfeeding

When facilitated, these autonomic nervous system functions overwhelmingly succeed in conferring a cascade of physical, psychological, and social benefits for the mother-baby dyad (Buckley 2004a; Odent 2001; Winberg 2005). When caregivers recognize and give priority to these capacities, mothers and babies experience these benefits and avoid risk of known short- and long-term harms and as yet unknown harms of avoidable, medically unnecessary interventions. By mobilizing these capacities, caregivers also humanize childbirth, show respect to women and fetuses/newborns as agents of these processes, enable all involved parties to experience the remarkable competence of

birthing women and newborns, strengthen mother-baby bonds, and foster a uniquely fulfilling and empowering experience (Wagner 2001).

Many historic and contemporary reports and studies confirm that the physiologic approach to childbirth, which has most consistently been provided by midwives (Brown and Grimes 1995; Hatem et al. in press; Kennedy and Shannon 2004; Waldenström and Turnbull 1998; Walsh and Downe 2004), has succeeded remarkably well in achieving positive outcomes for mothers and babies in diverse contexts. These include situations that are often viewed as involving elevated risk, such as care for women in remote and inner-city settings and care among low-income and underserved populations (Raisler and Kennedy 2005; Ulrich 1990). In addition to such physiologic care, childbearing women and newborns benefit when deprivation, disease, inadvertent use of unsafe practices, or other adverse circumstances are minimized. In all contexts, a portion of childbearing women and newborns require and gain benefit from specialized skills and knowledge and obstetric interventions that effectively address specific problems. Access to consultation, referral, shared care, transferred care, and transport is an essential complement to physiologic care.

Unlike most recipients of health care in the United States, childbearing women and newborns are primarily healthy and benefit especially from care that maintains good health (Lynn et al. 2007). It is a challenge to provide an overall estimate of the portion of this population that can benefit from more specialized care and procedures that intervene in physiologic processes. The federal Healthy People 2010 initiative provides one widely used proxy measure, which identifies low-risk women as those who are giving birth at term (thirty-seven completed weeks of gestation or beyond) with a single infant in a head-first position (U.S. Department of Health and Human Services 2000). In 2003, 82.6 percent of childbearing women met these criteria (National Center for Health Statistics 2006). By this estimate, more intensive and invasive care is appropriate for about one mother in six.

Physiologic childbirth is within reach of the great majority of mothers and babies. However, this approach is poorly recognized and supported at present in the United States and other industrial nations. External, professional-directed management of childbirth in hospitals (Table 3) typically interferes with these mother- and baby-led capacities. Results in the table from the national *Listening to Mothers II* survey of women who gave birth in U.S. hospitals in 2005 clarify the extent of use of obstetric interventions in this primarily healthy population. A project of Childbirth Connection, this survey was conducted by Harris Interactive in January–February 2006 among 1,573 women across the United States. The methodology was designed to describe the survey's target population of women aged eighteen through forty-five who gave birth to single babies in U.S. hospitals in 2005, with the baby still living at the time of the survey (a detailed appendix describes the methodology). The survey covered the time from before conception through the postpartum period. It included many items that are not available through other national data sources or appear to be undercounted in those sources; many validation studies (described in the survey's report appendix) have found that birth certificates and hospital discharge records do not capture a large proportion of actual occurrences for many data items. *The Listening to Mothers II* survey is thus a unique resource for describing contemporary

experiences of childbearing women and newborns in the United States and for comparing care that is actually received with optimal care (Declercq et al. 2006).

## TABLE 3. CHILDBIRTH IN U.S HOSPITALS, 2005: LISTENING TO MOTHERS II SURVEY

Medical Induction and Self-Induction	
Any attempt to induce labor with drugs and/or techniques	509
Professional attempted to induce labor	41%
Mother attempted to induce labor	229
Labor was actually induced	39%
Professional's actions started labor	349
Mother's actions started labor	4%
Fetal Monitoring (experienced labor)	
Any electronic fetal monitoring (EFM)	949
EFM continuously throughout labor	71%
EFM most of the time during labor	16%
Handheld device alone for monitoring	3%
Other Labor and Birth Interventions	
Synthetic oxytocin to induce and/or speed labor	579
Rupture of membranes to induce or speed labor	659
Epidural or spinal analgesia	76%
Narcotic analgesia	229
Intravenous drip	830
Bladder catheter	569
Restrictions	
No mobility after well-established contractions (experienced labor)	76%
No oral fluids (experienced labor)	599
No oral solids (experienced labor)	859
Back-lying position for giving birth (vaginal births)	579
Interventions at the Time of Birth (vaginal births)	
Staff pressure on belly to move baby out	17%
Staff-directed pushing	
Episiotomy	25%
(continued)	

### TABLE 3. (CONTINUED) Mode of Birth Hospital Practices That Can Interfere with Breastfeeding (mother intended to exclusively breastfeed at the end of pregnancy) Breastfeeding Note: Percentage is for all mothers, unless specified in parentheses. Source: Declercq et al. 2006

As shown in Table 3, labor is literally *pushed* by routine or common measures applied to this primarily healthy population—measures including labor induction, labor augmentation, staff-directed maternal pushing, and forceful pressure applied by staff on women's abdomens at the time of birth. Labor is also frequently *pulled* by interventions such as vacuum extraction/forceps, cesarean section, pulling on the cord to hasten birth of the placenta, and separation of babies from mothers after birth. About one-half of the items in Table 3 were experienced by a majority of women despite the overall healthy status of this population. These and other common interventions disrupt and preclude the physiologic capacities of the childbirth process (Buckley 2004b; Odent 2001) and incur a cascade of secondary interventions used to monitor, prevent, and treat the side effects of the initial interventions (Brody and Thompson 1981). As one intervention justifies or increases the likelihood of using others, the cumulative effect is to create a distorted understanding of childbirth as a time when things are likely to go wrong and intensive medical management is required (Mold and Stein 1986).

By learning from those with the skills and knowledge to enhance the innate physiologic capacities of the childbearing process, we can refrain from exposing mothers and babies to the harm and expense of avoidable interventions and use medical interventions appropriately, as needed. Table 4 compares rates of several interventions among a national group of low-risk women receiving usual care with those in a large prospective study of American women who gave birth with certified professional midwives (CPMs) in 2000 (Johnson and Daviss 2005). The usual care group is composed of all women who met Healthy People 2010 criteria for low-risk laboring woman. The contrast in experiences is striking, with national rates of intervention among low-risk women with usual care from two to sixteen times as great as the midwifery study rates. Notably, both the CPM study and an earlier large prospective U.S. study of low-risk women who also received physiologic care (Rooks et al. 1989) reported a cesarean section rate of 4 percent. By contrast, the low-risk mothers with usual care in 2000 were five times as likely to experience this procedure.

Infrequent use of interventions and other conditions of the CPM study were not associated with increased risk for study participants when compared with low-risk women giving birth in usual care hospital settings (Johnson and Daviss 2005). The low CPM study rates of intervention are benchmarks for what the majority of childbearing women and babies who are in good health might achieve.

TABLE 4. INTERVENTION RATES FOR LOW-RISK WOMEN IN THE UNITED STATES AND AMONG BIRTHS ATTENDED BY CERTIFIED PROFESSIONAL MIDWIVES, 2000

	Low-Risk, U.S.*	Certified Professional Midwives (n = 5,418)	
Intervention	(n = 3,360,868)		
Electronic fetal monitoring	84%	10%	
Intravenous drip	not reported	8%	
Epidural analgesia	not reported	5%	
Artificial rupture of membranes	not reported	5%	
Episiotomy	33%	2%	
Forceps	2%	1%	
Vacuum extraction	5%	1%	
Cesarean	19%	4%	

 $<sup>{\</sup>bf *\ Met\ Healthy\ People\ 2010\ criteria\ for\ low-risk\ laboring\ woman.}$ 

Source: Johnson and Daviss 2005

(See the sidebar titled "National U.S. Midwifery Credentials" to learn more about the relatively new CPM credential and the other two national midwifery credentials: certified nurse-midwife and certified midwife.)

Just as mothers and babies have much to gain by forgoing avoidable drugs, surgery, and other consequential procedures (as detailed in the following subsection), so can purchasers obtain exceptional value by using scientific evidence to provide effective care with least harm. Figure 4 contrasts the average charge for physiologic care in eighty-six freestanding birth centers across the United States with national average hospital charges for childbirth. In the best case, for uncomplicated vaginal birth, hospital charges were on average four times as high as birth center charges in 2003. Hospital charges were more than nine times as high as birth center charges when the pregnancy ended with a complicated cesarean. With wider application of care that facilitates physiologic processes, it is reasonable to expect that a notable proportion of births could shift from

### NATIONAL U.S. MIDWIFERY CREDENTIALS: CERTIFIED NURSE-MIDWIFE, CERTIFIED MIDWIFE, AND CERTIFIED PROFESSIONAL MIDWIFE

The style of care typically provided by midwives is well-suited to needs of childbearing women, including healthy women who anticipate an uncomplicated birth. Many midwives give priority to providing women with good information, involving them in decision making, offering flexible and responsive care, supporting physiologic processes, and avoiding unnecessary interventions. The accrediting body of the National Organization for Competency Assurance accredits three midwifery credentials in the United States.

Certified nurse-midwives (CNMs) are well-established maternity professionals in the United States. Educated in the two disciplines of nursing and midwifery, they provide prenatal, childbirth, postpartum, and well-woman care. CNMs are licensed to practice in all states and covered by a wide variety of insurance programs. Certified Midwives (CMs) are equivalent in training and practice to CNMs but do not have a nursing credential. This newer path to the midwifery profession is recognized in several states. CNMs and CMs practice in all settings and primarily attend hospital births (American College of Nurse-Midwives 2005). Another newer credential, the certified professional midwife (CPM), indicates a midwife who is educated to provide pregnancy, birth, and postpartum care for women who give birth in out-of-hospital birth centers or at home. The number of CPMs has grown rapidly in recent years. Nearly one-half of states license CPMs, and efforts are under way to extend licensure to all states. A new issue brief provides additional background information about CPMs (North American Registry of Midwives et al. 2008).

30

complicated to uncomplicated status and from cesarean to vaginal birth, with considerable benefit for those who receive and pay for care.

#### LONG-TERM HEALTH BENEFITS OF PHYSIOLOGIC MATERNITY CARE

It is critical to retain a long-term, life-course focus when planning and providing care for babies and mothers. A vast body of research is accumulating about lifelong implications for babies of the medical, physical, and social environment from conception through pregnancy and birth and into the postpartum period. This early period includes windows of heightened sensitivity for fostering many dimensions of optimal human development or generating harm. Many papers review specific topics within this work on the "developmental origins of health and disease" (see, for example Csaba 2007; Davis and Sandman 2006; Gluckman and Hanson 2006; Gluckman et al. 2005; Grandjean and Landrigan 2006; Heindel 2006; Horta et al. 2007; Ip et al. 2007; Johns, Jauniaux, and Burton 2006; Lewis, Poore, and Godfrey 2006; Olsen 2000; and Tchernitchin et al. 1999). Alterations in genes, cells, and tissues can have mutagenic, teratogenic, carcinogenic, and other adverse effects. Many health problems that manifest in later childhood or adulthood appear to have origins in this much earlier period, following impairment of immune, neurobehavioral, reproductive, metabolic, cardiovascular, and other functions. Due to delay or failure to recognize effects or to establish associations with early exposures, the concept of "silent epidemics" has been proposed as an extension of areas of current knowledge (Grandjean and Landrigan 2006). Collectively, this work suggests the importance of rigorous assessment of possible long-term effects of perinatal exposures. Given current uncertainty, it would be prudent to avoid needless exposures. (The sidebar titled "Diethylstilbestrol (DES) Clarifies Importance of Caution with Perinatal Exposures" provides an example of one of the most carefully and longest documented perinatal exposures, diethylstilbestrol, or DES.)

Growing evidence also suggests that maternity practices can have a long-term positive or negative impact on maternal well-being—for example, whether mothers use medication such as DES during pregnancy, have a cesarean, or breastfeed (*Ip et al. 2007*; Kennare et al. 2007; Labbok 2001; Lauver, Nelles, and Hanson 2005; Silver et al. 2006). It is a priority to understand longer-term effects of maternity interventions on mothers as well, and to consider this knowledge during decision making processes.

In addition to environmental exposures and aspects of pregnant and breastfeeding women's nutritional status, accumulating evidence finds that medical interventions used during childbirth may be associated with long-term harms (Odent 2006). These results and other possible impacts warrant further research and assessment in systematic reviews to strengthen our knowledge about long-term effects of widely experienced exposures during apparently sensitive windows of time in the perinatal period. A new narrative review describes research to date to understand mechanisms and effects of medical and environmental exposures in the perinatal period and to distinguish perinatal exposures from teratogenic exposures during early gestation (Csaba 2007; see also Tchernitchin et

al. 1999). The implication, which is consistent with the framework of this report, is that interventions should only be used when there is a well-supported clinical rationale for doing so. Further, decision making processes should take into account known harms and recognize the potential for harms that have not yet been established or well-publicized. Studies that point to potential adverse developmental consequences of intrapartum interventions consistent with the growing understanding of the developmental origins of health and disease include the following:

- Babies exposed to antibiotics during the birth process were more likely than unexposed babies to
  experience persistent wheezing measured at age six to seven years (Rusconi et al. 2007).
- In comparison with healthy term newborns delivered by planned cesarean, healthy term
  newborns who experienced labor had improved survival of white blood cells that destroy
  microorganisms (neutrophils) in their cord blood and better neutrophil function; this suggests
  that labor may be immunologically beneficial to normal newborns and may help explain excess
  neonatal morbidity and mortality with planned cesareans (Molloy et al. 2004).
- The initial colonization of the newborn intestine persists over a long period and has a pivotal effect on long-term health (Bedford Russell and Murch 2006; Glasgow et al. 2005; Grolund et al. 1999), and babies who experienced cesarean section, failure to breastfeed, intrapartum antibiotics, or hospital birth were less likely to have early colonization with beneficial bacteria than those who were, respectively, born vaginally, breastfed, not given antibiotics, or born at home (Penders et al. 2006).
- Cesarean section is associated with numerous adverse future harms in women, including abdominal adhesion formation and chronic pelvic pain (Almeida et al. 2002; Lyell et al. 2005; Morales, Gordon, and Bates Jr. 2007) and in mothers and babies in future pregnancies, including placenta previa, placenta accreta, placental abruption, uterine rupture, hysterectomy, small size for gestational age, low birthweight, preterm birth, stillbirth, and neonatal intensive care unit admission (Getahun et al. 2006; Kennare et al. 2007; Taylor et al. 2005). Serious maternal morbidity increases progressively as the number of previous cesareans increases (Nisenblat et al. 2006; Silver et al. 2006).
- In contrast with unmedicated babies, babies whose mothers received epidurals and/or systemic opioids during labor exhibited reduced breast-seeking and breastfeeding behaviors, were less likely to breastfeed within 150 minutes of birth, and cried more; from 90 percent to 100 percent of the unmedicated newborns exhibited all six measured breastfeeding behaviors (Ransjö-Arvidson et al. 2001). Numerous childbirth interventions decrease the likelihood of establishing breastfeeding (Forster and McLachlan 2007; Moore, Anderson, and Bergman 2007; Smith 2007), which confers many short- and long-term benefits to babies and mothers (American Academy of Pediatrics 2005; Horta et al. 2007; Ip et al. 2007; Labbok 2001; Labbok, Clark, and Goldman 2004).
- Adults who met diagnostic criteria for drug addiction were about five times as likely as sibling
  controls to have received three or more doses of opioid and barbiturate drugs within ten hours

- before birth (Nyberg, Buka, and Lipsitt 2000). When controlling for numerous potential confounders, researchers concluded that the association between pain medications and adult addiction appeared to have a dose-response effect and was not found with drugs administered more than ten hours before birth (Jacobson et al. 1990).
- After adjusting for numerous potential confounders, researchers found that men who committed
  suicide by violent means were about five times as likely as sibling controls to have experienced
  multiple trauma at birth (identified as events likely to cause pain to the baby). A sensitive window
  for effects ("imprinting") is postulated as the mechanism (Jacobson and Bygdeman 1998).

Tables 3 and 4 clarify the degree to which mothers and babies are experiencing many of these practices as well as the potential for reducing use of many interventions. In view of known and suspected adverse effects of such perinatal exposures, as well as much uncertainty about unintended effects, it would be wise to learn more about these relationships; to studiously avoid maternity interventions that do not offer clear, compelling, and well-supported benefits; and to give priority to effective practices that promote, protect, and support physiologic labor.

### DIETHYLSTILBESTROL (DES) CLARIFIES IMPORTANCE OF CAUTION WITH PERINATAL EXPOSURES

From 1947 to 1985, diethylstilbestrol, or DES, was administered to millions of women in the United States and elsewhere with the belief that it would prevent miscarriage. It was given to women with established problems and to healthy women as a "preventive" measure. Early advocates did not carry out controlled trials to establish efficacy, and health professionals continued to prescribe DES for two decades after it was shown to be ineffective in preventing miscarriage. Exposure of pregnant U.S. women and their offspring ceased in 1971 when the U.S. Food and Drug Administration withdrew approval several months after researchers linked intrauterine DES exposure to a rare form of vaginal cancer in teens and young women. Had a cluster of women with this cancer not been treated at Massachusetts General Hospital, where Harvard University clinicians had conducted early DES experiments, and had the origins of their illness not been investigated and associated with DES by researchers there, we might not know about the harmful nature of this medical measure today (Ibarreta and Swan 2001). We might instead be experiencing these effects as an unrecognized "silent epidemic" (Grandjean and Landrigan 2006).

Researchers have now investigated the harmful effects of DES for several decades. This evidence has emerged as an important cautionary example of the range and duration of adverse effects that are possible with perinatal exposures. DES mothers have increased

risk of developing breast cancer. Exposed during prenatal development, DES daughters have increased risk for vaginal and breast cancer, various reproductive tract abnormalities, endometriosis, spontaneous abortion, infertility, preterm births and other pregnancy complications, and immune disorders. DES sons are also at increased risk for a range of reproductive tract abnormalities. Implications for DES sons and daughters in later life are not yet known. Initial research now suggests that harm extends to the generation of DES grandchildren, which has been established as genetic and epigenetic effects in mice (Brouwers et al. 2007; Felix et al. 2007; Ibarreta and Swan 2001; Lauver, Nelles, and Hanson 2005; Newbold 2004; Newbold, Padilla-Banks, and Jefferson 2006; Tchernitchin et al. 1999).

This cautionary story about just one among a vast range of perinatal exposures that are or have been widely used shows that medical treatments and other exposures, including presumed advances from the most prestigious medical institutions, can cause widespread, long-term harm and may adversely impact evolutionary biology (Csaba 2007).

# OVERUSED INTERVENTIONS: EXAMPLES OF PRACTICES TO USE JUDICIOUSLY AND WITH CAREFUL ATTENTION TO INFORMED CONSENT NOTE: REFERENCES TO SYSTEMATIC REVIEWS ARE IN ITALICS

Many maternity practices originally developed to address specific problems have come to be used liberally and even routinely in healthy women (Simpson and Thorman 2005). This overuse exposes many mothers and babies to risk of harm with marginal medical benefit or none at all. This section presents evidence regarding several of these interventions and applies the principles articulated in preceding sections. Greatest attention is given to labor induction, epidural analgesia, and cesarean section, which have all increased considerably in use over the past decade in the United States. These interventions are experienced by a large proportion of childbearing women; are often applied without consideration of alternatives; involve numerous co-interventions to monitor, prevent, or treat side effects; are associated with risk of maternal and newborn harm; and greatly increase costs. As clarified in the following subsections, there are many signs that a notable proportion of use involves casual application with marginal medical benefit or none at all.

It is challenging for childbearing women to recognize that structure and process of care affect outcome; to gain access to full, high-quality information and learn about benefits and harms of common and consequential labor interventions, and of alternative measures; and to clarify their preferences, set goals, and make plans for achieving their goals. Women need opportunities to become informed about these matters and to weigh options well before labor, in addition to consistent, rigorous adherence to informed consent processes during labor. Due to personal values and preferences, women may exercise their right to informed choice and prefer a care path involving greater likelihood of harm than other possible paths. It is inappropriate, however, for clinicians, administrators, and other professionals to recommend, encourage, or give priority to use of care practices with increased risk of harm to mothers and newborns because the path is more convenient, efficient, or lucrative for professional work. Further, it is essential to improve the liability system and enable health professionals to make clinical decisions free of pressure to reduce their risk of legal liability.

### LABOR INDUCTION

Labor induction is the use of drugs and/or techniques to cause labor to start, as opposed to waiting for labor to begin on its own through a complex interplay of maternal and fetal factors (Liao, Buhimschi, and Norwitz 2005). Many putative indications are used to justify labor induction, and many agents and techniques are used to carry it out.

In considering this increasingly used intervention, it is important to distinguish labor that is in fact induced from unsuccessful attempts to bring on labor (as not all attempts cause labor to begin), and to distinguish women's attempts to self-induce from efforts of health professionals. The national Listening to Mothers II survey sheds light on these facets of labor induction among women who gave birth in U.S. hospitals in 2005 (Declercq et al. 2006). It is an important source of information because birth certificates only include one item about induction, that is, whether labor was actually brought on by any medical intervention. In addition, as referenced earlier, validation studies have

found that a large proportion of cases of induced labor is not in fact recorded on birth certificates. Still, the undercounted rate of medically induced labor derived from birth certificates increased by 135 percent from 1990, when it was 9.5 percent, to 2005, when it reached 22.3 percent of all women giving birth (Martin et al. 2007).

Reflecting increasingly casual professional and social attitudes toward intervening in the process of childbirth, 22 percent of *Listening to Mothers II* participants indicated that they had themselves tried to start their labor. Of these, 21 percent—or 4 percent of all of the mothers—reported actually inducing labor. Leading methods used for trying to bring on labor were walking/exercise (82 percent), sexual intercourse (71 percent), and nipple stimulation (41 percent). The most common reason was fully elective—the desire to end the pregnancy (58 percent of attempts to self-induce), followed by a desire to avoid a medical induction (33 percent), interest in controlling the timing (15 percent), and their provider's concerns about a large baby (10 percent) (sum of percentages exceeds 100 as the mothers were asked to identify all methods and reasons that applied) (Declercq et al. 2006).

Fully 41 percent of *Listening to Mothers II* participants reported that a health professional tried to induce their labor, with 84 percent of those—34 percent of all women—reporting that the attempt did in fact start labor. Combining self- and medical induction, 50 percent of all women were exposed to induction agents and/or techniques, and 39 percent of all labors were started by external means without waiting for labor to start on its own (Declercq et al. 2006).

Combining induced labor with cesareans that were carried out before the onset of labor, a majority of mothers (52 percent) experienced elective delivery rather than spontaneous onset of labor (Sakala 2006a), resulting in a social foreshortening of the length of human gestation. The most common gestational age at birth among single babies shifted from forty to thirty-nine weeks between 1992 and 2002 (Davidoff et al. 2006). This shift in the duration of gestation appears to be continuing despite evidence for progressive fetal development of vital organs such as the brain and lungs after thirty-seven completed weeks of gestation (Kinney 2006; Morrison, Rennie, and Milton 1995; Stutchfield, Whitaker, and Russell 2005; Zanardo et al. 2004), the current definition of full term.

We were unable to find any published study or professional statement identifying any absolute indication for inducing labor. Listening to Mothers II survey mothers who experienced medical attempts to induce labor revealed the most common reason(s) for use of this intervention. They reported a caregiver's concern that the baby was overdue (25 percent of women whose caregivers tried to induce labor), a maternal health problem that called for quick delivery (19 percent), mother's desire to end the pregnancy (19 percent), and a caregiver's concern about the size of the baby (17 percent). Less common reasons included concern about infection with ruptured (broken) membranes (9 percent), concern about baby's health (9 percent), mother's interest in controlling timing (8 percent), and mother's interest in giving birth with a specific provider (8 percent) (Declercq et al. 2006). As with self-inductions, many women reported use of this intervention with no expectation of a medical benefit.

Most Listening to Mothers II participants who experienced attempted medical induction were exposed to two or more methods of induction. Synthetic oxytocin was most commonly used (by

80 percent of this group), followed by breaking of membranes (49 percent), sweeping or stripping membranes loose (33 percent), and some form of prostaglandin applied near the cervix (24 percent). Forty-five percent of this group experienced both synthetic oxytocin and rupture of membranes (Declercq et al. 2006).

Wide practice variation in rates of induced labor appears to be unrelated to needs of mothers or babies. For example, an analysis of over thirty-one thousand births in 1998–1999 in sixteen hospitals in upstate New York found that 21 percent of all births were induced, and that there was no apparent reason for 25 percent of those. Rates of induction varied about fourfold across hospitals (from 10 percent to 39 percent) and about sevenfold across providers in hospitals (from 7 percent to 48 percent). There was even greater variation in the proportion that appeared to have no medical rationale across hospitals (from 12 percent to 55 percent) and across providers in hospitals (from 3 percent to 76 percent). The variation could not be explained by risk status of the women or other investigated factors (Glantz 2003).

Eleven percent of all *Listening to Mothers II* participants reported experiencing pressure from a health professional to undergo labor induction. Those who reported pressure were more likely to experience attempts to induce labor than those who did not report pressure (Declercq et al. 2006).

The large prospective CPM 2000 study of low-risk American women who received care with a focus on enhancing the physiology of childbirth suggests a benchmark labor induction rate that might be achieved for the majority of childbearing women who are at low risk at the end of pregnancy. In this population of 5,418 births in 2000, 9.6 percent experienced attempts to induce labor (Johnson and Daviss 2005), in contrast to the equivalent figure of 50 percent of *Listening to Mothers II* participants.

What do we lose when we forgo spontaneous labor and instead expose mothers and babies to induction agents and techniques and shorter gestation without sound evidence that the health benefits outweigh harms? Several examples and other possible impacts suggest that this question warrants further research and assessment in systematic reviews to improve knowledge about the impact of forgoing labor, foreshortening gestational age, and exposing mothers and babies to induction agents and techniques. Studies point to the importance of improving knowledge of potential effects, including the following:

- Synthetic oxytocin, which is widely used to induce labor, interferes with the functioning of a
  woman's own oxytocin receptors (Phaneuf et al. 2000). This may adversely affect other important
  functions of a mother's natural oxytocin release, such as reducing postpartum hemorrhage and
  contributing to attachment and the establishment of breastfeeding (Buckley 2004b).
- Prenatal methods for estimating gestational age are imprecise and have a margin of error of up
  to ± two weeks (Engle 2006), so elective labor induction will in many cases lead to delivery at an
  earlier gestational age than intended.
- Evolving understanding of normal fetal brain development has identified major changes continuing through forty-one weeks of gestation; for example, over one-third of brain volume

increase takes place in the final six to eight weeks, and a five-fold increase in white matter volume occurs from thirty-five to forty-one weeks gestation. There is uncertainty about how extrauterine brain development compares to intrauterine development during similar time periods from conception (Kinney 2006).

• Induction appears to increase the likelihood of cesarean in first-time mothers, when the cervix is not ready for labor and at earlier gestational ages (Kaufman, Bailit, and Grobman 2002).

In the national *Listening to Mothers II* survey, childbearing women in the United States expressed a strong desire to know about all or most potential complications of labor induction before deciding to have one, yet their demonstrated knowledge of labor induction complications was quite poor, whether they had one or not (Declercq et al. 2006). This identifies the need for improved education and informed consent processes.

Induction for convenience or for a medical indication that is not supported by clear evidence may be expected to offer minimal benefit at best. It is important to identify any harm that may be associated with the extensive use of elective induction, and a systematic review of effects of elective induction is being completed. A recent narrative review (Grobman 2007) identified concerns with elective induction, including increased likelihood of the following:

- fetal monitoring
- epidural analgesia
- cesarean section in first-time mothers
- cesarean section when the cervix is not ready for labor
- assisted delivery (vacuum extraction or forceps)
- postpartum hemorrhage and transfusion
- longer intrapartum period and longer postpartum stay
- costs (with increases in multiple cost centers)

Given such concerns, it is important to avoid exposure of mothers and babies and costs to payers of labor induction that lacks a clear medical benefit. In addition to inductions for convenience, a major area for improving practice in the United States is with respect to those that are initiated for a suspected large baby (macrosomia). Best current evidence identifies no benefits for mothers and babies when labor is induced for suspected fetal macrosomia (National Collaborating Centre for Women's and Children's Health 2008b; Sanchez-Ramos, Bernstein, and Kaunitz 2002) and limitations of leading methods for estimating fetal size (Chauhan, Grobman, et al. 2005; Coomarasamy et al. 2005; Dudley 2004; Pattinson and Farrell 1997).

Economic analyses find that induction increases costs associated with childbirth. The costs are especially high for first-time as opposed to experienced mothers, when carried out at earlier gestational ages, and when a woman's cervix does not show signs of readiness for labor. One estimate of the extra cost associated with induction of one hundred thousand first-time mothers with a cervix that did not have clinical signs of readiness for labor at thirty-nine weeks was \$91,000,000 (Kaufman, Bailit, and Grobman 2002), an average of \$910 per woman. Another analysis reported that induction

added an average of 11 percent to the cost of childbirth among low-risk women (Tracy and Tracy 2003). By implementing a program to reduce inappropriate elective labor induction at eleven hospitals, a health care system estimated that the average total maternal and newborn variable cost decreased by \$300 (The Commonwealth Fund 2004).

In sum, an evidence-based framework does not support elective nonmedical induction or induction for a medical rationale that is not supported by strong evidence, as these expose mothers and babies to risk without clear health benefit. Such practices are unlikely to be in the best interests of mothers and babies and increase the cost of maternity services. From a clinical perspective, the preferred alternative is "watchful waiting" for the spontaneous onset of labor and readiness to intervene should a clear justification arise. The strategies identified in the section of this report on policy recommendations might be used to address overuse.

#### EPIDURAL ANALGESIA

Epidural analgesia, a regional form of pain medication administered into the epidural space of the spinal cord, is the most effective form of pain relief commonly available for use during labor. The rate of use of epidurals during labor has rapidly increased in recent years, and 76 percent of participants in the national *Listening to Mothers II* survey experienced epidural analgesia or the spinal variant in 2005 (Declercq et al. 2006).

The effectiveness of this method of pain relief comes at a cost. Labor epidurals alter the physiology of labor and increase risk for numerous adverse effects. Undesirable maternal effects include immobility, voiding difficulty, sedation, fever, hypotension, itching, longer length of the pushing phase of labor, and serious perineal tears. Undesirable fetal/newborn risks include rapid fetal heart rate, hyperbilirubinemia, increased workup for sepsis and administration of antibiotics (due to fever in mothers), and poorer performance on newborn assessment scales (*Leighton and Halpern 2002*; *Lieberman and O'Donoghue 2002*; *Mayberry, Clemmens, and De 2002*). The spinal variant of this regional analgesia method is associated with increased likelihood of bradycardia, or abnormally low heart rate, in the fetus (*Mardirosoff et al. 2002*). Under some conditions—when initiated early in labor or when used with low- as opposed to high-dose synthetic oxytocin—epidural appears to be associated with increased likelihood of cesarean section (*Klein 2006*; *Kotaska, Klein, and Liston 2006*).

Numerous co-interventions, which may further alter the course of labor and have their own side effects, are used to monitor, prevent, and treat unintended consequences of the epidural. Continuous electronic fetal monitoring, intravenous infusions, and frequent blood pressure monitoring are standard precautions with epidural analgesia that would otherwise be unnecessary in healthy women. Women with an epidural are also more likely to experience bladder catheterization, synthetic oxytocin, medication for hypotension, vacuum extraction or forceps, and episiotomy. The original and cascading interventions transform normal labor into a technology-intensive experience.

Many laboring women welcome the pain relief of epidural analgesia, but they do not appear to be well-informed about the side effects. Although childbearing women in the United States overwhelmingly want to be informed of complications of epidurals before deciding to have one (Declercq et al. 2006), their demonstrated knowledge of epidural complications in a national survey was poor, whether they used this method or not (Declercq et al. 2002). This identifies the need for improved education and informed consent processes.

Due to costs of purchasing, operating, maintaining, and providing this package of interventions, epidurals substantially increase costs of childbirth. In one analysis, epidural was associated with as much as a 32 percent increase in the cost of care among low-risk first-time mothers and a 36 percent increase in cost among low-risk experienced mothers (Tracy and Tracy 2003).

Both pharmacologic and nonpharmacologic alternatives to epidurals are available. Although systemic opioids and self-administered nitrous oxide gas both provide less complete pain relief than epidural analgesia, most women who used them rated them in a national survey as very or somewhat helpful for pain relief (Declercq et al. 2002). Both methods have less adverse impact on the course of labor and on mothers. Opioids have the established and undesirable residual side effect of sedation, which can result in depressed newborns; when nitrous oxide is discontinued, the effects appear to cease immediately (*Bricker and Lavender 2002*; *Kronberg and Thompson 2005*; *Rosen 2002*). Twenty-two percent of *Listening to Mothers II* participants used narcotics, and 3 percent used nitrous oxide in 2005 (Declercq et al. 2006).

Many *Listening to Mothers II* survey participants gave favorable ratings to a broad range of drugfree pain relief methods (Declercq et al. 2006). Some of the most favorably rated, however, were underutilized (due to lack of access and of high-quality information and other reasons):

- tubs—very or somewhat helpful according to 91 percent who used them, but used by just 6 percent
- use of hot or cold objects—very or somewhat helpful: 81 percent, but used by just 6 percent
- showers—very or somewhat helpful: 78 percent, but used by just 4 percent
- birthing balls-very or somewhat helpful: 67 percent, but used by just 7 percent

Systematic reviews of drug-free measures, including hypnosis (Cyna, McAuliffe, and Andrew 2004), immersion in water (Cluett et al. 2002; Simkin and O'Hara 2002), acupuncture (Lee and Ernst 2004), and other methods (Simkin and O'Hara 2002), have found that these measures are helpful for many women, are associated with decreased use of medications, and appear to have excellent safety profiles. In addition, access to a companion who is present exclusively to provide continuous support throughout labor is associated with substantially decreased use of pain medication and increased satisfaction with the childbirth experience in comparison with usual care, and has no known adverse effects (Hodnett et al. 2007; Simkin and O'Hara 2002). A classic study to understand factors that are associated with women's experience of labor pain found that women's degree of confidence in their ability to handle labor was most important and had a bigger impact than such matters as their childbirth preparation, fear of pain, cervical dilation, and frequency of uterine contractions (Lowe 1989).

Labor support from a trained doula or other companion and many drug-free techniques and comfort measures appear to enhance normal labor physiology rather than disrupting it, which contributes to optimal outcomes (Simkin and Ancheta 2005). Many measures for increased comfort can be used in combination—for example, labor support and hydrotherapy. In contrast to narcotics and epidurals, all can be readily discontinued with little or no residual effect if inadequate, and others can readily be tried.

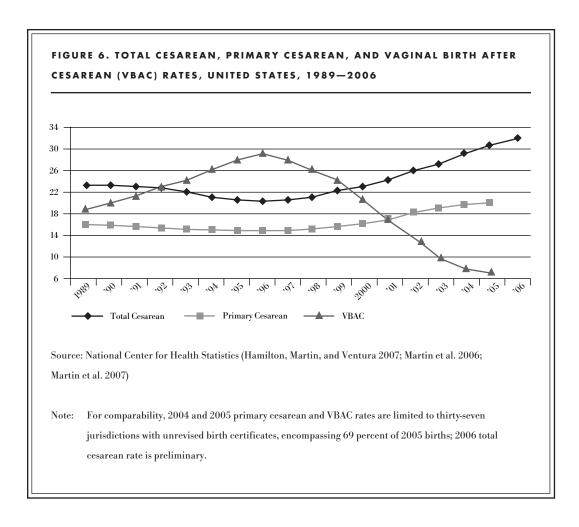
The evidence-based framework in this report suggests that optimal outcomes in mothers and babies and best value for payers would result from using safer, less invasive physiology-enhancing methods for comfort and labor pain relief as first-line care for most women, and using more consequential methods if women find that a series of simpler ones have been inadequate. First-line epidural analgesia would be optimal in selective situations, such as the small proportion of women with extreme fear of labor pain. Such a strategy would elevate appreciated and effective but underused pain relief methods and lead to more conservative use of narcotics and epidurals. It would require that women and health professionals clearly understand the pros and cons of the leading pharmacologic and nonpharmacologic methods of pain relief, that women have opportunities well before labor and again during labor to learn about and discuss these matters, that health professionals are educated to provide a range of methods, and that women have access to these methods and are supported in their decisions about pain relief.

#### **CESAREAN SECTION**

Delivery by cesarean section is a clearly beneficial and even life-saving procedure for mother and/or baby in selected circumstances. Absolute indications for cesarean section include prolapsed umbilical cord (cord precedes the baby's head through birth passage), placenta previa (placenta has grown over the opening of the cervix), placental abruption (placenta has separated from uterus before birth of baby), and persistent transverse lie (fetus is fixed in a horizontal position).

The absolute indications for cesarean section apply to a small proportion of births, yet rates of cesarean section are steadily increasing in the United States and many areas of the world (Betrán et al. 2007). Figure 6 illustrates recent U.S. trends for the overall cesarean rate, the first-time or "primary" cesarean rate, and the rate of vaginal birth among women with a previous cesarean (vaginal birth after cesarean, or VBAC, rate). When first measured nationally in 1965, the U.S. cesarean rate was 4.5 percent (Taffel, Placek, and Liss 1987). Since 1996, it has risen steadily from 20.7 percent to the provisional 2006 rate of 31.1 percent, a 50 percent increase (Hamilton, Martin, and Ventura 2007). A new record level has been reached every year in the present century, and the trend is for continued increase. In 2008 an estimated one mother in three is giving birth by cesarean in the United States. This reflects both a steady rise in primary cesareans and a sharp 72 percent decline in vaginal births among women with a past cesarean, from 28 percent in 1996 to 8 percent in 2005 (Martin et al. 2007).

Contrary to recent trends, national Healthy People 2010 objectives call for a substantial decrease in the cesarean rate and an increase in the rate of vaginal birth after cesarean from 2000 to 2010 (U.S.



Department of Health and Human Services 2000). Recent analyses substantiate the World Health Organization's recommendation that optimal national cesarean rates are in the range of 5 percent to 10 percent of all births and that rates above 15 percent are likely to do more harm than good (Althabe and Belizán 2006). Participants in two large prospective studies of American women experienced cesarean rates that were compatible with this recommendation: both low-risk populations experienced cesarean rates of 4 percent and no observed increase in harms through use of care that enhanced physiologic labor (Johnson and Daviss 2005; Rooks et al. 1989).

What is lost with unnecessary deviation from physiologic labor through planned prelabor cesareans or cesareans initiated during labor? Several examples and other possible effects suggest that this question warrants further research and assessment in systematic reviews to strengthen our knowledge about the impact of forgoing labor, deliberately foreshortening gestational age, and/or exposing mothers and babies to cesarean section. Studies point to the importance of improving knowledge of potential effects, including the following:

- When babies do not experience labor, they fail to benefit from physiologic changes that precede
  spontaneous onset of labor to help clear fluid from their lungs, and from further clearance
  during the process of labor, which appear to protect against serious breathing problems in
  newborns with the sudden transition to extrauterine life (Jain and Eaton 2006).
- Following the sterile intrauterine environment, passage through the vagina increases the likelihood that the newborn intestines will be colonized with beneficial bacteria and reduces colonization with harmful bacteria, in comparison with cesarean delivery (Penders et al. 2006); initial colonization influenced by mode of birth endures over time (Bedford Russell and Murch 2006; Grolund et al. 1999) and may help to explain the association of cesarean birth with asthma and allergy (Renz-Polster et al. 2005; Salam et al. 2006).
- As methods of estimating fetal gestational age are imprecise (Engle 2006), planned cesareans may inadvertently lead to iatrogenic prematurity. In Florida, between 1995 and 2003, 50 percent of the increase in the preterm birth rate among single births was associated with increasing numbers of cesarean births. Further examination of the relationship between cesarean birth and late preterm birth (thirty-four to thirty-six weeks of gestation) among births of single babies to Florida women with low documented medical risk revealed that cesarean without labor (suggesting planned cesarean) was associated with a 53 percent increase in the estimated risk of a late preterm birth, while cesarean with labor was not associated with increased risk of late preterm birth (women with a previous cesarean and with fourteen potential risk factors for cesarean were excluded) (Goodman, Sappenfield, and Thompson 2007), which may help explain why the recent increase in preterm birth has been concentrated in the late preterm weeks (Russell et al. 2007).
- In comparison with vaginal or intended vaginal birth, delivery by elective cesarean is consistently
  associated with increased risk of respiratory morbidity in near-term newborns and full-term
  newborns (Hansen et al. 2007).

Although many health professionals, journalists, and others have proposed that the rising cesarean rate is largely a consequence of women's requests for planned cesarean without a medical rationale, surveys of mothers themselves find that this phenomenon is very limited (Declercq et al. 2006; Kingdon, Baker, and Lavender 2006; McCourt et al. 2007). Similarly, increased genuine need for cesarean in the population of childbearing women—associated, for example, with more multiple births and childbearing among older women who are more likely to have chronic medical conditions—appears to play a limited role in recent trends, as the cesarean rate is rising for all classes of women, at all levels of risk, including those with no indicated risk at all. The increase reflects changing professional standards, with growing casual acceptance of cesarean surgery, lowered thresholds for applying traditional indications, and the appearance of new and unsupported justifications such as "baby seems large" (Declercq, Menacker, and MacDorman 2006; Declercq et al. 2006). Consistent with this supply-side interpretation, fully 25 percent of Listening to Mothers II

participants who had both primary and repeat cesareans reported having experienced pressure from a health professional to have a cesarean (Declercq et al. 2006). This style of professional practice is efficient and lucrative for professionals and hospitals (Sakala 2006a) and is widely viewed as reducing risk for malpractice claims and suits (Lockwood 2004). There is considerable practice variation in the use of cesarean, and higher rates are associated with inappropriate use in healthy women (see sidebar "Is the Most Resource-Intensive Care the Best Care?").

As major surgery, cesarean section has potential for great harm when overused. Most comparisons of effects of cesarean and vaginal birth are based on single studies, focus on a small set of outcomes, and fail to bring into view the full range of effects that are relevant to decision making. A systematic review that aimed to identify all known harms that differ in likelihood by mode of birth found a large inventory of differences that strongly favored vaginal birth (*Sakala 2006b*). A booklet to help women become informed about these matters is based on the review and describes the full range of outcomes (summarized in the following paragraphs) and the added likelihood of experiencing them when having a cesarean or, in several cases, a vaginal birth; it has been endorsed by over thirty organizations and is freely available online (*Childbirth Connection 2006*).

Short-term harms to mothers that were more likely with cesarean section included

- maternal death
- emergency hysterectomy
- blood clots and stroke
- surgical injury
- longer hospitalization and more likely rehospitalization
- infection
- poor birth experience
- less early contact with babies
- intense and prolonged postpartum pain
- poor overall mental health and self-esteem
- poor overall functioning

Possibly due to postsurgical adhesion formation, cesarean mothers were also more likely to experience the longer-term problems of chronic pelvic pain and bowel obstruction. The review found that cesarean born babies were more likely than vaginally born babies to experience

- respiratory problems
- surgical injuries
- failure to establish breastfeeding
- asthma in childhood and adulthood

The review also identified many adverse effects impacting a woman's future reproductive life and mothers and babies in future pregnancies, including greater likelihood of

- involuntary infertility
- reduced fertility due to decreased desire to have more children

#### IS THE MOST RESOURCE-INTENSIVE CARE THE BEST CARE?

John Wennberg and colleagues at Dartmouth Medical School have for several decades examined the problem of wide variation in medical practice—for example, differences in rates of performing a procedure across physicians, hospitals, or geographic areas—that cannot be explained by needs and preferences of the people receiving care. Such variation reflects differences in professional practice styles and other nonclinical factors. Baicker and colleagues recently extended this analysis to cesarean section. Using U.S. linked birth-death data from 1995 through 1998, with an overall cesarean rate of 20.6 percent, they found that risk-adjusted cesarean rates varied by more than fourfold across the largest U.S. counties. Medical need explained some variation, but nonmedical factors such as provider and health system supply, malpractice pressure, and practice style appeared to account for most of the variation. Areas with higher rates were associated with more inappropriate care and use of surgery in healthier women. Highest rates were not associated with lower maternal or neonatal mortality but were associated with increases in morbidity and costs (Baicker, Buckles, and Chandra 2006).

As cesarean birth poses greater risk than vaginal birth for many short-term and longer-term adverse effects in mothers, babies, and outcomes of future pregnancies (*Childbirth Connection 2006*), and the cesarean rate has risen by about 50 percent since the period of Baicker and colleagues' analysis, its implications are more troubling at present. An analysis of nearly one-quarter million births in 124 facilities in 2004 found variation of 200 to 300 percent in primary cesarean rates within regions and concluded that "a pattern of almost random decision making" exists for use of this invasive procedure (Clark et al. 2007).

The relationship between poor quality and most expensive and intensive care has been consistently reported in many U.S. contexts, including a large national evaluation of nearly one million Medicare beneficiaries. Although high cost was associated with more visits, hospitalizations, tests, and procedures, the researchers found no evidence of better quality, better access to care, better satisfaction, or better health outcomes. Rather, highest-cost care was associated with less effective care, compromised access, poorer satisfaction for several measures, and a slightly increased risk of death (Fisher et al. 2003a, 2003b). Similar results have been reported with system-wide changes in care within the Veterans Health Administration (Ashton et al. 2003) and with health plan analysis of proprietary data (Schaeffer and McMurtry 2005).

- cesarean scar ectopic pregnancy
- placenta previa
- placenta accreta
- placental abruption
- uterine rupture
- hemorrhage
- low birthweight
- preterm birth
- stillbirth
- maternal death

The likelihood of many of these conditions was found to increase as the number of previous cesareans increased (*Childbirth Connection 2006*; *Sakala 2006b*).

A scarred uterus appears to be less likely to provide a hospitable environment for the developing fetus than an unscarred uterus and may contribute to placental insufficiency (Smith, Pell, and Bobbie 2003). Many women with an interest in vaginal birth after cesarean (VBAC) are unable to find a health provider or hospital willing to support this choice (Declercq et al. 2006), and many are thus forced to accept the risks associated with repeated cesareans. (See sidebar titled "The Evidence about Vaginal Birth after Cesarean (VBAC)" in the following section.)

The review that aimed to identify the full range of harms that differ in likelihood by mode of birth identified several maternal outcomes that favored cesarean section: increased perineal pain, urinary incontinence, and anal incontinence (Sakala 2006b). Research does not yet exist to clarify the degree to which these conditions, which generally are mild and abate in the months after birth, are associated with vaginal birth per se or with the common use of practices that increase the likelihood of injury, such as episiotomy, staff-directed pushing, supine birthing position, and staff-applied abdominal pressure to push babies out (Albers and Borders 2007). A single outcome in babies favored cesarean section, brachial plexus shoulder nerve injury, which is primarily transient and occasionally permanent in limiting use of the affected arm (Childbirth Connection 2006; Sakala 2006b). By one estimate, one permanent brachial plexus injury occurs in ten thousand vaginal births (Chauhan, Rose, et al. 2005).

A series of recent studies has confirmed this broad range of excess risk associated with cesarean section even when conducted under optimal conditions for limiting harm in healthy, low-risk women without medical or obstetric conditions having planned, nonurgent cesareans (Declercq et al. 2007; Hansen et al. 2007; Kolas et al. 2006; Liu et al. 2007; MacDorman et al. 2008; Tracy, Tracy, and Sullivan 2007). In continuing reports of large studies, downstream adverse reproductive effects were more likely in women with a history of cesarean than in women who had vaginal births (Kennare et al. 2007; Silver et al. 2006), and repeat cesareans were associated with significant cumulative abdominal adhesion formation and adverse reproductive effects (Morales, Gordon, and Bates Jr. 2007; Nisenblat et al. 2006).

Although childbearing women in the United States expressed in a national survey a strong desire to know about complications of cesarean section before deciding to have one, their demonstrated knowledge of cesarean complications was quite poor, whether they had one or not (Declercq et al. 2006), pointing to the need for improved education and informed consent processes.

As shown in Figure 4, the average hospital charge for an uncomplicated cesarean is almost twice as high as the average hospital charge for an uncomplicated vaginal birth. The average charge for an uncomplicated cesarean is about seven times the average charge for a physiologic vaginal birth, as carried out in out-of-hospital birth centers across the country. Most expensive of all are hospital charges for cesareans with complications, which averaged \$15,960 in 2005. These figures do not include charges for anesthesia services and newborn care services in hospitals and maternity provider services for all births. The substantial cesarean-vaginal differential was also found in a systematic review of individual economic analyses (*Henderson et al. 2001*). Most studies in the latter were based on charge data from the United States. The differential was also found in a new analysis of payments from a commercial database of privately insured women (Thomson Healthcare 2007). The analyses are limited to the initial hospitalization period and exclude rehospitalization and other subsequent medical costs, as well as indirect costs of recovery from surgery to the woman and her family.

Adjusting the Thomson Healthcare (2007) figures for national health expenditure inflation rates of 6.5 percent in 2005 and 6.7 percent in 2006 (Centers for Medicare and Medicaid Services 2008), and applying them to the 31.1 percent cesarean rate in 2006, we estimated 39 percent of all payments for childbearing women were for women with cesareans. If, by contrast, the U.S. cesarean rate had been 15 percent in 2006, an estimated point at which harms begin to exceed benefits (Althabe and Belizán 2006), just 20 percent of payments for mothers' care would have been devoted to women with cesareans, with a net reduction in expenses of more than \$2.5 billion.

As over nine out of ten births following a previous cesarean are repeat cesareans at this time in the United States, the cost of the initial cesarean is magnified over time. Capital costs to reconfigure facilities for more planned births and surgical births with longer lengths of stay increase overall expense and generate pressure to sustain this level of revenue and style of practice involving high rates of surgery and weekday deliveries.

In addition to the strategies described in the section on policy recommendations, the following strategies are associated with reduced likelihood of cesarean section:

- in clinical settings, multifaceted interventions, including audit and feedback, were effective in reducing cesarean rates (Chaillet and Dumont 2007), for example, a hospital program combining stringent requirements for a second opinion, objective criteria for the most common indications, review of all cesareans, and reporting of rates of individual physicians providing childbirth services (Myers and Gleicher 1988)
- for pregnant women, providing access to and seeking settings and caregivers with conservative practice styles and low overall rates of cesarean section (Kennedy and Shannon 2004; Reime et al. 2004)

- for women in labor, working with caregivers to delay going to the hospital until labor is well established (Jackson et al. 2003; Klein et al. 2004)
- for women in labor, having a companion (such as a doula, friend, or family member) who is not
  a member of the hospital staff and is present during labor exclusively to provide continuous
  support (Hodnett et al. 2007)
- for maternity care providers, retaining and applying skills to facilitate vaginal birth, including a broad range of strategies that foster progress and comfort during labor (Simkin 2002; Simkin and Ancheta 2005), manually turning babies that are not in a head-first position (Collaris and Oei 2004; Hofmeyr and Kulier 1996), skillful vaginal breech birth (Hofmeyr and Hannah 2003), skillful vaginal twin birth (Hogle et al. 2003), and vaginal birth after cesarean (Guise, Berlin, et al. 2004; Guise, McDonagh, et al. 2004; Mozurkewich and Hutton 2000; National Collaborating Centre for Women's and Children's Health 2004)
- in facilities, avoiding whenever possible interventions that can increase the likelihood of
  cesarean section, including continuous electronic fetal monitoring (Alfirevic, Devane, and Gyte
  2006), labor induction (especially in first-time mothers with an "unfavorable" cervix (Kaufman,
  Bailit, and Grobman 2002), and early epidural (Klein 2006)
- in facilities, limiting cesarean section to clearly established indications and addressing inappropriate use of unsupported indications, such as "large baby" (Chauhan, Grobman, et al. 2005; Coomarasamy et al. 2005; Pattinson and Farrell 1997; Rouse and Owen 1999), twin birth, preterm birth, and babies that are small for gestational age (Hogle et al. 2003; National Collaborating Centre for Women's and Children's Health 2004)

#### BRIEF NOTES ABOUT SOME OTHER OVERUSED MATERNITY INTERVENTIONS

## **Continous Electronic Fetal Monitoring**

It is important during labor to periodically monitor the fetal heart rate as a way to check on the baby's well-being. Electronic fetal monitoring (EFM) is the predominant means of doing this in the United States. Ninety-four percent of women who experienced labor in U.S. hospitals in 2005 reported using EFM, and among those, 93 percent were monitored either continuously (76 percent) or for most of the time (17 percent) during labor. Just 3 percent were monitored using a handheld device alone (Declercq et al. 2006).

A recently updated systematic review pooling studies that compared continuous EFM with intermittent EFM monitoring found that continuous EFM did not reduce the likelihood of perinatal death or cerebral palsy, but increased the likelihood of cesarean section and vaginal birth assisted with vacuum extraction or forceps. Other adverse effects of continuous EFM were impairment of mobility, increased discomfort, and focus on the machine rather than the woman. The sole advantage documented of continuous EFM was a slight reduction in newborn seizures, with

no known long-term impact on babies. The rarity of this event would require 66l women to be continuously monitored to avert one seizure. Similar results were found for lower-risk and higher-risk subgroups (*Alfirevic*, *Devane*, and *Gyte* 2006). Although expected benefits for continuous EFM have been disproven, the practice has become the standard of care. Intermittent monitoring with various devices is more consistent with an evidence-based maternity care framework.

Two systematic reviews have also assessed the impact of a baseline period of fetal monitoring shortly after hospital admission with the machine used for continuous monitoring. The most recent review found no benefit for newborns and increased likelihood of both cesarean section and assisted delivery among low-risk women experiencing such baseline monitoring (Gourounti and Sandall 2007). The earlier review reported a nonsignificant trend toward cesarean and assisted delivery; increased likelihood of use of epidural analgesia, continuous EFM, and fetal blood sampling; and no newborn benefit in randomized controlled trials of low-risk women experiencing the baseline test; and other types of studies were difficult to interpret (Blix et al. 2005). Both reviews concluded that there is no support for using this admission test with low-risk women.

## **Rupturing Membranes**

Breaking the membranes containing the fetus, amniotic fluid, and umbilical cord with a tool similar to a crochet hook (amniotomy) is a common procedure for inducing labor and—after labor has begun—for hastening labor. Forty-seven percent of *Listening to Mothers II* participants reported that their caregivers had ruptured their membranes after labor had begun (Declercq et al. 2006). A recent systematic review concludes that there is no evidence of shorter labor, increased maternal satisfaction, or improved newborn outcomes with amniotomy after the start of spontaneous labor, whether the labor is progressing well or is prolonged. The researchers found a possible increase in cesarean section with this procedure and identified concerns about adverse effects on the fetal heart rate and the serious problem of umbilical cord prolapse and compression (*Smyth*, *Alldred*, *and Markham 2007*).

#### **Episiotomy**

Episiotomy is a cut made to enlarge the vaginal opening just before birth. Although the rate of use has declined in recent years, 25 percent of women with vaginal births continued to experience this intervention in 2005 (Declercq et al. 2006).

A recent systematic review reaffirmed longstanding evidence: the routine or liberal use of this practice does not confer benefits and rather exposes women to risk of harm. Depending on circumstances, the literature reviewed found that routine episiotomy was associated with an increase in the following conditions: perineal injury, need for stitches, experience of pain and tenderness, healing period, likelihood of leaking stool or gas, and pain with intercourse (*Hartmann et al. 2005*). The review authors recommended that with judicious use, the rate of episiotomy could be below 15 percent of all vaginal

births in the United States. Benchmark episiotomy rates of 2 percent or less have recently been reported in large studies of American women with physiologic care (Albers et al. 2005; Johnson and Daviss 2005).

#### **Certain Prenatal Care Practices**

The United Kingdom's National Institute for Health and Clinical Excellence carries out systematic reviews and develops guidelines for clinical practice. A broad, in-depth report that was updated in 2008 and not limited to studies from the United Kingdom concluded that the following practices should not be included in prenatal care, as they have either been disproven or there is inadequate evidence to support their use (National Collaborating Centre for Women's and Children's Health 2008a):

- routine iron supplementation
- · routine ultrasound after twenty-four weeks
- routine fetal movement counting
- routine chlamydia screening
- routine hepatitis C screening
- routine toxoplasmosis screening
- routine bacterial vaginosis screening
- routine preterm labor screening
- routine ultrasound to estimate fetal size if large baby is suspected
- routine vaginal examination to assess gestational age, predict preterm birth, or estimate a tight passage during birth

# UNDERUSED INTERVENTIONS: EXAMPLES OF PRACTICES TO USE WHENEVER POSSIBLE AND APPROPRIATE NOTE: REFERENCES TO SYSTEMATIC REVIEWS ARE IN ITALICS

This section highlights effective, noninvasive forms of care with modest or no known adverse effects and low plausibility of serious unknown harms. They are suitable for routine use. It is reasonable to anticipate that greater fidelity in providing these forms of care to childbearing women and newborns would lead to considerable improvement in outcomes. The inventory here is not meant to be exhaustive but rather illustrative of the broad range of generally safe, effective interventions that are underused, could offer benefits to a large segment of the childbearing population, and should be more widely available. In selecting these examples, we have also given preference to measures that can prevent problems (primary prevention) and measures that can help resolve problems (secondary prevention).

#### MIDWIVES AND FAMILY PHYSICIANS

In the United States, midwives are the lead maternity caregivers for 8 percent to 9 percent of women during pregnancy and childbirth (Declercq et al. 2006). Of the three national midwifery credentials, certified nurse-midwives (CNMs) are regulated in all states, certified midwives (CMs) are regulated in several states, and certified professional midwives (CPMs) are regulated in about one-half of the states, with efforts under way to develop legislation in the remaining states.

Several systematic reviews have summarized the evidence for midwifery care relative to physician-led or shared care. A meta-analysis of fifteen studies of care by CNMs in U.S. settings found that when differences in process and outcome were identified, they favored CNMs with the exception of increased likelihood of spontaneous perineal tears, primarily smaller first-degree tears, compatible with considerably reduced rates of episiotomy (a second-degree incision) in CNM groups. Other pooled differences in studies that controlled for risk status of mothers included less use of analgesia, anesthesia, intravenous fluids, electronic fetal monitoring, artificially ruptured membranes, and forceps; greater likelihood of spontaneous vaginal birth; and reduced low birthweight in midwifery groups (Brown and Grimes 1995). A systematic review comparing midwifery care in freestanding birth centers to obstetrician-led care in hospitals found that differences favored the midwifery groups, including reduced likelihood of episiotomy and cesarean section (Walsh and Downe 2004). Another systematic review compared midwifery-led care from prenatal through postpartum periods in a diversity of delivery settings with usual care in the locality of the study. Differences favored women who received midwifery care, who were less likely to experience labor induction, labor augmentation, electronic fetal monitoring, pain medications, assisted vaginal birth, and episiotomy, and were more likely to be satisfied with all phases of their care (Waldenström and Turnbull 1998). A Cochrane review comparing midwifery-led care to other models will be published in 2008 and further contribute to this body of reviews (Hatem et al. in press).

Family physicians are the lead maternity caregivers in the United States for about 6 percent to 7 percent of childbearing women (Declercq et al. 2006). Many studies compare the safety and effectiveness of family physicians to other maternity caregivers, primarily obstetricians, yet we were unable to find a systematic review of this literature. The most recent narrative review (Klein 1993)

preceded a number of studies of this question and found consistent results across more than twenty-five reports; when differences in process and outcomes were identified in mothers at low and mixed risk, they favored family physicians over specialized care. Family physicians routinely provide pre- and interconceptional care, offer continuity of care, care for all family members, and increase access in rural settings (Klein 1993). Updated and systematic reviews of family physician maternity care are urgently needed to provide rigorous guidance about maternity care workforce issues.

A systematic review comparing provision of prenatal care led by midwives and/or general practitioners and by obstetricians found that the differences in outcome favored midwives and general practitioners, who were associated with reduced likelihood of pregnancy-induced hypertension and preeclampsia, greater satisfaction, and lower costs (*Khan-Neelofur*, *Gülmezoglu*, and *Villar* 1998).

#### PRENATAL MULTIVITAMINS FOR PREVENTING CONGENITAL ANOMALIES

A systematic review summarized results of studies that evaluated whether prenatal folic acid-fortified multivitamins were protective against congenital anomalies. Use of the multivitamin supplements was consistently protective against neural tube defects, cardiovascular defects, and limb defects. For other outcomes examined, either no effects were shown or effects were only shown in weaker quality study designs (Goh et al. 2006).

#### SMOKING CESSATION INTERVENTIONS FOR PREGNANT WOMEN

Short- and longer-term hazards of smoking in pregnancy are well established (Castles et al. 1999; Pattenden et al. 2006). Smoking cessation programs for pregnant women have been shown to reduce smoking and prematurity and to increase birthweight (Lumley et al. 2004). The following interventions appear to be effective in reducing smoking in pregnant women: advice from caregivers, group sessions, and behavioral therapy with self-help manuals. Smoking cessation interventions are more effective in pregnant than nonpregnant participants (Law and Tang 1995).

## GINGER FOR NAUSEA AND VOMITING IN PREGNANCY

A growing body of evidence finds ginger (Zingiber officinale) to be helpful for nausea and vomiting in pregnancy, and no side effects have been identified to date (Borrelli et al. 2005; National Collaborating Centre for Women's and Children's Health 2008a).

### INTERVENTIONS FOR PREVENTING PRETERM BIRTH

Most assessments of interventions to prevent prematurity have failed to identify effective measures. In addition to smoking cessation programs for pregnant women, noted above (*Lumley et al. 2004*), the

following measures are associated with reductions in preterm birth: having a birth to conception interval of eighteen to fifty-nine months versus less than eighteen months or more than fifty-nine months (Conde-Agudelo, Rosas-Bermúdez, and Kafury-Goeta 2006) and use of progesterone in women at increased risk of preterm birth (Dodd et al. 2006; Mackenzie et al. 2006; Sanchez-Ramos, Kaunitz, and Delke 2005).

It is also important to avoid iatrogenic prematurity, as a result of labor induction or planned cesarean before the thirty-seventh completed week of pregnancy, if there is no evidence-based indication to justify ending the pregnancy prematurely (Fuchs and Wapner 2006), and to recognize that prenatal methods for estimating gestational age have a margin of error up to  $\pm$  two weeks (Engle 2006).

If results of an initial promising randomized controlled trial are confirmed in further studies, the CenteringPregnancy® model of group prenatal care may prove to be a crucial tool for prematurity prevention. In this model, groups of eight to twelve women/couples/teens meet during pregnancy and in the early postpartum period with facilitators for discussion, sharing, learning, and health assessment. The trial found a 33 percent reduction in risk of prematurity with group prenatal care, in comparison with usual prenatal care, and stronger effects among black mothers (Ickovics et al. 2007). Because a cesarean in a previous pregnancy has been associated with preterm birth in a subsequent pregnancy (Kennare et al. 2007; Smith, Pell, and Bobbie 2003; Taylor et al. 2005), judicious use of cesarean section may help reduce prematurity over time.

#### EXTERNAL VERSION TO TURN BREECH BABIES AT END OF PREGNANCY

Using hands-to-belly maneuvers to try to turn babies to a head-first position (external version) at the end of pregnancy succeeds in doing so in many instances and reduces the likelihood of cesarean section (*Hofmeyr and Kulier 1996*). Best available studies on the safety of this procedure indicate a low likelihood of adverse effects (*Collaris and Oei 2004*; *Nassar et al. 2006*).

#### PRACTICES TO FOSTER WOMEN'S SATISFACTION WITH THEIR CHILDBIRTH EXPERIENCE

A systematic review examining factors that are most consistently associated with women's satisfaction with the childbirth experience found that four conditions overrode the many other factors that have been examined: amount of support from caregivers, involvement in decision making, quality of mother-caregiver relationship, and having high expectations for the childbirth experience or experiences that exceeded those expectations (*Hodnett 2002*).

### CONTINUOUS LABOR SUPPORT

The continual presence of a labor companion who has an exclusive focus on providing emotional support, comfort, and information has been found to offer important benefits to laboring women,

in comparison with usual care. A friend, family member, or doula can assist women in this way. Benefits include reduced likelihood of the following interventions/conditions: pain medications, cesarean section, assisted delivery with vacuum extraction or forceps, and dissatisfaction with the childbirth experience. Such support also increased the likelihood of spontaneous vaginal birth. Benefits were not found or were weaker when support was provided by a member of the hospital staff. No adverse effects were identified with the continual presence of a labor companion (*Hodnett et al. 2007*; *Simkin and O'Hara 2002*). A book is available to guide a partner, friend, or relative who might wish to take on this role (Simkin 2008).

# MEASURES TO RELIEVE PAIN, BRING COMFORT, AND/OR PROMOTE PROGRESS DURING LABOR

Fourteen percent of Listening to Mothers II survey participants gave birth without the use of pain medications (Declercq et al. 2006). Systematic reviews have concluded that many women find several noninvasive methods of pain relief helpful during labor, including immersion in water (Cluett et al. 2002; Simkin and O'Hara 2002), hypnosis (Cyna, McAuliffe, and Andrew 2004), acupuncture (Lee and Ernst 2004), and intradermal sterile water injections for low back pain (Huntley, Coon, and Ernst 2004; Simkin and O'Hara 2002). The acupuncture and hypnosis reviews are each based on several initial consistent studies. Initial evidence also suggests that a hands-and-knees position helps reduce pain among women with "posterior" babies (forward-facing position that is less common, more painful, and associated with more difficult labor) (Hunter, Hofmeyr, and Kulier 2007). The reviews found that these measures increase comfort for many women, are associated with decreased use of medications, and appear to have excellent safety profiles. Simkin and Bolding provide an overview of the evidence on many nonpharmacologic methods of labor pain relief (2004). As noted above, the continuous presence of a supportive labor companion also reduces the likelihood of using pain medications (Hodnett et al. 2007).

#### DELAYED AND SPONTANEOUS PUSHING

Very frequently, hospital staff coach women to push their babies out and direct them in forceful, sustained pushing as soon as a cervical dilation of ten centimeters is documented. Twenty-eight percent of *Listening to Mothers II* survey participants who gave birth vaginally pushed exclusively with staff calling out, 47 percent pushed with staff calling out and their body's own sensations, and 21 percent relied solely on their own pushing reflexes (Declercq et al. 2006). Women with epidural analgesia who delay pushing for some period of time (from up to one hour to up to three hours in studies included in the review) have the opportunity for spontaneous descent of the baby, spontaneous rotation of the baby's head through the pelvic passage, and onset of the involuntary pushing reflex; and the women are more likely to have a spontaneous vaginal birth with neither assisted delivery (vacuum extraction or forceps) nor cesarean section (*Brancato, Church, and Stone 2008*; *Roberts et al. 2004*). In women without epidural analgesia, staff-directed pushing does not appear to confer presumed benefits (such as shorter labor and improved

fetal status) and rather appears to increase the likelihood of late fetal heart decelerations and the frequency and severity of perineal trauma in mothers (Bosomworth and Bettany-Saltikov 2006).

#### NONSUPINE POSITIONS FOR GIVING BIRTH

Most women who give birth vaginally in the United States lie on their backs while pushing their babies out (Declercq et al. 2006). However, in studies of women without epidurals, upright and sidelying positions are associated with less severe pain for mothers, less use of episiotomy, less use of vacuum extraction or forceps, fewer heartbeat abnormalities in babies, and a shorter pushing phase of labor (Gupta, Hofmeyr, and Smyth 2004). In two small studies of women with epidural analgesia, the pushing phase was shortened and there was a nonsignificant trend for reduced assisted and cesarean delivery with upright positions (Roberts et al. 2005). Larger studies are needed to clarify the value of upright positions in women with epidurals.

#### DELAYED CORD CLAMPING IN FULL-TERM AND PRETERM NEWBORNS

Immediate cord clamping is standard procedure in U.S. hospitals at present. However, in term newborns, delaying cord clamping for a minimum of two minutes was associated with improved hematologic status, iron status, and iron stores, as well as reduced anemia, with benefits measured from two to six months after birth (*Hutton and Hassan 2007*). Delayed clamping also offers benefits to preterm babies (*Rabe, Reynolds, and Diaz-Rossello 2004*; *Rabe, Reynolds, and Diaz-Rossello 2008*).

#### EARLY SKIN-TO-SKIN CONTACT

Thirty-nine percent of *Listening to Mothers II* survey participants reported that their baby was primarily with staff for routine care during the first hour after birth (Declercq et al. 2006). Skin-to-skin contact between mothers and babies right after birth and during the first twenty-four hours postpartum, in comparison with usual hospital care, was associated with improved performance on measures of breastfeeding status and duration, improved newborn temperature regulation, reduced newborn crying, and more affectionate maternal behaviors, with some evidence of long-term effects, and no evidence of harm (*Moore, Anderson, and Bergman 2007*; see also Winberg 2005).

## BREASTFEEDING AND INTERVENTIONS TO PROMOTE ITS INITIATION AND DURATION

Best current evidence suggests that exclusive breastfeeding for at least six months provides optimal nourishment for infants (*Kramer and Kakuma 2004*); benefits of breastfeeding for the baby extend into and beyond childhood; and mothers experience long-term benefits from breastfeeding as well

(Horta et al. 2007; Ip et al. 2007). As they neared the end of pregnancy, 61 percent of Listening to Mothers II survey participants intended to exclusively breastfeed, yet just 51 percent were doing so a week after the birth, a missed opportunity for about four hundred thousand mother-infant pairs annually in the United States. Among mothers who had given birth at least seven months before taking the survey, 27 percent met the international standard of exclusive breastfeeding for at least six months (Declercq et al. 2006).

Focused individual or group education sessions (which may include skills training, provision of equipment, and/or discussion) increased initiation and short- but not long-term duration of breastfeeding. One-to-one in-person or telephone support increased short- and longer-term duration (but not initiation) (*Dyson, McCormick, and Renfrew 2005*; *Guise et al. 2003*) and initiation among low-income women (*Fairbank et al. 2000*). Lay, professional, or combined support was effective in extending duration in settings where initiation and duration were low (*Britton et al. 2007*). Effective interventions tended to span the prenatal period or both prenatal and postpartum periods and to offer face-to-face information, guidance, and support. Intensive interventions combining group and individual sessions and/or home visits over time were associated with increased duration (*de Oliveira, Camacho, and Tedstone 2001*). WIC (Women, Infants, and Children) programs were effective in increasing breastfeeding (*Fairbank et al. 2000*). (See also Shealy et al. 2005.)

The Baby-Friendly Hospital Initiative, promoted by the World Health Organization and the United Nations Children's Fund, is effective in increasing rates of breastfeeding. However, in June 2008, just sixty-four hospitals and birth centers in the United States were designated as "Baby-Friendly" (BFHI USA 2008). Elements of this ten-step program include early postpartum skin-to-skin contact, rooming in, "demand" feeding, avoiding commercial discharge packs, and avoiding formula or water supplementation (Demott et al. 2006; Guise et al. 2003; U.S. Government Accountability Office 2006; see also Merewood et al. 2005; World Health Organization 1998).

As cesarean section is associated with decreased initiation of breastfeeding (DiMatteo et al. 1996), judicious use of cesarean section can play a role in increasing breastfeeding. Mixed messages of support for breastfeeding and for formula, and brief nonintensive interventions are not successful in increasing breastfeeding (de Oliveira, Camacho, and Tedstone 2001).

#### INTERVENTIONS TO REDUCE NEWBORN PROCEDURE PAIN

Blood sampling and other routine and less common procedures can be painful to newborns. Infants who were breastfed during these procedures, in comparison with swaddling, pacifiers, and other measures, had better scores on several measures of pain experience (Shah, Aliwalas, and Shah 2007). Babies with blood drawn from veins similarly appeared to experience less pain than babies with blood drawn by heel lance (Shah and Ohlsson 2007).

#### PSYCHOSOCIAL AND PSYCHOLOGICAL INTERVENTIONS FOR POSTPARTUM DEPRESSION

Due to concerns about adverse effects of maternal medications on breastfed children, effective nonpharmacologic treatments for postpartum depression are of special interest for postpartum women. Best current evidence suggests that both psychosocial interventions (such as peer support and nondirective counseling) and psychological interventions (such as cognitive behavioral therapy and interpersonal psychotherapy) reduce the likelihood of depressive symptoms among new mothers with depression (*Dennis and Hodnett 2007*). A second review confirms the effectiveness of psychological interventions (*Lumley, Austin, and Mitchell 2004*). The reviews found that one mother was helped for every two to four who received these interventions.

#### THE EVIDENCE ABOUT VAGINAL BIRTH AFTER CESAREAN (VBAC)

As shown in Figure 6, the proportion of women with a previous cesarean who gave birth vaginally rose steadily leading up to 1996 but has sharply declined since that time. Access to VBAC has fallen off sharply in recent years (Roberts et al. 2007), and more than nine out of ten women with previous cesareans now have repeat cesareans. Forty-five percent of *Listening to Mothers II* survey participants would have liked the option of VBAC in 2005, but most of those women did not have this option, primarily due to an unwilling caregiver (45 percent) or hospital (23 percent) (Declercq et al. 2006). Best evidence can provide clarifying guidance about mode of birth after cesarean for the large population of childbearing women with at least one previous cesarean—annually in the United States, about a half million women, and rising.

In considering the options of repeat cesarean or VBAC, the focus has been on the possibility that the scar could give way during labor (uterine rupture) among VBAC mothers, requiring an immediate cesarean and possibly leading to serious problems for the mother and/or baby. A systematic review that examined outcomes related to uterine rupture in the present pregnancy concluded that about 370 women would need to have a repeat cesarean to prevent one symptomatic uterine rupture, and over 7,100 women would need to have a repeat cesarean to prevent the death of one baby from this situation. The review found that the likelihood a mother would have an emergency hysterectomy or would die did not differ between VBAC and repeat cesarean (Guise, Berlin, et al. 2004; Guise, McDonagh, et al. 2004; see also Landon et al. 2004). A subsequent report from the prestigious National Institute of Child Health and Human Development Maternal—Fetal Medicine Units Network clarified that multiple prior cesareans were not associated with increased risk of uterine rupture in women planning vaginal birth after cesarean in comparison with those with a single prior

cesarean. The research identified several modifiable risk factors that were associated with increased risk of uterine rupture in women who labored after a previous cesarean: labor induction, labor augmentation with synthetic oxytocin, and an interval of twenty-four or fewer months since previous cesarean (Landon et al. 2006).

Discussions about how women with a previous cesarean might give birth generally fail to consider the many outcomes that differ in likelihood between vaginal birth and repeat cesarean but are not related to the possibility of uterine rupture in the index pregnancy. As discussed in the previous section, these strongly favor vaginal birth and include a broad range of shorter- and longer-term adverse effects of cesarean section in mothers and babies, as well as increased risks of cesareans for mothers and babies in future pregnancies. Many future reproductive risks increase as the number of previous cesareans grows. Two large additional studies from the Maternal-Fetal Medicine Units Network depict a striking contrast between repeat cesarean and VBAC/repeat VBAC paths. The following conditions/ procedures increased as the number of cesareans grew: placenta accreta, cystotomy, bowel injury, ureteral injury, ileus, need for postoperative ventilation, intensive care unit admission, hysterectomy, blood transfusion requiring four or more units, duration of operative time, and duration of hospital stay (Silver et al. 2006). By contrast, as the number of VBACs grew, the likelihood of VBAC success increased and the likelihood of the following conditions/procedures decreased: uterine rupture, scar separation, surgical complications, transfusion, and endometritis. The investigators found no increase in newborn morbidity or mortality with increasing VBAC (Mercer et al. 2008).

The failure to offer access to VBAC to many eligible women in many settings inevitably involves a high and growing level of iatrogenic harm and excess costs that are playing out over time. About 36 percent of U.S. mothers have given birth three or more times, and 38 percent of mothers aged twenty-five to forty-four reported having had an unwanted or mistimed birth (Chandra et al. 2005). As many women will have additional children, future childbearing is difficult to predict, and hazards increase as the number of previous cesareans grows, it would be wise for women without a clear and compelling need for cesarean section in the present pregnancy to avoid the extra risks of surgery and to get off the repeat cesarean track.

# CHALLENGES TO CLOSING EVIDENCE-PRACTICE GAPS IN MATERNITY CARE IN THE UNITED STATES NOTE: REFERENCES TO SYSTEMATIC REVIEWS ARE IN ITALICS

Two recent systematic reviews about the effectiveness of strategies for improving the quality of maternity care found consistent evidence that interventions identifying and addressing barriers to improvement are effective in improving care (Chaillet and Dumont 2007; Chaillet et al. 2006). This section summarizes some of the leading factors that are contributing to the usual patterns of maternity care described in this report.

#### LACK OF A NATIONAL STANDARDIZED SET OF MATERNITY PERFORMANCE MEASURES

Various entities have independently developed quality measures to assess the performance of health professionals, facilities, or health plans that provide maternity care (Agency for Healthcare Research and Quality 2007). However, to date, a full, national standardized set of perinatal measures has not been available to assess and report performance and reward good performance. The National Quality Forum (NQF) is currently working with measure developers, prospective measure users, and other stakeholders to develop a robust, standardized set of NQF-endorsed perinatal measures and to identify gaps in available perinatal measures. When this initial measure set is endorsed in 2008, it will be vital to ensure that it is widely used to assess maternity care performance, with adequate technical assistance and other support for facilitating and assessing this process. Further, it will be important to publicly report performance and to help consumers and purchasers use this information to make informed decisions about choosing and purchasing services. Purchasers may also elect to reward good performance. The information can also help those who deliver maternity care to improve practice. Finally, it will be important for measure developers to design, evaluate, and submit to NQF measures to fill important gaps and for NQF to incorporate the best new maternity measures into its perinatal measure set and refine existing measures on the basis of their performance (Sakala in press).

#### A PAYMENT SYSTEM THAT INCURS PERVERSE INCENTIVES

The present system of payment for maternity care provides strong incentives for inappropriate care of healthy childbearing women. Recent market pressures, such as tightened reimbursement from payers and costly malpractice insurance premiums, appear to be driving providers to respond more directly to unintended payment system incentives than they did in the past (Ginsburg and Grossman 2005). Many practitioners who do not respond directly to financial interests will nonetheless be influenced by resulting shifts in the standard of care.

In the United States, maternity providers are paid a fixed global fee for a bundle of services. The fee schedule code and size of payment are based on the portion of prenatal, labor and birth, and postpartum services the caregiver has provided and the type of birth the patient had. Some fee schedules pay the same amount for vaginal and cesarean birth, while many pay more for cesarean. In one recent analysis, employer-sponsored insurance paid providers an additional \$723 on average

for cesarean births in comparison with vaginal births in 2004 (Thomson Healthcare 2007). Extra payments for cesarean birth provide an incentive for this procedure.

In addition to the size of the payment, providers must consider the time and effort involved in obtaining a payment. This effort affects their availability for providing other reimbursable hospital and office services, for meeting the needs of others in their practice, and for balancing their work and personal lives. A planned cesarean offers the advantages of predictable scheduling and a short time commitment, along with a higher average fee. A vaginal birth that begins on its own involves no control of timing and often means that another provider who is on call will collect the payment for the birth, which is generally much larger than the prenatal and postpartum components. This provides an incentive for induced labor or planned cesarean that is coordinated with a provider's hospital schedule. Many obstetric interventions may help providers who care for women in labor move on more quickly to provide care and reimbursable services to other patients or gain time for their personal lives. These include practices that are believed to hasten and compress the length of labor (such as augmentation with synthetic oxytocin, ruptured membranes, and staff-directed pushing) as well as converting in labor from vaginal to cesarean birth.

Hospitals can benefit from use of interventions to control birth as well. Scheduled inductions and cesareans can help plan for nurse staffing. Nursing staff may especially appreciate weekday hours, and hospitals may find it easier and less expensive to hire nurses for those shifts. Quicker turnover of delivery rooms or an even briefer period in an operating room can reduce staff time required for a given birth and free up the space for a new mother. A recent study estimated that employer-sponsored insurance paid hospitals an additional \$2,090 for cesarean births in comparison with vaginal births in 2004 (Thomson Healthcare 2007). Cesarean birth involves extra days in the hospital and more intensive care, and further analysis is needed to understand whether the larger payments provide an incentive for cesarean birth. In other clinical areas, hospital admissions for surgical procedures have been found to be much more profitable than admissions for medical procedures (Ginsburg and Grossman 2005).

Charting of birth by time of day, day of week, and holiday versus non-holiday shows that birth in the United States takes place disproportionately during non-holiday weekday hours (Goodman 2007; Peltier 2007). While some of this variation reflects scheduling for appropriate inductions and cesareans, a very large proportion of these procedures is discretionary, with troubling implications for the welfare of mothers and babies and the cost of maternity care.

Thus, the present reimbursement system involves strong disincentives for support of physiologic childbirth. Providers and hospitals who give optimal care to women can pay a price in the amount of reimbursement they receive for their considerable effort, in their ability to obtain payments for other services, and/or in their ability to control personal and personnel time. The current payment system provides disincentives to limit use of induction, cesarean section, and other labor and birth interventions, and disincentives to offer women patient support for their own efforts, capacities, and time frames. Those who provide optimal care do not get extra monetary rewards and are thus

penalized for such high-quality service and for the benefit to purchasers of more appropriate use of costly interventions. Those who maintain such high standards may have difficulty remaining in competitive markets.

We were unable to find data on the appropriateness of use of neonatal intensive care unit (NICU) services for healthier newborns and on NICU use due to problems that might have been avoided, such as respiratory problems in babies with avoidable planned cesareans. If NICUs are functioning as profitable hospital service lines with incentives for inappropriate care, this may involve avoidable exposure to tests and treatments, disruption of family life at this important time, and expense for costly care. It is a priority to better understand the role of financial incentives in patterns of newborn hospital care.

#### MALPRACTICE CONCERNS

A full examination of the negative impact of the present liability environment on maternity care and options for addressing the adverse effects is needed at this time. Key points are noted here. First, the liability system continues to uphold current standards of care and use of professional experts without regard to lessons from the best scientific research (Massie 2004; Peters 2000). This is a troubling disincentive for the provision of evidence-based maternity care. It is a priority to identify ways to align legal incentives with care that is consistent with the best scientific research.

Second, leading allegations in obstetric claims involve infant neurologic injury or stillbirth/ neonatal death (Wilson and Strunk 2007). Fear of high-cost awards to compensate families of children with disabilities appears to generate some undesirable defensive behavior. Many of these awards do not in fact involve the legal malpractice standard of negligent injury, and rather reflect a willingness of involved parties to help families in need. Other mechanisms are needed for this purpose.

Third, population-based studies that led to recognition of the high level of medical error in the United States and to the Institute of Medicine's landmark *To Err Is Human* report (Kohn et al. 2000) clarified that maternity care does involve a notable amount of negligent injury of newborns and especially of mothers (Brennan et al. 1991; Thomas et al. 2000). More recently, an adverse event rate of at least 2.1 percent and possibly as high as 5.4 percent was reported for a teaching hospital obstetrics unit (Forster et al. 2006). The present malpractice system is not doing a good job of providing incentives to limit this injury or to compensate those who experience it.

Fourth, implementing a culture of safety and quality and more cooperative methods for responding to concerns about error and injury may go a long way toward giving health personnel and families who receive care increased confidence about the care that is delivered and may help limit adverse effects of the liability system (Pearlman 2006; Sage 2003; Schoenbaum and Bovbjerg 2004).

Fifth, care by midwives and in birth centers is often well-suited to childbearing women and can provide excellent value to purchasers. However, midwives and birth centers face some special challenges in the present liability environment. For example, a large payout within their smaller pools

can lead to a major increase in the size of premiums, making it unaffordable to remain in the market with professional liability insurance. Moreover, the trend has been for conventional commercial insurers to be replaced by malpractice insurance providers that are owned by or closely allied with physicians and hospitals. The new carriers may have limited commitment to ensuring that midwives and birth centers are able to remain in the market. Further, policies of some physicians interfere with provision of back-up services to midwives. Also, due to their commitment to a conservative practice style, midwives and birth centers may be unwilling to intensify use of procedures to increase volume of services and reimbursement in response to the pressure of high premiums. Also, such procedures may be beyond their scope of practice. Although this focus on avoiding unwarranted services is desirable from the perspective of quality care, it further limits the ability of midwives and birth centers to remain in the market. Finally, maternity providers who have the relatively new certified professional midwife credential may have difficulty finding access to liability insurance products.

# SPECIALIST ORIENTATION CARE TYPICAL FOR HEALTHY, LOW-RISK MOTHERS AND BABIES

Although most pregnant women in the United States are healthy and at low risk for complications, pathology- and surgery-oriented obstetric specialists are the lead caregivers for about 79 percent of women during both pregnancy and labor (Declercq et al. 2006). The predominant orientation of this specialty is external management of childbirth, as opposed to facilitation of physiologic processes (Reime et al. 2004). Among developed nations, only the United States and Canada rely to this degree on specialists rather than midwives to provide care to healthy birthing women (Wagner 1998).

A cluster analysis in British Columbia helped clarify variation in attitudes within and across the main types of maternity caregivers. The analysis associated 79 percent of obstetricians and 16 percent of family physicians with the obstetric attitude cluster, 21 percent of obstetricians and 58 percent of family physicians with the family physician cluster, and 26 percent of family physicians and 100 percent of midwives with the midwife cluster (Reime et al. 2004). A study of practice style across the three groups in Washington State controlled for biological and demographic differences in the women receiving care. Investigators found pronounced differences in care provided by certified nurse-midwives (fewer interventions) and both types of physicians. There were more modest differences between obstetricians and family physicians (the latter had lower epidural rates and more women who used no pain medication) (Rosenblatt et al. 1997).

Midwives are more likely to have skills that support physiologic processes in healthy women and newborns, to value such supportive care, and to make judicious and conservative use of interventions (Brown and Grimes 1995; Cragin and Kennedy 2006; Hatem et al. in press; Kennedy and Shannon 2004; Waldenström and Turnbull 1998; Walsh and Downe 2004). Nationally, risk-adjusted outcomes of care by certified nurse-midwives caring for women with single vaginal births at thirty-five to forty-three weeks of gestation demonstrated better outcomes than physician caregivers with respect to low

birthweight and neonatal and infant mortality, which may reflect well-documented differences in practice style (MacDorman and Singh 1998; see also Raisler and Kennedy 2005). Yet midwives are vulnerable to marginalization and experience obstacles that benefit powerful interests at the expense of the health care system and the best interests of women and babies (Goodman 2007). They are the lead caregivers for just 8 to 9 percent of U.S. mothers during pregnancy and childbirth (Declercq et al. 2006). In the United States, certified nurse-midwives (CNMs), certified midwives (CMs), and certified professional midwives (CPMs) have passed certification exams of entities accredited by the accrediting body of the National Organization for Competency Assurance and met the criteria of the International Confederation of Midwives for the definition of a midwife. Projected cost savings from shifting to a system of care with midwives as primary caregivers for most U.S. birthing women are considerable (Wagner 1998).

In the United States, family physicians (FPs) are important providers of maternity care, with a disproportionate provision of maternity services in many geographic areas. About 28 percent of FPs provide some type of maternity care, and 20 percent attend births in hospitals, while about 73 percent of all FPs accept Medicaid beneficiaries (American Academy of Family Physicians 2007). They bring to maternity services the value of a primary care orientation and of care provided to entire families, with continuity through the life course. Overall, the practice style of family physicians falls between obstetricians and midwives (Reime et al. 2004). Family physicians are the lead pregnancy caregivers for just about 8 percent of women and the birth attendant about 7 percent of the time in the United States (Declercq et al. 2006). The most recent review comparing the process and outcomes of maternity care provided by family physicians and by obstetricians found that differences favor family physicians (Klein 1993).

#### CURRENT MATERNITY PRACTICE GUIDELINES EXCESSIVELY RELIANT ON OPINION

A recent analysis of American College of Obstetricians and Gynecologists (ACOG) obstetrical practice bulletins published from June 1998 through December 2004 reported that a small proportion of the recommendations in the bulletins met high standards of evidence. Just 23 percent of obstetrics recommendations were Level A ("based on good and consistent scientific evidence"), whereas 35 percent were Level B ("based on limited or inconsistent scientific evidence") and fully 42 percent were Level C ("based primarily on consensus and expert opinion"). Among references cited for the obstetric and gynecologic bulletins that were assessed, just 1 percent were for systematic reviews from the *Cochrane Database of Systematic Reviews*, and 3 percent were for meta-analyses (Chauhan et al. 2006), collectively representing a minute proportion of the large, growing inventory of available systematic reviews and meta-analyses on maternal, newborn, and women's health topics.

Within evidence-based medicine, expert opinion that is not based on critical appraisal of research is viewed as the lowest and least valid level of evidence, and a systematic review of the most

rigorous primary studies is considered optimal research, offering the most valid results (Centre for Evidence-Based Medicine 2001; Eden et al. 2008).

Some current ACOG guidelines have lowered or removed the bar for use of consequential interventions, in comparison with previous versions. For example, current guidance on labor induction accepts "psychosocial indications" (American College of Obstetricians and Gynecologists 1999), and current guidance on slow or stalled labor progress (dystocia) has removed previous explicit criteria for diagnosing dystocia before turning to a cesarean (American College of Obstetricians and Gynecologists 2003). Despite the weak foundation of guidelines from the leading U.S. obstetric professional society, the recommendations influence professional practice. To reduce risk of legal liability, providers may experience pressure to practice according to recommendations without good scientific support.

#### LACK/LOSS OF PROFESSIONAL CORE KNOWLEDGE/SKILLS FOR OPTIMAL CHILDBIRTH

Support for physiologic labor is the safest care for healthy women experiencing normal labor. This is also the most economical care for purchasers of maternity services. Most midwifery education programs offer an opportunity to observe physiologic childbirth and to learn about and become competent in supporting innate capacities of women and their fetuses/newborns. However, given current standards of practice (Table 3), many physicians may have limited opportunities to observe and support physiologic childbirth during their education and beyond. Adequate knowledge about appropriate choice and timing of interventions is a special concern, including knowing whether and when to intervene in nonurgent matters, how to do so safely without imposing needless harm, and when more invasive interventions are truly of value.

Instead of relying on a breadth of core childbirth skills and knowledge, first-line care often involves use of interventions such as synthetic oxytocin (used by 57 percent of mothers in the *Listening to Mothers II* survey), epidural analgesia (76 percent), and cesarean section (32 percent) (Declercq et al. 2006; Gawande 2006; Savage 2007). A related concern is the proposition that a scheduled cesarean is a good way to preserve pelvic floor function (O'Boyle, Davis, and Calhoun 2002), when caregivers could instead emphasize safer vaginal birth practices that limit episiotomy, forceful pushing, "fundal pressure" on the mother's abdomen, back-lying positions for giving birth, and other practices that are prevalent (Declercq et al. 2006) and increase risk for pelvic floor injury (Albers and Borders 2007; *Bosomworth and Bettany-Saltikov 2006; Gupta, Hofmeyr, and Smyth 2004; Hartmann et al. 2005*).

Despite lengthy and expensive health professional education programs, recently educated practitioners may have limited opportunity to acquire and maintain core skills, including those needed for the following:

facilitation of labor progress and provision of comfort measures and pain coping skills through
patient, individualized care that might involve emotional support; use of positioning and
movement; guarding energy reserves; a private and calm environment; use of heat, cold, pressure,

- and/or warm water; and so forth as appropriate and helpful to a laboring woman (Simkin 2002; Simkin and Ancheta 2005; Simkin and Bolding 2004)
- skillful, judicious assisted delivery (vacuum extraction and forceps) (Spencer, Murphy, and Bewley 2006)
- external version to manually turn babies to a head-first position (Spencer, Murphy, and Bewley 2006)
- vaginal breech birth (American College of Obstetricians and Gynecologists 2006; Lavin Jr., Eaton, and Hopkins 2000; Queenan 2004; Spencer, Murphy, and Bewley 2006)
- vaginal twin birth (Spencer, Murphy, and Bewley 2006)
- support for breastfeeding (Freed et al. 1995; Philipp, Merewood, and O'Brien 2001)

#### HARMS AND IATROGENESIS OFTEN NOT ADEQUATELY UNDERSTOOD/CONSIDERED

Despite heightened concerns about the potential for harm during sensitive developmental periods (as discussed earlier in the Physiologic Foundation section) and women's interest in knowledge of harms of interventions (Declercq et al. 2006), adverse effects are often underemphasized in medicine. An optimism bias prevails (Chalmers and Matthews 2006), and many evidence sources focus primarily or exclusively on benefits, while comprehensive high-quality data on harms are often unavailable. In primary studies, harms are less likely than benefits to be studied at all, in enough participants, or over a long enough period; adequately measured; reported when studied; and well-referenced in articles (Chan et al. 2004; Ioannidis et al. 2004). The biases persist in systematic reviews due to this professional ethos and the deficiencies of the primary studies (McIntosh, Woolacott, and Bagnall 2004; Papanikolaou and Ioannidis 2004). Randomized controlled trial evaluations of interventions and systematic reviews limited to RCTs are unlikely to be able to measure serious but rare outcomes or effects that may manifest when study participation has ended. Liberal use of maternity interventions with limited caution about harms reflects these pervasive patterns and values.

#### KNOWLEDGE TRANSFER AND APPLICATION CHALLENGING

It is a challenge to stay abreast of and interpret the vast and ever-growing body of research on pregnancy and childbirth. As the initial work to systematically appraise best research was carried out in this field, there are far more Cochrane reviews for this clinical area than any other, in addition to a large number of pregnancy and childbirth systematic reviews from other sources. Busy professionals need support to keep up with best pregnancy and childbirth evidence.

Even with access to lessons from the best available research, it is often difficult to move beyond established beliefs and routines and put evidence into practice without reconfiguring education, practice settings, and policies. Nonetheless, a growing body of systematic reviews identifies effective strategies for health practice quality improvement (see Appendix), and the National Institutes of Health have identified translational research as a priority.

#### PRESSURE FROM INDUSTRY

Industry pressure compromises maternity care. Drugs, devices, and other products with commercial value are more likely to be evaluated, adopted into practice, and promoted than simpler measures with little or no commercial value. One of the most striking examples in maternity care is the commercial value of formula, in contrast to breast milk, which is optimal for nearly all babies. Before and after giving birth, many women receive numerous formula samples/offers, and the formula industry influences policies and practices in hospital maternity units. As a result, even women who wish to exclusively breastfeed experience numerous hospital practices that disrupt breastfeeding, such as the distribution of formula "supplements" and promotional materials (Declercq et al. 2006; Kaufman and Lee 2007).

#### INFORMED CONSENT PROCESSES OFTEN INADEQUATE

Studies of decision making in maternity settings consistently raise concerns about the adequacy of informed consent processes (e.g., Akkad et al. 2004; Dixon-Woods et al. 2006; O'Cathain et al. 2002; Turnbull et al. 1999). Among women who experienced episiotomy in U.S. hospitals in 2005, just 18 percent reported having had a say about the procedure (Declercq et al. 2006). In recent national surveys, virtually all women expressed the wish to know all or most of the complications of labor induction, epidural, and cesarean before deciding to undergo these respective procedures, but mothers had poor knowledge of their actual side effects, whether they had experienced the specific intervention or not (Declercq et al. 2002; Declercq et al. 2006).

In many if not most jurisdictions in the United States, the legal standard of informed consent has shifted from what a health professional believes a person should understand about offered care to what a reasonable patient would want to know (American College of Obstetricians and Gynecologists 2005). Improved consumer education and informed consent processes are needed to ensure that women have the information they desire and that informed consent processes meet evolving legal standards.

Adequate informed consent processes for labor and birth interventions are especially difficult to achieve while women are experiencing the challenges of labor. At that time, women have limited options for obtaining second opinions, gathering further information, and making other care arrangements. On the other hand, pregnant women have many months to prepare and would benefit from access to high-quality information and decision support relating to labor and birth well before labor. Informed choice requires access to a range of options, good understanding of best evidence about benefits and harms of offered care and of alternatives, and solid support for the choices women make.

# MEDIA DEPICTION OF THE CHILDBIRTH EXPERIENCE OFTEN LIMITED

It is difficult for journalists, the general public, and childbearing women themselves to understand the nature, extent, and causes of the evidence-practice gaps in maternity care. Increasingly, there is little other frame of reference for all stakeholder groups than the pattern of care summarized in Table 3. The *Listening to Mothers II* survey found that far more pregnant women were exposed to the childbirth experience through often sensational TV shows than through the didactic and interactive process of childbirth education provided by trained educators (Declercq et al. 2006).

# INCREASED HARM/EXPENSE AND MORE ENTRENCHED PROBLEMS TO RESULT IF POLICY INTERVENTION DELAYED

Millions of mothers, newborns, and families cannot wait for a delayed response and would benefit from timely improvement of maternity care. In addition, improving the quality of maternity care is critical to avoiding more deeply entrenched problems.

First, as described in this section, loss of skills and knowledge among maternity professionals is a serious concern. Younger professionals have fewer core skills for supporting childbearing women than those nearing retirement (American College of Obstetricians and Gynecologists 2006; Gawande 2006). It is a priority to stem these skill losses, to benefit from those professionals who have retained these essential skills, and to ensure that the large investment in the education of health professionals results in caregivers who are prepared to provide appropriate care.

Second, as standards of maternity care and the culture of maternity care shift (Simpson and Thorman 2005), fewer and fewer professionals, administrators, policymakers, journalists, and women themselves have a frame of reference for what is appropriate care, and it is becoming difficult for all stakeholder groups to know what care is possible and optimal and to provide and seek such care.

Finally, altering the present course can head off unintended downstream consequences. The rising rate of first-time cesareans and the increasing trend for repeat cesareans have health risk implications that will play out over a long period of time, and more so in an environment where repeat cesarean is the norm and many women who desire VBAC do not have this option. With growing use of labor induction and cesarean section, hospital maternity units are reconfiguring to accommodate more surgeries, more labor and birth services scheduled during weekday hours, and more postpartum beds due to longer postsurgical lengths of stay. Supplier-induced demand is likely to be a formidable force after hospitals make these costly capital investments and become dependent upon the increased revenue from cesarean as opposed to vaginal birth, face pressure to receive a return on their investments, and shape practice through new facility designs.

# POLICY RECOMMENDATIONS DEVELOPED IN COLLABORATION WITH MEMBERS OF THE REFORMING STATES GROUP

Members of the Reforming States Group worked together with the authors of this report to identify the following policy recommendations and strategies to increase the provision of evidence-based maternity care.

Evidence-based health care methodologies were developed within the field of pregnancy and childbirth over a quarter century ago. Despite a strong and continually refined knowledge base, contemporary maternity care in the United States involves considerable overuse of harmful or ineffective practices (e.g., episiotomy, cesarean section, early separation of mothers and babies) and underuse of beneficial practices (e.g., smoking cessation programs in pregnancy, continuous support during childbirth). Further, many important research questions have not been adequately investigated, including questions about the potential for longer-term unintended consequences of numerous widely used maternity interventions in both children and women.

Maternity care decisions should be guided by the best available evidence and the principle of effective care with least harm, as well as the informed preferences of women and their families, rather than by unsupported beliefs about appropriate care, convenience, liability pressure, or other extrinsic factors. Subject to the availability of resources, policymakers can use educational, research, fiscal, and performance measurement strategies to encourage the health system to provide, and women to seek, evidence-based maternity care.

Malpractice concerns are a troubling disincentive for the provision of evidence-based maternity care. The medical liability system continues to drive standards of care and use of professional experts without regard to lessons from the best scientific research. An example of this paradox is the legal system's prevailing assertion that continuous electronic fetal monitoring (EFM) is a standard of care for all deliveries despite the available wealth of evidence identifying intermittent monitoring as preferable. More research and fruitful discussions among all stakeholders need to occur to better align the legal system with best available evidence.

To foster increased provision of evidence-based maternity care, we recommend the following:

- Increasing the knowledge and use of evidence-based maternity care by educating and advising
  a wide range of stakeholders. These stakeholders include state and federal policymakers in
  legislative and executive branches, health professionals and health profession educators, hospital
  and health plan administrators, insurers, employers, researchers, childbearing women and their
  families, consumer advocates, and journalists.
  - Distribute this report to the multiple stakeholders.
  - Carry out public health education campaigns in support of evidence-based maternity care.
  - Create model professional education programs with evidence-based maternity care
    curricula and practicum experiences at public colleges and universities. Support medical
    students, family medicine and obstetric residents, and nursing and midwifery students
    with interdisciplinary training involving maternity care providers such as midwives, nurses,
    lactation consultants, perinatologists, and obstetricians.

- Support the development, provision, and updating of independent sources of highquality evidence-based education and decision support materials in accessible formats for childbearing women.
- Develop clinical practice guidelines that promote evidence-based maternity care and reflect
  the principle of effective maternity care with least harm to guide health professionals and
  institutional and organizational policies.
- 2. Supporting research to further evidence-based maternity care.
  - Investigate available studies on the impact of the liability system on maternity care, and identify ways to strengthen that system and limit unintended effects.
  - Prioritize research needs for evidence-based maternity care and the principle of
    effective maternity care with least harm, and close continuing gaps in knowledge. Give
    careful attention to possible harms of interventions. Improve knowledge of longer-term
    effects in children and women, in recognition of the significance of maternity care to
    the developmental origins of health and disease. Identify pre- and interconceptional
    opportunities to improve maternity outcomes.
  - Include comparison groups of women with physiologic care to clarify relative benefits and harms of maternity interventions whenever appropriate.
  - Apply research results to the domains of education, payment and financing, and quality measurement.
- 3. Reforming the current reimbursement system to promote evidence-based maternity care and extending payment reform to all payers, including private insurers.
  - Support a comprehensive, high-level exploration of ways to align the payment and financing
    system with the principle of effective care with least harm, including support for physiologic
    childbirth in healthy women. Involve leading experts on health care payment and
    financing, advocates for childbearing women and families, and other stakeholders in this
    work. Mechanisms to consider include reducing payment for overused services; increasing
    payment for underused services, including support for physiologic childbirth; rewarding
    high-performing providers and facilities; and providing incentives for women to select highperforming providers and facilities.
  - Modify distribution of Medicaid graduate medical education funds to incentivize medical schools and residency programs to develop and utilize curricula for evidence-based maternity care.
  - Encourage the federal government to implement and evaluate demonstrations of the most promising ways to align payment and financing with evidence-based maternity care.
  - Address the need to retain and expand the supply of family physicians who include maternity
    care in their scope of practice (most crucial in rural and underserved areas) through
    financial incentives and/or funding of dedicated programs to provide loan repayment
    support, early career mentoring, and locums physicians offering relief and support.

- Foster broad access to safe, effective midwifery care by setting adequate Medicaid and Medicare reimbursement rates for certified nurse-midwives, certified midwives, and certified professional midwives.
- Apply successful mechanisms broadly throughout the nation, with leadership from the Centers for Medicare and Medicaid Services, state Medicaid programs, and other purchasers of maternity services, including large employers.
- 4. Requiring performance measurement, reporting, and improvement.
  - Develop a national standardized evidence-based set of maternity performance measures and fill gaps in available measures to address current patterns of overuse, underuse, and unjustified practice variation.
  - Support the establishment and implementation of statewide or regional maternity care
    quality improvement collaboratives and develop statewide or regional database/reporting
    systems that provide useful information to the public about the performance of maternity
    professionals and facilities, and also provide practitioners with information about their
    performance. Use performance measurement to identify disparities and to initiate focused
    quality improvement.
  - Incorporate maternity care performance measures into Medicaid quality improvement activities, including Medicaid managed care contracts. Encourage private insurers to adopt and incorporate similar performance measures.
  - Set aggressive goals for maternity care quality improvement in public agency contracts for Medicaid clients, public employees, and others.

These recommendations reflect the need to increase the public's awareness of evidencebased maternity care practices, to support further research in this area, and to develop a reimbursement system and performance measures that promote evidence-based care. Implementing these recommendations has the potential to greatly increase access to evidence-based maternity care in the United States and to provide excellent value for purchasers of maternity services.

# APPENDIX: LEADING RESOURCES AND TOOLS FOR EVIDENCE-BASED MATERNITY CARE NOTE: AN ASTERISK INDICATES THAT THE RESOURCES ARE AVAILABLE WITHOUT CHARGE OF SUBSCRIPTION

Agency for Healthcare Research and Quality, Evidence-based Practice Program\* http://www.ahrq.gov/clinic/epcix.htm (accessed June 13, 2008).

BMJ Clinical Evidence, updated monthly http://www.clinicalevidence.com (accessed June 13, 2008).

Childbirth Connection: What Every Pregnant Woman Needs to Know about Cesarean Section\* http://www.childbirthconnection.org/cesareanbooklet/ (accessed June 25, 2008).

Childbirth Connection website: For Women section\* http://www.childbirthconnection.org/home.asp?Visitor=Woman (accessed June 13,2008).

Cochrane Central Register of Controlled Trials, updated quarterly http://www.thecochranelibrary.com (accessed June 13, 2008).

Cochrane Database of Systematic Reviews, updated quarterly provides free access to detailed abstracts and plain language summaries for all reviews http://www.thecochranelibrary.com (accessed June 13, 2008).

Current Resources for Evidence-Based Practice, updated quarterly\* http://www.childbirthconnection.org/article.asp?ClickedLink=199&ck=10268&area=2 (accessed June 13, 2008).

Database of Abstracts of Reviews of Effects (DARE), updated monthly\* http://www.crd.york.ac.uk/crdweb/ (accessed August 13, 2008).

Evidence-Based Maternity Care Resource Directory\*
covers systematic reviews about effective professional practice and organization of care, reports that summarize this body of work, reports about maternity quality improvement initiatives and many

http://www.childbirthconnection.org/article.asp?ClickedLink=184&ck=10263&area=2 (accessed June 13, 2008).

Family Medicine Obstetrics, 3rd edition (Ratcliffe, S.D., ed.). Amsterdam: Elsevier Health Sciences, 2008.

http://www.elsevier.com/wps/find/bookdescription.cws\_home/713090/description#description (accessed June 13, 2008).

A Guide to Effective Care in Pregnancy and Childbirth, 3rd edition (Enkin, M., M.J.N.C. Keirse, J. Neilson, C. Crowther, L. Duley, E. Hodnett, and J. Hofmeyr eds). Oxford: Oxford University Press, 2000.\* http://www.childbirthconnection.org/article.asp?ClickedLink=194&ck=10218&area=2 (accessed June 13, 2008).

# Listening to Mothers Surveys\*

These survey questionnaires may be adapted to help states, health plans, hospitals, and other entities better understand the childbearing experiences of their constituents and to develop policies and programs to improve care for specific populations. The questionnaires, full survey reports (with appendices detailing the study methodology and summarizing validation studies of birth certificate and hospital discharge data), and other related documents are available at http://www.childbirthconnection.org/listeningtomothers/ (accessed June 13, 2008).

National Institute for Health and Clinical Excellence\* http://www.nice.org.uk/ (accessed June 13, 2008).

National Institutes of Health, PubMed meta-analysis search function\* http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=Limits&DB=pubmed (accessed June 13, 2008).

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## THE AUTHORS

Maureen P. Corry, MPH, is Executive Director and Carol Sakala, PhD, MSPH, is Director of Programs of Childbirth Connection, a not-for-profit organization that has made significant contributions to maternity care quality in the United States for ninety years. Founded in 1918 as Maternity Center Association, the organization has been based continuously in New York City. Its mission is to improve the quality of maternity care through research, education, advocacy, and policy.

Together, Corry and Sakala have conceived, planned, and led the implementation of Childbirth Connection's long-term national program to promote evidence-based maternity care, which was established in 1999. The program works with policymakers, health professionals, childbearing women, and journalists to close gaps between current practice and practice supported by best evidence. The authors are active in helping stakeholders understand and apply best evidence that is ready for implementation, commissioning systematic reviews and other appropriate research to fill gaps in evidence, and carrying out research on selected priority topics. The award-winning Childbirth Connection website (http://www.childbirthconnection.org) is an important vehicle for this work.

Under the authors' leadership, the organization commissioned leading investigators to prepare systematic and narrative reviews to clarify best evidence about the nature and management of labor pain. The resulting papers were presented and discussed at a multidisciplinary invitational symposium jointly sponsored with the New York Academy of Medicine and then peer-reviewed and published in the *American Journal of Obstetrics & Gynecology* (May 2002).

The authors are co-investigators of the landmark Listening to Mothers surveys. The initial survey (2002) marked the first time that women in the United States were polled at the national level about their maternity experiences and assessment of those experiences. Listening to Mothers II, covering continuing and new topic areas, was carried out and reported in 2006, and a follow-up survey with the same mothers was reported in 2008 in New Mothers Speak Out: National Survey Results Highlight Women's Postpartum Experiences. Harris Interactive conducted all three surveys, which enable a new level of understanding of the maternity experience in the United States.

Through the authors' leadership, Childbirth Connection carried out the only systematic review to identify the full range of harms that differ in likelihood by mode of birth, and then developed and issued a decision tool for women that summarized the review's findings. The consumer booklet What Every Pregnant Woman Needs to Know about Cesarean Section (revised edition 2006) has been endorsed by over thirty organizations.

At present, the authors focus especially on health policy and are active in the National Quality Forum, the Consumer-Purchaser Disclosure Project of the National Partnership for Women and Families, and Consumers United for Evidence-Based Healthcare. They are also planning Childbirth Connection's ninetieth anniversary symposium, *Transforming Maternity Care: A High Value Proposition*, which will be held in April 2009 and will bring together stakeholders from across the health care system to develop a blueprint for action to improve the quality of maternity care in the United States.

Carol Sakala has twenty-five years of experience as a researcher, educator, advocate, and policy analyst, with a continuous focus on maternity care quality improvement. From 2003 through

2007, she contributed a quarterly column, Current Resources for Evidence-Based Practice, for simultaneous publication in *Journal of Obstetric, Gynecologic, & Neonatal Nursing* and *Journal of Midwifery & Women's Health*. She has served for many years as Consumer Coordinator for North America of the Cochrane Pregnancy and Childbirth Group's Consumer Panel and also referees draft systematic reviews as a Panel member. She is a co-author of the influential Cochrane Review "Continuous Support for Women during Childbirth," prepares an annual Letter from North America for the journal *Birth*, and is the author of numerous other publications. She serves on the Steering Committee of the Guidelines International Network's Working Group on Patient and Public Involvement. She was a Pew Health Policy Fellow at Boston University, which awarded her doctorate in health policy in 1993.

Maureen Corry has thirty years of experience as a researcher, educator, advocate, and policy analyst focusing on maternal and infant health promotion and maternity care quality improvement. She has served as a board member of several national maternal and child health organizations and is currently Vice Chair of the Consumer Council of the National Quality Forum (NQF). She co-chaired NQF's National Voluntary Consensus Standards for Perinatal Care Steering Committee, which developed a national set of standardardized performance measures for care at the end of pregnancy and during the intrapartum period. She referees systematic reviews under development for the Cochrane Pregnancy and Childbirth Group, is the author of numerous articles and consumer education resources, and is a frequent speaker at professional meetings. She received her MPH in 1991 from Yale School of Medicine in health services administration.

In their personal lives, both authors have experienced two pregnancies and births. Sakala is the mother of a teenaged daughter and son, and Corry is the mother of adult sons with families of their own.

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\*New Mothers Speak Out: National Survey Results Highlight Women's Postpartum Experiences by Eugene R. Declercq, Carol Sakala, Maureen P. Corry, and Sandra Applebaum 2008 69 pages

Achieving the Institute of Medicine's Six Aims for Improvement in Maternity Care by Carol Sakala and Maureen P. Corry 2008 Women's Health Issues 18(2):75–78

\*Continuous Support for Women during Childbirth by Ellen D. Hodnett, Simon Gates, G. Justus Hofmeyr, and Carol Sakala 2007 Cochrane Database of Systematic Reviews, Issue 3

Listening to Mothers II Reveals Maternity Care Quality Chasm by Carol Sakala and Maureen P. Corry 2007 Journal of Midwifery & Women's Health 2(3):183–85

\*What Every Pregnant Woman Needs to Know about Cesarean Section, revised edition by Childbirth Connection

2006 27 pages

\*Listening to Mothers II: Report of the Second National U.S. Survey of Women's Childbearing Experiences

by Eugene R. Declercq, Carol Sakala, Maureen P. Corry, and Sandra Applebaum 2006 104 pages

\*The Rights of Childbearing Women, second edition by Childbirth Connection 2006

Letter from North America by Carol Sakala (2006–) annual column published in December issue of *Birth* 

Vaginal or Cesarean Birth?: Application of an Advocacy Organization-Driven Research Translation Model by Carol Sakala and Linda J. Mayberry 2006 Nursing Research 55(2, supplement 1):S68–S74.

\*Current Resources for Evidence-Based Practice
by Carol Sakala (2003–2007) and R. Rima Joliet (2008–)
quarterly column published simultaneously in *Journal of Midwifery & Women's Health* and *Journal of Obstetric, Gynecologic, & Neonatal Nursing* 

\*Listening to Mothers: Report of the First National U.S. Survey of Women's Childbearing Experiences by Eugene R. Declercq, Carol Sakala, Maureen P. Corry, Sandra Applebaum, and Peter Risher published by Maternity Center Association 2002 59 pages

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by Donald Caton, Maureen P. Corry, Frederic D. Frigoletto, David P. Hopkins, Ellice Lieberman,
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2002 American Journal of Obstetrics & Gynecology 186(5, supplement):S1–S15.

What Is Evidence-Based Health Care? by Carol Sakala and Maureen P. Corry 2001 Journal of Midwifery & Women's Health 46(3)127–28

Consumer-Professional Partnership to Improve Research: The Experience of the Cochrane Collaboration's Pregnancy and Childbirth Group by Carol Sakala, Gill Gyte, Sonja Henderson, James P. Neilson, and Dell Horey 2001 *Birth* 28(2):133–37.

Information about other work of Childbirth Connection is available from Childbirth Connection at 281 Park Avenue South, 5th Floor, New York, NY 10010. Telephone: (212) 777-5000. Fax: (212) 777-9320. Email: info@childbirthconnection.org. On the web: www.childbirthconnection.org.

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Childbirth Connection is a national notfor-profit organization founded in 1918 as Maternity Center Association. Its mission is to improve the quality of maternity care through research, education, advocacy, and policy. Childbirth Connection promotes safe, effective, and satisfying evidence-based maternity care and serves as a voice for the needs and interests of all childbearing women and their families.

Childbirth Connection 281 Park Avenue South, 5th Floor New York, NY 10010 (212) 777-5000 www.childbirthconnection.org

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CHILDBIRTH CONNECTION

281 PARK AVENUE SOUTH, 5TH FLOOR

NEW YORK, NY 10010

REFORMING STATES GROUP

MILBANK MEMORIAL FUND
645 MADISON AVENUE
NEW YORK, NY 10022



#### **Perinatal Mortality**

The Centers for Disease Control and Prevention defines perinatal mortality as a death occurring after 28 weeks of gestation through the first week of life.

- The major causes of perinatal deaths are congenital anomalies, low birth weight, maternal complications, complications of the placenta, cord and membranes, and infections.
- Rates of perinatal mortality in the United States have remained consistent at 6 deaths per 1000 births since 2011. While the overall perinatal mortality rates have remained steady, there are significant variations in these rates based on both maternal demographics and geographic location.
- The lowest perinatal mortality rate occurs among Asian and white women at 5 deaths per 1000, with the highest rate occurring among black women at 10.5 deaths per 1000.
- Rates are also higher for women younger than 20 or over the age of 35.
   Wyoming has the lowest overall perinatal mortality rate at 4.3 deaths per 1000 births, while Alabama has the highest rate at 8.3 deaths per 1000 births.
- The latest report shows Colorado's perinatal mortality rate at 5.5 deaths per 1000 births.

It is difficult to compare statistics from the Colorado Direct-Entry Midwives program to these state and national rates due to the way the program collects this data.

- Information collected does not conform to the CDC definition of perinatal mortality. Colorado data includes deaths occurring both earlier in pregnancy and later than one week after the birth.
- The relatively small number of births attended by registered midwives results in significant year to year variation in the rate of occurrence of rare events such as perinatal deaths.
- Over the last five years, the perinatal death rate based on program data is 9 deaths per 1000 births including births at home and those occurring in the hospital after transfer of care either before or during labor.
- However, it is nearly impossible to conclude if this number reflects an actual higher rate of perinatal loss under midwifery care or is a result of the variation in the data collected and the lack of verification of reported data.

Year	#MW	Births	Prenatal Transfers	Intrapartum Transports	Total	Perinatal Deaths				Total	
					Prenatal Care	Antepartum	Intrapartum	Postpartum	After Transfer	Perinatal Deaths	Rate/1000
2018	66	612	93	95	800	8	0	2	3	13	16.2
2017	62	783	102	110	995	6	0	0	5	11	11.1
2016	57	777	88	101	966	3	1	0	2	6	6.2
2015	60	810	105	137	1052	1	1	1	1	4	3.8
2014	56	802	102	120	1024	4	1	2	2	9	8.8
TOTAL		3784	490	562	4837	22	3	5	13	43	8.9

We recommend that the Direct-Entry Midwives Program begin collecting perinatal mortality data consistent with the CDC definition, limited to losses after 28 weeks gestation during pregnancy and before 7 days following the birth.

- In order to have statistical data that would be meaningful to inform efforts to reduce perinatal losses, all data needs to be verified for accuracy and the causes of perinatal deaths must be included in these statistics.
- It is clear that such efforts are well beyond the capacity of the current 0.15 FTE position administering this program at DORA. Alternatively, the program could rely on data collected by the Department of Vital Statistics if the intended place of birth at onset of labor is added to birth records and linked to neonatal death records.
- While any avoidable loss is of grave concern, we would like to assess better data on perinatal losses to determine if and what efforts could prevent avoidable deaths.
- It is important to keep in perspective that according to Colorado Vital Statistics data, Direct-Entry Midwives were the primary provider involved or transferred care in 1.6% of perinatal deaths in Colorado in 2014-2018 attending 1.3% of Colorado birth (Based on RM perinatal loss data from DORA, and total Colorado infant mortality from perinatal causes data from Vital Statistics).
- There are some nationally available, reliable, well-validated data collection systems available that could be used to collect more accurate data.

#### Midwifery integration is critical to achieve the best outcomes.

- Two recently published studies find that the best birth outcomes occur in health care systems that support collaboration between all maternity care providers and smooth transfers of care between facilities and providers when complications develop that indicate a need for a higher level of medical care.
- Vedum et al found that states with the highest degree of integration of all types of midwives in the healthcare system have the lowest rates of preterm birth, low birth weight infants, and neonatal death. (1) The degree of midwifery integration into the healthcare system was rated based on the following factors:
  - Regulated practice of all types of midwives;
  - Midwives access to routine medications:

- Ability of midwives to practice autonomously to the full scope of their training;
- Lack of restrictions on place of practice for all maternity care providers;
- Insurance and Medicaid coverage of care provided by all midwives;
- Culture of collaboration and consultation between all providers.
- Lower rates of neonatal mortality were strongly correlated with higher scores of midwifery integration.
- The 2020 report from the National Academies of Sciences evaluates practices to improve outcomes in all birth settings. Regarding factors to improve outcomes in community birth settings this reports concludes:
  - "Integrating home and birth center settings into a regulated maternity and newborn care system that provides shared care and access to safe and timely consultation; written plans for discussion, consultation, and referral that ensure seamless transfer across settings; appropriate risk assessment and risk selection across settings and throughout the episode of care; and well-qualified maternity care providers with the knowledge and training to manage first-line complications may improve maternal and neonatal outcomes in these settings."(2)

### We support changes to midwifery regulations that would increase midwives integration into the maternity care system in Colorado.

- In particular, there is an opportunity to create incentives for medical providers to engage in collaboration and consultation with midwives, and provide protection for midwives from harassment complaints, especially when they appropriately transfer clients to hospital care.
- Including registered midwives as eligible providers in the Medicaid program would also support a more integrated maternity care system and foster increased collaboration between providers.
- Vedam S, Stoll K, MacDorman M, Declercq E, Cramer R, Cheyney M, et al. (2018) Mapping integration of midwives across the United States: Impact on access, equity, and outcomes. PLoS ONE 13(2): e0192523. <a href="https://doi.org/10.1371/journal.pone.0192523">https://doi.org/10.1371/journal.pone.0192523</a>
- National Academies of Sciences, Engineering, and Medicine 2020. Birth Settings in America: Outcomes,
  Quality, Access, and Choice. Washington, DC: The National Academies Press. <a href="https://doi.org/10.17226/25636">https://doi.org/10.17226/25636</a>.
  Susan Scrimshaw and Emily P. Backes, Editors; Committee on Assessing Health Outcomes by Birth Settings;
  Board on Children, Youth, and Families; Division of Behavioral and Social Sciences and Education; Health and Medicine Division; National Academies of Sciences, Engineering, and Medicine.

## Least Restrictive Form of Regulation - Analysis

# What's in this section- analyzing whether the direct-entry midwifery program is the least restrictive form of regulation:

- Overview
- Colorado Informed Consent example
- Wisconsin example

### Least Restrictive? Probably Not.

As recommended by the report, "Principles for Model U.S. Midwifery Legislation and Regulation", DORA relies on national agencies such as NARM and MEAC to establish criteria to best regulate the profession of Direct Entry Midwifery. DORA's mission to protect the public is met by not just adhering to the national standards in initial registration but an ongoing reliance to help interpret regulation.

Midwifery is a profession that is autonomous, separate and distinct from nursing and medicine. What sets midwives apart from nurses and doctors is that only midwives can exercise the full scope of midwifery practice and provide all the competencies within this scope.

Due to the politically charged nature of the development of the Direct-Entry Midwifery program in Colorado, the law is too long, and the statute contains provisions and details that are better suited to regulations.

We are providing an example of a simpler midwifery law from Wisconsin, for comparison. We are also providing an example of a section of Colorado's law that would be better suited to being in regulations.

Nonetheless, as a whole the law adequately satisfies its obligation to being the least restrictive form of regulation.

12-225-105. Mandatory disclosure of information to clients.

- (1) Every direct-entry midwife shall provide the following information in writing to each client during the initial client contact:
  - (a) The name, business address, and business phone number of the direct-entry midwife;
  - (b) A listing of the direct-entry midwife's education, experience, degrees, membership in any professional organization whose membership includes not less than one-third of all registrants, certificates or credentials related to direct-entry midwifery awarded by any such Colorado Revised Statutes 2019 5 Uncertified Printout organization, and the length of time and number of contact hours required to obtain the degrees, certificates, or credentials:
  - (c) A statement indicating whether or not the direct-entry midwife is covered under a policy of liability insurance for the practice of direct-entry midwifery;
  - (d) A listing of any license, certificate, or registration in the health care field previously or currently held by the direct-entry midwife and suspended or revoked by any local, state, or national health care agency;
  - (e) A statement that the practice of direct-entry midwifery is regulated by the department. The statement must provide the address and telephone number of the office of midwifery registration in the division and shall state that violation of this article 225 may result in revocation of registration and of the authority to practice direct-entry midwifery in Colorado.
  - (f) A copy of the emergency plan as provided in section 12-225-106 (6);
  - (g) A statement indicating whether or not the direct-entry midwife will administer vitamin K to the client's newborn infant and, if not, a list of qualified health care practitioners who can provide that service; and
  - (h) A statement indicating whether or not the direct-entry midwife will administer Rho(D) immune globulin to the client if she is determined to be Rh-negative and, if not, a list of qualified health care practitioners who can provide that service.
- (2) Any changes in the information required by subsection (1) of this section shall be reflected in the mandatory disclosure within five days after the change.

### Wisconsin Statute Chapter 440 "Department of Safety and Professional Services" Subchapter XIII Licensed Midwives

#### **440.9805 Definitions.** In this subchapter:

- (1) "Health care provider" means a health care provider, as defined in s. 146.81 (1) (a) to (p), a person licensed or issued a training permit as an emergency medical services practitioner under s. 256.15, or a person certified as an emergency medical responder under s. 256.15 (8) (a).
- (2) "Licensed midwife" means a person who has been granted a license under this subchapter to engage in the practice of midwifery.
- (3) "Practice of midwifery" means providing maternity care during the antepartum, intrapartum, and postpartum periods.

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

#### 440.981 Use of title; penalty.

- (1) No person may use the title "licensed midwife," describe or imply that he or she is a licensed midwife, or represent himself or herself as a licensed midwife unless the person is granted a license under this subchapter or is licensed as a nurse-midwife under s. 441.15.
- (2) Any person who violates sub. (1) may be fined not more than \$250, imprisoned not more than 3 months, or both.

History: 2005 a. 292.

#### 440.982 Licensure.

- (1) No person may engage in the practice of midwifery unless the person is granted a license under this subchapter, is granted a temporary permit pursuant to a rule promulgated under s. 440.984 (2m), or is licensed as a nurse-midwife under s. 441.15.
- (1m) Except as provided in sub. (2), the department may grant a license to a person under this subchapter if all of the following apply:
- (a) The person submits an application for the license to the department on a form provided by the department.
- **(b)** The person pays the initial credential fee determined by the department under s. 440.03 (9) (a).
- (c) The person submits evidence satisfactory to the department of one of the following:
- **1.** The person holds a valid certified professional midwife credential granted by the North American Registry of Midwives or a successor organization.
- **2.** The person holds a valid certified nurse-midwife credential granted by the American College of Nurse Midwives or a successor organization.
- (d) The person submits evidence satisfactory to the department that the person has current proficiency in the use of an automated external defibrillator achieved through instruction provided by an individual, organization, or institution of higher education approved under s. 46.03 (38) to provide such instruction.
- (2) The department may not grant a license under this subchapter to any person who has been convicted of an offense under s. 940.22, 940.225, 944.06, 944.15, 944.17, 944.30 (1m), 944.31, 944.32, 944.33, 944.34, 948.02, 948.025, 948.051, 948.06, 948.07, 948.075, 948.08, 948.081, 948.09, 948.095, 948.10, 948.11, or 948.12 or under s. 940.302 (2) if s. 940.302 (2) (a) 1. b. applies.

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

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

#### 440.983 Renewal of licensure.

- (1) The renewal date for licenses granted under this subchapter is specified in s. 440.08 (2) (a). Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee determined by the department under s. 440.03 (9) (a).
- (2) A licensed midwife shall, at the time that he or she applies for renewal of a license under sub. (1), submit proof satisfactory to the department of all of the following:
- (a) He or she holds a valid certified professional midwife credential from the North American Registry of Midwives or a successor organization or a valid certified nurse-midwife credential from the American College of Nurse Midwives or a successor organization.
- **(b)** He or she has current proficiency in the use of an automated external defibrillator achieved through instruction provided by an individual, organization, or institution of higher education approved under s. 46.03 (38) to provide such instruction.

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

#### 440.984 Rule making.

- (1) The department shall promulgate rules necessary to administer this subchapter. Except as provided in subs. (2), (2m), and (3), any rules regarding the practice of midwifery shall be consistent with standards regarding the practice of midwifery established by the National Association of Certified Professional Midwives or a successor organization.
- (2) The rules shall allow a licensed midwife to administer oxygen during the practice of midwifery.
- (2m) The rules shall provide for the granting of temporary permits to practice midwifery pending qualification for licensure.
- (3) The rules may allow a midwife to administer, during the practice of midwifery, oxytocin (Pitocin) as a postpartum antihemorrhagic agent, intravenous fluids for stabilization, vitamin K, eye prophylactics, and other drugs or procedures as determined by the department.
- **(4)** The rules may not do any of the following:
- (a) Require a licensed midwife to have a nursing degree or diploma.
- **(b)** Require a licensed midwife to practice midwifery under the supervision of, or in collaboration with, another health care provider.
- **(c)** Require a licensed midwife to enter into an agreement, written or otherwise, with another health care provider.
- (d) Limit the location where a licensed midwife may practice midwifery.
- (e) Permit a licensed midwife to use forceps or vacuum extraction.

History: 2005 a. 292.

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

- **140.985 Informed consent.** A licensed midwife shall, at an initial consultation with a client, provide a copy of the rules promulgated by the department under this subchapter and disclose to the client orally and in writing all of the following:
- (1) The licensed midwife's experience and training.
- (2) Whether the licensed midwife has malpractice liability insurance coverage and the policy limits of any such coverage.
- (3) A protocol for medical emergencies, including transportation to a hospital, particular to each client.
- (4) Any other information required by department rule.

History: 2005 a. 292.

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

#### 440.986 Disciplinary proceedings and actions.

- (1) Subject to the rules promulgated under s. 440.03 (1), the department may conduct investigations and hearings to determine whether a violation of this subchapter or any rule promulgated under this subchapter has occurred.
- (2) Subject to the rules promulgated under s. 440.03 (1), the department may reprimand a licensed midwife or deny, limit, suspend, or revoke a license granted under this subchapter if the department finds that the applicant or the licensed midwife has done any of the following:
- (a) Intentionally made a material misstatement in an application for a license or for renewal of a license.
- **(b)** Subject to ss. 111.321, 111.322, and 111.34, practiced midwifery while his or her ability to engage in the practice was impaired by alcohol or other drugs.
- (c) Advertised in a manner that is false or misleading.
- (d) In the course of the practice of midwifery, made a substantial misrepresentation that was relied upon by a client.
- **(e)** In the course of the practice of midwifery, engaged in conduct that evidences an inability to apply the principles or skills of midwifery.
- (f) Obtained or attempted to obtain compensation through fraud or deceit.
- **(g)** Allowed another person to use a license granted under this subchapter.
- **(h)** Violated any law of this state or federal law that substantially relates to the practice of midwifery, violated this subchapter, or violated any rule promulgated under this subchapter.
- (3) Subject to the rules promulgated under s. 440.03 (1), the department shall revoke a license granted under this subchapter if the licensed midwife is convicted of any of the offenses specified in s. 440.982 (2).

History: 2005 a. 292.

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

- **440.987 Advisory committee.** If the department appoints an advisory committee under s. 440.042 to advise the department on matters relating to the regulation of licensed midwives, the committee shall consist of only the following:
- (1) Two members who are licensed midwives.
- (2) One member who is licensed as a nurse-midwife under s. 441.15 and who practices in an out-of-hospital setting.
- (3) One member who is a physician specializing in obstetrics and gynecology.
- **(4)** One public member who has received midwifery care in an out-of-hospital setting.

History: 2005 a. 292.

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

History: 2005 a. 292.

**(III)** 

### Efficiency and Effectiveness - Analysis

## What's in this section about the efficiency and effectiveness of the program:

- Overview
- Homebirth Fact Sheet
- Midwives Model of Care
- Maternity Care in the U.S. Infobrief
- Overuse and Underuse Infographic

## Efficiency and Effectiveness of the Direct-Entry Midwifery Law

In the last 5 years, 3,784 babies were born in the care of a DEM in Colorado and about 70 active midwives were state registered.

To the extent there are inefficiencies or ineffectiveness in the program stems from inefficiencies and ineffectiveness in perinatal health care in general.

There is a general misunderstanding of the midwife model of care, and a misunderstanding of risks during pregnancy and birth, leading to over utilization of technological interventions and under utilization of non-technological interventions.

One area in particular where the program is ineffective is with regard to complaints and discipline, which will be discussed further in a subsequent section.

Midwives are champions of public health. DEM's have a significantly lower cesarean rate than the national average, as well as lower numbers of episiotomies. Parents experience a strong sense of involvement in their care. The birthing person has the freedom to move around during their labor and may choose their birthing position. Water birth may be an option. DEM's provide significant support to help initiation and continuation of lactation. This support translates to drastically improved exclusive lactation rates. At the completion of care at 6 weeks postpartum 97.7% are exclusively breastfeeding (MANA homebirth fact sheet). Important to note, the national rate of exclusive breastfeeding at 3 months is 46.9% and the CDC recognizes this low rate is due to lack of support during the early postpartum period (https://www.cdc.gov/breastfeeding/data/reportcard.htm). DEM's are meeting and exceeding the goals of Healthy People 2020 for baby friendly care.



Fact Sheet

#### New home birth study from the MANA Statistics Dataset shows that Planned Home Birth with Skilled Midwives is Safe for Low-Risk Pregnancies

The largest study of planned, midwife-led home birth in the U.S. to date, reported outcomes for nearly 17,000 women who went in to labor intending to deliver at home between 2004 and 2009.

#### **Safe Outcomes with Positive Benefits**

- High rate of completed home birth (89.1%)
- High rate of vaginal birth (93.6%)
- High rate of completed vaginal birth after cesarean (VBAC; 87.0%)
- Low intrapartum and neonatal fetal death rate overall:
  - 2.06 per 1000 intended home births (includes all births)
  - 1.61 per 1000 intended home births excluding breech, vbac, twins, gestational diabetes, and preeclampsia.
- Low rate of low APGAR scores
- Extremely high rate of breastfeeding (97.7%) at 6 weeks

#### **Few Emergency Transfers to Hospital Care**

 Primary reason for transport was "failure to progress." Transfer for urgent reasons, such as "fetal distress" was rare.

#### Low Rates of Intervention

- Cesarean section rate of 5.2%
- Less than 5% used pitocin or epidural anesthesia

#### **More Information**

Results for low-risk mothers are consistent with most studies of planned homebirth. For more information on relative risks and decision making see MANA Home Birth Data 2004-2009 Consumer Considerations at <a href="http://www.cfmidwifery.org/pdf/MANAHBStudy04-09Considerations.pdf">http://www.cfmidwifery.org/pdf/MANAHBStudy04-09Considerations.pdf</a> and "Safety" in Childbirth: What Does This Mean? What is "Safe" Enough? at <a href="http://cfmidwifery.org/pdf/Safety%20FINAL.pdf">http://cfmidwifery.org/pdf/Safety%20FINAL.pdf</a>.

Data were collected prospectively. Midwives logged in information for each client throughout her pregnancy, birth, and up to 6 weeks postpartum. This method of data collection reduces selection bias since outcomes were not known at the time they were entered into the MANA Stats system at onset of care.

#### References:

- 1. Cheyney, M., Bovbjerg, M., Everson, C., Gordon, W., Hannibal, D., and Vedam, S. (2014). Development and Validation of a National Data Registry for midwife-led births: The Midwives Alliance of North America Statistics Project 2.0 dataset. *Journal of Midwifery and Women's Health*, 59(1).
- 2. Cheyney, M., Bovbjerg, M., Everson, C., Gordon, W., Hannibal, D., and Vedam, S. (2014). Outcomes of care for 16,924 planned home births in the United States: The Midwives Alliance of North America Statistics Project, 2004 to 2009. *Journal of Midwifery and Women's Health*, 59(1).



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"In every country where I have seen real progress in maternity care, it was women's groups working together with midwives that made the difference."

Blog

myspace

- Marsden Wagner, MD, MSPH

#### . The Midwives Model of Care

- Midwives Model of Care Definition
- About the Definition
- Midwives Model of Care Brochure
- Order Brochures

#### 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 and referring women who require obstetrical attention

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

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#### Related Organizations

- Midwives Alliance of North America
- North American Registry of Midwives
- Midwifery Education Accreditation Council
  - 2005 Citizens for Midwifery



## Maternity Care in the United States: We Can – and Must – Do Better

#### February 2020

Too often, maternity care in the United States fails women and families – in not being accessible, safe, equitable, woman-centered, evidence-based or affordable. Further, maternity services often fail to mobilize housing, transportation and other non-medical factors that strongly affect birth outcomes. Poor – and for many key indicators, worsening – maternal and newborn health outcomes signal that major improvements are overdue. Getting maternity care right is urgent for this and future generations.

#### **Quality Maternity Care Is a Foundation of Our Nation's Health**

Maternity care provided from pregnancy through birth and the postpartum/newborn period affects every one of us. No other part of our health care system has a greater effect on the health of our population.

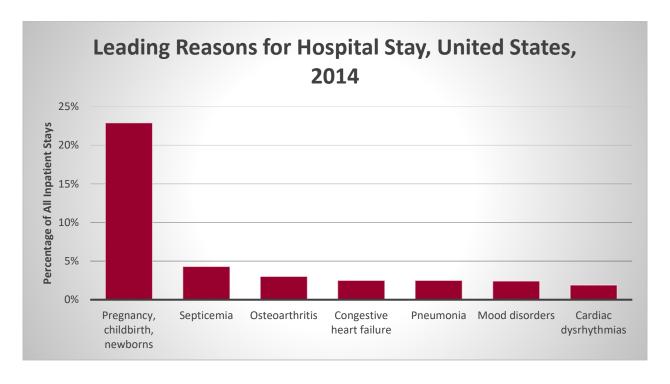
- Reliably delivering better care is an under-recognized way to affect a new baby's health and wellness for a lifetime. Studies of the "developmental origins of health and disease" (including knowledge of epigenetics, the human microbiome, life course health development and hormonal physiology of childbearing) increasingly point to long-term, even lifelong positive and negative effects of care during this sensitive period of development.
- The quality of prenatal, labor and birth and postpartum care also affects shorter- and longer-term health<sup>6</sup> of the women who give birth one or more times.

Maternity Care in the United States: We Can – and Must – Do Better was supported through the generosity of the Yellow Chair Foundation. The author is Carol Sakala.

#### Maternity Care Is a Major Segment of the Health Care System

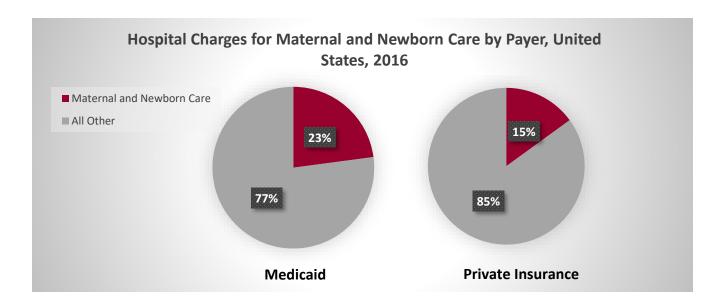
Maternity care is also a major segment of the health care system. A baby is born every eight seconds in the United States. Within hospital-based care, maternal and newborn care towers over other conditions.

• More hospital stays are for pregnancy, childbirth and newborn care – 23% – than any other reason by far.<sup>8</sup>



(Source: 10)

- Six of the 16 most common hospital procedures are for maternal or newborn care, including the nation's most common operating room procedure: cesarean birth.<sup>9</sup>
- Maternal and newborn care makes up 22.9% of all hospital charges billed to Medicaid, a medical assistance program for people with low incomes, and 15.0% of all hospital charges billed to private insurers.<sup>10</sup>



(Source: 11)

#### **Many Women Struggle to Access Maternity Care**

Women in the U.S. face financial, geographic, and other barriers to accessing maternity care. These challenges especially affect those already vulnerable to poorer outcomes.

- Medicaid covers 42.3% of births, and private insurance covers 49.6%. For many women, the childbearing year involves changes in health insurance coverage (called "churn"), 12 including becoming eligible for and then losing Medicaid coverage.
- The loss of access to contraceptive care and abortion services, including restrictions on access to Planned Parenthood clinics, which also provide prenatal and postpartum care, harms women and newborns.<sup>13</sup> Just 67.1% of pregnancies are intended.<sup>14</sup>
- 35% of counties are "maternity care deserts" with neither a hospital maternity unit nor any obstetrician-gynecologist or certified nurse-midwife. Most rural women have to drive more than a half hour to the nearest hospital with maternity services. 16
- Almost one woman in five is unable to have her first prenatal visit as soon as she wants it. Women cite financial, insurance, and other reasons for this undesirable delay.<sup>17</sup>
- About 10% of women have no postpartum visit, and many with postpartum care report that contraception, depression and other core topics are not discussed. 18

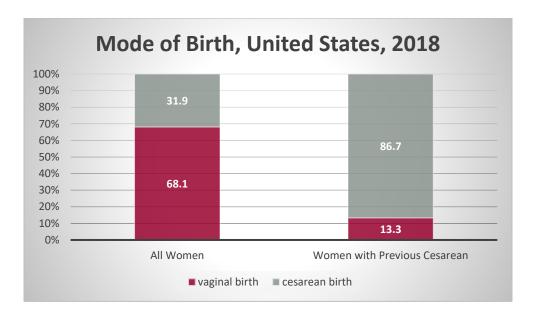
- While women frequently experience new health concerns after giving birth, <sup>19</sup> and about 12% of pregnancy-related deaths occur from seven weeks to one year after birth, <sup>20</sup> loss of or changes in health insurance after birth often makes seeking care and treatment difficult. <sup>21</sup>
- Limited or no access to paid maternity leave burdens and constrains many families in the postpartum period.<sup>22</sup>
- Political turbulence in the health care environment (e.g., threats to Affordable Care Act and attempts to weaken Medicaid coverage) imperils many women's access to public and private insurance coverage and creates uncertainty for their service providers.

#### Too Often, Maternity Care Does Not Align With Quality or Choice

Delivering the right maternity care is a challenge in the U.S.: patterns of overuse and underuse are common.<sup>23</sup> Overuse is use of procedures, drugs or tests that offer no clear benefit and possible harm – often in healthy women. Underuse is when safe, beneficial practices are not routinely available. Every woman should have access to evidence-based maternity care and experience shared decision making and support for her informed choices, a sequence that often does not occur.

- About four in 10 women experience labor induction,<sup>24</sup> yet research does not support many indications used for inducing labor.<sup>25</sup>
- A pattern of many fewer births on weekends (and at night and on holidays) shows the extent of scheduled births, and suggests that they are often timed for hospital and workforce convenience versus interests of women and babies.<sup>26</sup>
- A steep increase in the cesarean rate (now at 31.9% of all births<sup>27</sup>) over the last two decades was not accompanied by any improved health outcomes for women or babies; instead, many have been needlessly exposed to the additional short- and long-term risks and complications of cesarean, compared with vaginal birth.<sup>28</sup>
- A low-risk, first-time mom is up to 15 times more likely to have a cesarean birth at one hospital than another, and rates of vaginal birth after cesarean vary nearly tenfold by hospital.<sup>29</sup> Hospital culture and care management factors, rather than the health needs of women or babies, are responsible for much variation in practice and many cesarean births.<sup>30</sup>

• Almost half of women who are interested in having a vaginal birth after cesarean (VBAC) are denied that option, despite evidence and guidelines that support offering VBAC to nearly all women with one or two past cesareans.<sup>31</sup> This lack of access to evidence-based care contributes to a very high 86.7% repeat cesarean rate.<sup>32</sup>



(Source: 12)

- Often, patterns of care fail to harness the benefits of innate healthy physiologic processes of women and their fetuses/newborns around the time of birth.<sup>33</sup> Most women now value avoiding unneeded maternity interventions; their interest in midwives, birth centers and other forms of care that support these capabilities and limit unneeded intervention far exceeds current use.<sup>34</sup>
- The many effective care practices that are not widely provided include smoking cessation interventions in pregnancy, hand maneuvers to turn a fetus to a headfirst position at term, planned labor after one or two cesareans, continuous support during labor, intermittent auscultation for fetal monitoring, being upright and mobile during labor, and treating perinatal depression.<sup>35</sup>

There are major concerns with the quality of care provided in the nation's neonatal intensive care units (NICUs).

- Care varies considerably across NICUs: most variation is unrelated to needs of newborns and preferences of families and thus is "unwarranted." Another non-medical factor shaping NICU care is supply-sensitive admission of lower and lower risk newborns due to a nearly 70% increase in the number of NICU beds per newborn and large growth in the number of neonatologists from 1995 to 2013.<sup>36</sup>
- Due to these factors, many newborns get too much care and pay the price of unneeded separation from mothers and harmful exposures with little or no benefit, while others get too little care or the wrong care.<sup>37</sup>

#### Maternity Care Outcomes Are Unacceptable, and Many Are Worsening

Trends are going in the wrong direction for a series of consequential outcomes in women and babies.

- Pregnancy-related deaths rose from 7.2 per 100,000 live births in 1987 to 16.9 per 100,000 in 2016.<sup>38</sup> A portion of this rise is due to efforts to improve measurement and better measurement.<sup>39</sup>
- The distribution of pregnancy-related deaths clarifies that improvements are needed across the continuum of care: about one-third occur during pregnancy, one-third on the day of birth through first week, and one-third from day 7 through the first year postpartum.<sup>40</sup>
- Severe maternal morbidity (21 conditions and procedures signaling a "near miss" of dying) rose 45% from 2006 through 2015, from 101.3 to 146.6 per 10,000 hospitalizations for birth.<sup>41</sup>
- Preterm birth (before 37 weeks of pregnancy) rose from 9.57% in 2014 to 10.02% in 2018.<sup>42</sup>
- Low birthweight (less than 5.5 pounds) rose from 8.00% in 2014 to 8.28% in 2018.<sup>43</sup>

Many women face less dire yet distressing and debilitating pregnancy experiences and birth outcomes.

• Despite broad recognition that the steep rise in the cesarean rate since the mid-1990s involved no discernible gains in maternal or infant health,<sup>44</sup> that this procedure poses many excess risks for women and cesarean-born babies,<sup>45</sup> and that too many women give birth by cesarean,<sup>46</sup> the nation's cesarean rate has essentially plateaued for a decade at nearly one in three.<sup>47</sup>

- In the postpartum period, women experience a broad array of new-onset morbidities including pain, exhaustion and infections and in many instances these persist to six or more months after birth.<sup>48</sup>
- Anxiety and depression are prevalent during both pregnancy and the postpartum period, and the great majority who screen positive for these conditions do not receive treatment.<sup>49</sup>

Breastfeeding, which offers multiple shorter- and longer-term preventive benefits to both women<sup>50</sup> and babies,<sup>51</sup> falls far short of recommendations.

- Just 26.1% of babies are born in "Baby-Friendly" facilities with demonstrated provision of supportive breastfeeding practices.<sup>52</sup>
- Just 24.9% of babies are exclusively breastfed through six months, the standard that professional societies recommend.<sup>53</sup> Considerably more women intend to meet this goal, but unsupportive health care practices and social and workplace policies often interfere.<sup>54</sup>
- Professional societies also recommend continued breastfeeding to one year or beyond, yet just 35.9% are breastfeeding at 12 months.<sup>55</sup>

Substance use disorders affect many childbearing women and their babies.

- In 2016, 91,800 births or 24.3 per 1,000 hospital stays for birth had a substance use disorder (SUD) diagnosis involving opioids, cocaine and other stimulants.<sup>56</sup>
- Compared with births without this diagnosis, those with SUD were more likely to experience a series of consequential adverse clinical outcomes.<sup>57</sup>

### On Key Maternal and Infant Indicators, the United States Compares Very Unfavorably to Most-Similar Nations

Despite the nation's affluence and outsized expenditure for maternal-newborn care (see below), many other nations achieve superior results for key perinatal indicators.

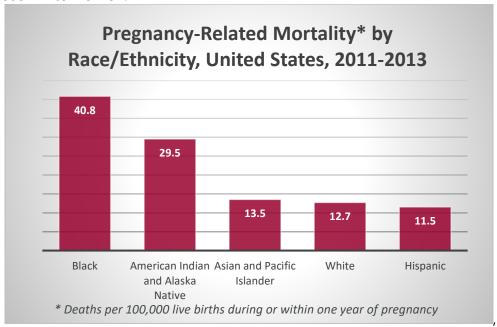
O Compared with 10 other high-income nations (Australia, Canada, Denmark, France, Germany, Japan, the Netherlands, Sweden, Switzerland, United Kingdom), the U.S. has the highest: maternal mortality (26.4/100,000 live births, versus mean 8.4 for these nations), neonatal mortality (4/1,000 live births, mean 2.6), infant mortality 5.8/1,000 live (births, mean 3.6) and cesarean rate (33% of live births, mean 25%), and second highest low birth weight rate (8.1% of live births, mean 6.6%).<sup>58</sup>

• The United States ranks 33rd among world nations on Save the Children's Mothers Index, a composite of maternal health, child wellbeing, education, economic security and political participation.<sup>59</sup>

#### **Outcomes of Maternity Care Are Inequitable**

Racial and ethnic disparities are often extreme and especially impact Black and Native women and newborns. Rural and low-income women also face disproportionately adverse maternal-infant outcomes.

- Black women are more than three times as likely and Native women more than twice as likely as white women to experience pregnancy-related death.<sup>60</sup>
- 60% of pregnancy-related deaths are considered preventable, including by access to and provision of quality care, with no difference in preventability by Black or Hispanic versus white women.<sup>61</sup>



(Source: 59)

• Black women, Hispanic women and women of other races/ethnicities disproportionately experience births with severe maternal morbidity (66%, 10% and 15% higher, respectively), relative to white women. SMM is associated with a high rate of preventability.<sup>62</sup>

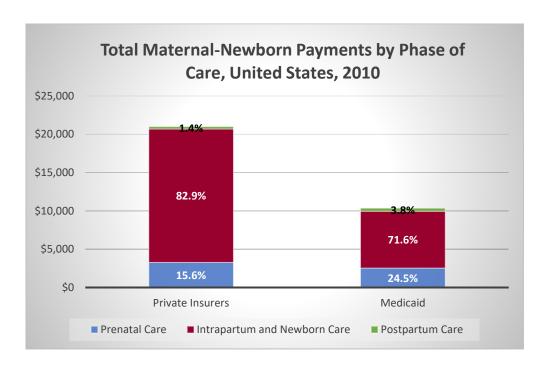
- Rural women are 9% more likely than urban women to experience a composite measure of severe maternal morbidity and maternal mortality, 63 and 59% more likely to have a substance use disorder diagnosis at the time of birth. 64
- Infant, neonatal and post-neonatal mortality rates are higher in rural than urban counties.<sup>65</sup>
- Babies born in the Delta Regional Authority (252 counties in AL, AR, IL, KY, LA, MO, MS, TN) and the Appalachian Regional Commission (420 counties in AL, GA, KY, MD, MS, NY, NC, OH, PA, SC, TN, VA, WV) are more likely than babies born in the rest of the nation to experience preterm birth, low birth weight and infant mortality, reflecting geographic variation in levels of economic distress and disadvantage<sup>66</sup> and racism.<sup>67</sup>
- Rates of teen birth vary fourfold across states, from 7.2 per 1,000 births in Massachusetts to 30.4 per 1,000 births in Arkansas.<sup>68</sup>
- Infant mortality and neonatal mortality reflect a two- to three-fold gradient similar to the above pregnancy-related mortality chart, ranging from highest rates among infants of Black women to lowest rates among infants of Asian women.<sup>69</sup>
- Other practices and outcomes that vary by race and ethnicity include rate of births to teens aged 15 through 19, proportion initiating prenatal care in the first trimester, rate of smoking during pregnancy, rates of labor induction and cesarean birth, rates of preterm birth and low birth weight, and rates of breastfeeding initiation and duration.<sup>70</sup>

### Maternity Care is Very Costly, and Resources Are Poorly Aligned With Need

High-value maternity care means good birth outcomes paired with wise spending. On top of unacceptable outcomes, the cost of maternity care in the U.S. is very high and rising.<sup>71</sup> Outdated payment systems (paying for doing things regardless of whether good care was provided and good outcomes attained), patterns of intensive procedure use and high prices contribute to care that is unnecessarily and unsustainably expensive.

• The nation's overall health care costs exceed those of other nations by far, whether measured as proportion of gross domestic product or average cost per person.<sup>72</sup> In available international comparisons of maternity care costs, those in the United States are regularly the highest.<sup>73</sup>

- Together, maternal and newborn care are the most expensive hospital conditions for Medicaid, private insurance and all payers.<sup>74</sup>
- The average actual price paid for hospital fees alone was \$11,200 for a vaginal birth and \$15,000 for a cesarean birth when covered by private insurers in 2017.<sup>75</sup> This figure does not include provider fees; services such as anesthesiology or pharmacy; nor any prenatal or postpartum care.
- Historically, actual prices paid for all maternal and newborn care are about 50% higher when the birth is cesarean rather than vaginal. Costs of a primary, or first, cesarean compound over time with the high rate of routine repeat cesarean.
- Historically, actual prices that Medicaid pays to service providers for all maternal and newborn care are about half the amount of private payments, despite the frequently greater health needs of women covered by Medicaid.<sup>78</sup> (Even Medicaid payments are on the high end of the international range.)<sup>79</sup>
- About four in five of all dollars paid on behalf of maternal and newborn care go to the facility and other payments for the relatively brief hospital phase of care. 80 High rates of costly procedures (e.g., induced labor, epidural analgesia, cesarean birth) in this largely young and healthy population contribute to the expense of hospital birth.
- Highly profitable newborn intensive care units (NICUs) also contribute to in-hospital resource use. A steep growth in the number of NICUs and number of neonatologists has been associated with supply-induced demand and admission of healthier and healthier newborns to NICUs,<sup>81</sup> in addition to sicker babies who are likely to benefit from such care.
- Limited resources allocated to prenatal and postpartum care (just one in five of all dollars paid for maternal and newborn care<sup>82</sup>) limit the care team's ability to address individual needs at a time when women are engaged, motivated and have extended contact with the health care system. Lack of resources for linking to needed social and community services and coordinating care across the clinical episode is deeply troubling.



(Source: 79)

- Considering just low-risk births, cost varies widely,<sup>83</sup> and hospital factors but not quality are associated with higher costs.<sup>84</sup>
- Out-of-pocket costs of childbearing families with commercial insurance can be especially high<sup>85</sup> due to their contribution to premiums, deductibles (possibly incurred twice across two plan-years), co-pays, co-insurance, unexpected hefty out-of-network charges (e.g., for anesthesiologist) and uncovered costs (e.g., for labor doula). This comes at a time when families incur increased non-health expenses and many lack paid family and medical leave.

#### **Sustained Stakeholder Commitment Can Transform Maternity Care**

The shortcomings of the U.S. maternity care system provide extensive opportunities for improvement, and many stakeholders are taking up the challenge. Recent, promising signs of momentum in the right direction include:

• Growing recognition that inequity and harmful "social determinants of health" such as systemic racism; lack of access to paid family and medical leave; and inadequate housing, transportation and economic security shape birth outcomes and must be addressed to achieve optimal health outcomes.

- Efforts to provide ready access to maternity care for all women, including through universal coverage extending to one year postpartum and by reversing the loss of maternity services in rural areas
- Practice recommendations that support provision of beneficial, underused care practices while avoiding unneeded, harmful ones
- Episode, maternity care home and other alternative payment models that incentivize high-quality care, increasingly used by Medicaid and other payers
- Increasing use of high-value maternity care models, including midwifery-led care, birth center care, team-based care, doula support, and culturally concordant services of community-based perinatal health workers
- Quality measurement that can inform all stakeholders about opportunities for improvement and increase accountability, along with quality improvement initiatives such as perinatal quality collaboratives and Council on Patient Safety in Women's Health Care maternal safety bundles
- Decision aids and other toolsto help women obtain safe, effective care aligned with their individual needs and preferences

These positive changes are just the beginning of the transformation that can and must occur. Until we reliably pay for the right care, change the culture of practice and scope of care and avoid the waste of less effective and all-too-often harmful care, families and payers will be vulnerable to unacceptable outcomes and excessive costs. Policymakers, clinical leaders, advocates and other stakeholders must commit to long-term, far-reaching efforts to create a uniformly high-quality, high-value maternity care system that is equitable for all women and families.

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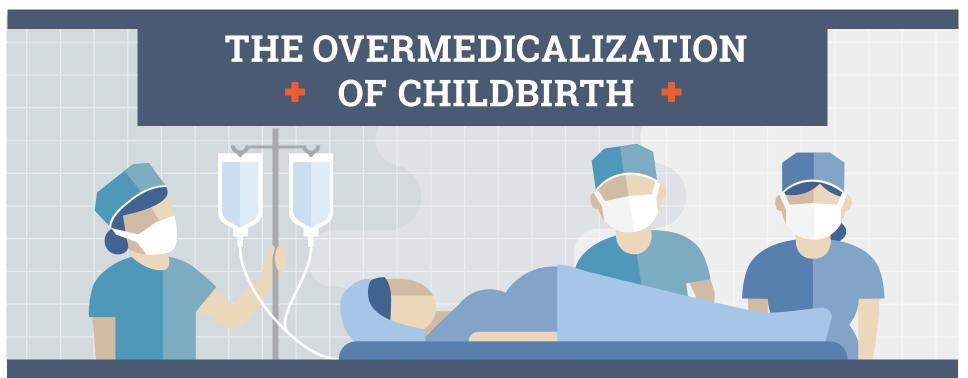
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According to the Listening to Mothers in California survey, 74% of California mothers agreed that childbirth should not be interfered with unless medically necessary, but only 5% gave birth with no major medical intervention. Maternity care experts agree that many medical interventions are not necessary for a safe childbirth, and could increase risks for both mother and baby.

## Too many unwanted and unneeded interventions...

Unneeded interventions can make childbirth harder and less safe for mothers and babies, and can waste resources.



14%

of women had **labor induced** solely for reasons
that are not evidence-based.
Induction can increase the
risk of other labor
interventions and the
baby's use of NICU care.<sup>2</sup>

**61%** 

of women in labor were immobilized<sup>3</sup>, which can prolong labor, decrease the woman's comfort, and increase the likelihood of cesarean birth.

68%

of women with vaginal births had an **epidural**, which may prolong labor and make pushing harder, among other downsides. 31%

of women had a
c-section; 85% who had
a past c-section had a
repeat c-section. C-section
surgeries can put mother
and baby at risk for serious
complications in the short
and long term.

## ...when less invasive alternatives are available.

A number of safe and effective practices can help women avoid unneeded medical interventions during labor and while giving birth, but these practices are underused in California hospitals.



ONLY

23%

of women in labor stayed home until they were dilated to 5 or more centimeters.<sup>4</sup>

Staying home until active labor (dilation of at least 5 or 6 cm) can greatly reduce the risk of cesarean birth.

ONLY

9%

of women<sup>5</sup> had labor support from a doula.

Working with a doula can reduce the need for medical interventions, such as a c-section and use of pain medications. ONLY

11%

of women in labor used a tub or shower to manage pain.

Drug-free methods to cope with labor pain have no adverse effects on the mother, baby, or progress of labor. ONLY

3%

of women in labor had their baby's heartbeat monitored exclusively with a handheld device.

Using a handheld device to monitor the baby's heartbeat frees the woman to walk around, and reduces the risk of cesarean birth.

1. Using the definition of physiologic childbirth from The American College of Obstetricians and Gynecologists reVITALize project. 2. This is a low estimate, as the survey and related documentation show that many women incorrectly indicated an evidence-based reason for induction. For example, the average gestational age of those who chose "overdue" was well short of the medical definition of "post term," which is 42 weeks or more. 3. Because they had, for example, an epidural, bladder catheter, or were attached to an IV drip or to continuous electronic fetal monitoring. 4. Of women who had a vaginal exam during labor after hospital admission. 5. Of women who primarily speak English at home.





(IV)

### **Economics and Competition - Analysis**

# What's in this section about economics and competition:

- Overview
- University of Minnesota School of Public Health Policy Brief on Midwife Led Care
- Elephant Circle's "Insurance by the Numbers" fact sheet
- The Cost of Having a Baby in the United States Executive Summary
- Delivering High Quality High Value Maternity Care
- Health Affairs Antitrust article
- Promoting Midwifery in High Value Care in Medi-Cal

# Economics and Competition Regarding Regulation of Direct-Entry Midwives

The United States spends more on health care than any other country. Hospital charges related to pregnancy and birth are a large part of that total, amounting to about 80 billion. The existing system, despite its flaws, maintains the status quo due at least in part to the economics. For example, despite evidence that the United States performs too many cesarean surgeries (for approximately 15% of these, the benefits do not outweigh the risks and the national rate is near 30%) and without addressing the economics of surgical versus non-surgical births this rate is likely to remain the same. This is true for the lack of integration of midwives into the system as well. Midwives cost less/charge less and often remain marginalized as a result. For example a nurse-midwifery practice closed in Colorado recently because the parent-company wasn't making enough money from the practice compared to its physician practices.

When it comes to Colorado direct-entry midwives, lack of integration (as discussed in section I) is a major part of the economics of practice. Most direct-entry midwives are not considered "in-network" in any insurance plans, and are not reimbursed by Medicaid, which means that direct-entry midwives in Colorado rely on customers who can pay for their services out-of-pocket. To some extent this means that they are in their own market since most people are limited to the providers covered by their insurance (whether it is public or private).

To fully integrate all kinds of midwives, including direct-entry/CPMs, would transform the system because of economics. This is one reason why potential competitors, doctors and hospitals spend so many resources opposing midwifery integration - despite its proven public health benefits. Regulation of direct-entry midwifery should be rooted in this reality. A few major issues related to economics and competition of DEMs are mandating liability insurance, the role of non-midwife providers in complaints, and the over-reliance on competitors in legislation and regulation.

We are providing a short fact-sheet on the liability insurance issue and an article on State Boards as an antitrust issue. It is important that DORA remains vigilant so that market competitors like doctors do not exert a monopolizing influence on the regulation of midwives; keeping them out and maintaining a lack of integration to their benefit. We discuss the anti-competitive effects of doctor-complaints in Section V.

November 2019



## MORE MIDWIFE-LED CARE COULD GENERATE COST SAVINGS AND HEALTH IMPROVEMENTS

#### **AUTHORS AND AFFILIATIONS**

Katy B. Kozhimannil, PhD University of Minnesota School of Public Health

Laura Attanasio, PhD University of Massachusetts Amherst

Fernando Alarid-Escudero, PhD Drug Policy Program, Center for Research and Teaching in Economics - CONACYT, Aguascalientes, Mexico

#### **KEY FINDINGS**

Increasing the percentage of pregnancies with midwife-led care from the current level of 8.9% to 20% over the next 10 years could result in:

- \$4 billion in cost savings
- 30,000 fewer preterm births
- 120,000 fewer episiotomies

For an electronic version, visit: z.umn.edu/midwife-care

#### **PURPOSE**

The purpose of this policy brief is to describe the potential cost savings that could result from a shift toward greater use of midwifery-led care for low-risk pregnancies in the United States.

#### **BACKGROUND AND POLICY CONTEXT**

Childbirth is the most common and most costly reason for hospitalization in the U.S.¹ Improving quality and value of maternity care is a high policy priority, especially since nearly half of U.S. births are funded through state Medicaid programs.²

In the U.S., maternal morbidity and mortality have increased over the last several decades, and use of obstetric procedures, including labor induction and cesarean delivery, has also increased, beyond levels that are generally considered medically necessary.<sup>3-7</sup> After several years of small decreases in the cesarean delivery rate, provisional data indicate that the cesarean rate increased between 2016 and 2017.<sup>8</sup> Preterm births have been on the rise since 2015, reversing the trend in several years of declines from 2007 to 2014.<sup>8</sup> Overuse of medical procedures and poor outcomes indicate low quality of care and contribute to high costs.<sup>9</sup> There is an urgent need to improve value in U.S. maternity care.

Currently, more than 90% of births in the U.S. are attended by physicians, and midwives attend only about 9% of births.<sup>6</sup> Evidence shows that low-risk pregnant women who are cared for by midwives have similar outcomes to those cared for by physicians, but are less likely to experience unnecessary obstetric procedures.<sup>10–12</sup> Additionally, physician shortages in obstetrics contribute to problems of limited access to care during pregnancy.<sup>13</sup> This policy brief draws upon published research to describe the cost and policy implications of increasing the number of pregnancies cared for by midwives in the U.S.

#### **APPROACH**

We used previously published estimates of clinical outcomes and costs associated with midwife-led vs obstetrician-led care to calculate projected changes in costs, procedures and outcomes if midwife-attended births were incrementally increased from the current level of 8.9% to 20% by 2027. That is, we modeled the

November 2019



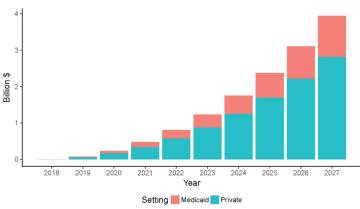
potential cost-savings and clinical benefits of a shift toward greater use of midwife-led care for low risk pregnancies over the coming decade.

Recognizing that payments and costs differ between Medicaid and private health insurance, with private plans paying approximately 50% more than Medicaid for childbirth-related care, 15 we calculated potential cost savings separately for Medicaid and private health insurance, in addition to showing total potential cost savings. Potential clinical benefits are shown for the U.S. as a whole.

#### **RESULTS**

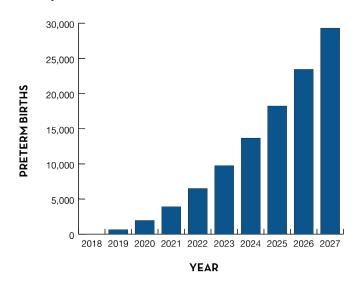
As shown in Figure 1, increasing the percentage of pregnancies with midwife-led care from 8.9% to 15% would result in over \$1 billion in cost savings by 2023. By 2027, if midwives were leading care for 20% of births, savings would reach \$4 billion. About three-quarters of these cost savings are attributable to lower costs for births covered by private insurance, while one-quarter of the cost savings would be from Medicaid-covered births. Specifically, by 2027, cost savings associated with this modest shift toward midwife-led care would reach \$2.82 billion for private health plans and \$1.13 billion for state Medicaid programs.

**Figure 1**Projected Cumulative Cost Savings for an Increase in Midwiferyled Care from 8.9% to 20% of Births, 2018-2027

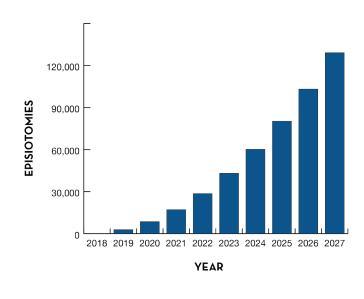


Additionally, with midwives leading care for 20% of pregnancies, 30,000 preterm births and 120,000 episiotomies would be avoided by 2027 across the U.S. (Figures 2 and 3).

**Figure 2**Projected Cumulative Preterm Births Avoided for an Increase in Midwifery-led Care from 8.9% to 20% of Births, 2018-2027



**Figure 3**Projected Cumulative Episiotomies Avoided for an Increase in Midwifery-led Care from 8.9% to 20% of Births, 2018-2027



November 2019



#### **POLICY IMPLICATIONS**

Projected cost savings associated with a shift to midwife-led care are modest for each individual birth, but aggregated across the U.S. population, cost savings are significant. Nearly 4 million births occur each year in the U.S., and improving value – even incrementally – for each birth could have a large cumulative impact across populations and over time.

Furthermore, our models indicate that having a greater percentage of pregnancies cared for by midwives would result in fewer preterm births and fewer episiotomies. Preterm birth, in particular, is an important outcome to track and avoid, as it is a top cause of infant mortality in the U.S.<sup>16</sup>

Projected cost savings associated with a shift toward greater midwife-led care would impact both employers and employees, who predominantly finance private health plans, as well as taxpayers and state and federal budgets, which jointly finance Medicaid programs.

Achieving greater access to midwife-led care during pregnancy is within reach, and may be facilitated by policy change. Some potential options include the following:

- Health plans could adopt midwifery as the default model for low-risk pregnancy care, with more complicated pregnancies requiring higher-acuity care being referred to obstetricians or maternalfetal medicine specialists. Similar strategies are used by other countries.<sup>17,18</sup>
- States that allow a more autonomous scope-ofpractice for midwives have more midwife-attended births. 11,19,20 Implementing more state-level policies supporting midwives practicing without physician supervision may lead to greater midwifery care access.
- Further attention to and public investment in midwifery education, including diverse workforce recruitment, may increase the capacity of U.S.

midwives to care for a larger proportion of pregnant women.<sup>21–23</sup>

November 2019



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#### **Mandating Insurance is Bad for Business**

On average a <b>metro</b> midwife serves 16 families a year. <sup>1</sup> @\$4000/family Minus: -Business expenses (average of 30%) -Annual registration fee to DORA -A \$500,000/\$1,500,000 policy in the first year <sup>2</sup>	Estimated Gross Income: \$64,000° -\$19,200 -\$387⁴ (including authorities) -\$5000+ = \$39,413⁵(income after expenses) In year 2: \$38,663 In year 3: \$37,800
On average a <b>rural</b> midwife in Colorado serves 12 families a year.  @\$3000/family  Minus: -Business expenses (average of 30%)  -Annual registration fee to DORA  -A \$500,000/\$1,500,000 policy in the first year	Estimated Gross Income: \$36,000 -\$10,800 -\$387 (including authorities) -\$5000+ = \$19,813 (income after expenses) In year 2: \$19,063 In year 3: \$18,200
A <b>new</b> midwife sees only 5-8 clients per year.  This creates a big barrier to entry for new midwives.	It would be hard to make more than \$10,000 in the first three years depending on geography and other factors.

Comparing the business model of these midwives to other maternity care providers in the state is like comparing apples to oranges.

<sup>1</sup> This could go up a bit for so

<sup>&</sup>lt;sup>1</sup> This could go up a bit for some midwives but the demands of seeing two clients for 9 months prenatally and 6 weeks postpartum, in addition to being on-call for births 24/7/365 means that there is a firm limit to how many clients any one provider can take in this model of care, and how much additional income they can expect to make.

<sup>&</sup>lt;sup>2</sup> With a small risk pool (around 2000 of these midwives nationwide) less products are available, the existing products are more likely to leave the market, and they cost more. A policy for \$100,000/\$300,000 coverage would cost about \$2500 the first year, \$2,875 the second year and \$3,306 in the third year. *This policy is not advised because the coverage is much too low.* A policy for \$500,000/\$1,500,000 coverage would cost \$5000 the first year, \$5,750 the second year and \$6,613 the third year. The coverage provided by this policy is better than the first, but will only cover the costs of a single event. Most premiums increase by 15% each year.

<sup>&</sup>lt;sup>3</sup> It is uncommon for all of a midwife's clients to pay the full fee. Most clients pay out-of-pocket. Some midwives accept barter for their services.

<sup>&</sup>lt;sup>4</sup> The annual registration fee changes yearly for DEMs and has been as high as \$1300, including authorities

<sup>&</sup>lt;sup>5</sup> This is right around 300% of the Federal Poverty Guidelines level for a single individual.

<sup>&</sup>lt;sup>6</sup> This is right around 150% of the Federal Poverty Guidelines for a single individual.

<sup>&</sup>lt;sup>7</sup> There are between 100 and 200 CNMs in the state of Colorado at any given time. More than 90% are covered by policies paid for by their practice (birth center or hospital). The home birth CNMs in Colorado are subject to the same insurance costs detailed above, but can be reimbursed by private insurance and therefore typically charge higher rates.

# THE COST OF HAVING A BABY IN THE UNITED STATES Executive Summary

#### TRUVEN HEALTH ANALYTICS MARKETSCAN® STUDY

#### Prepared for:

Childbirth Connection
Catalyst for Payment Reform
Center for Healthcare Quality and Payment Reform

January 2013









#### **FORFWORD**

Better care, better outcomes, and lower costs in health care are all possible through use of innovative delivery systems. supported by value-based payment systems and effective performance measurement. One of the greatest opportunities for improving health care value is in maternity care, which impacts everyone at the beginning of life and about 85% of women during one or more episodes of care. Most childbearing women are healthy, have healthy fetuses, and have reason to expect an uncomplicated birth, yet routine maternity care is technology-intensive and expensive: combined maternal and newborn care is the most common and costly type of hospital care for all payers, private payers, and Medicaid, Childbirth Connection. Catalyst for Payment Reform, and the Center for Healthcare Quality and Payment Reform commissioned this report to focus the attention of all stakeholders on the need to better align maternity care payment and quality.

Significant improvements in quality and savings in costs can be achieved by reducing unwarranted practice variation and the overuse of some interventions and underuse of others. High-performing maternity care providers and settings and the women and families they serve demonstrate the potential for dramatic improvement in care, outcomes, and value relative to usual care and population norms. Childbirth Connection's multi-stakeholder, deliberative Transforming Maternity Care project developed two direct-setting consensus reports: "2020 Vision for a High-Quality, High-Value Maternity Care System" and a "Blueprint for Action" to chart the path toward such a system. From its inception, the project's key informants and Steering Committee members understood that a multi-faceted strategy, including payment reform, changes in benefit structures, public education, and provider engagement, is essential for successfully driving needed improvement. This new report on the Cost of Having a Baby in the United States" clarifies that significant savings can be achieved by advancing priority Blueprint recommendations.

Catalyst for Payment Reform (CPR), a nationwide nonprofit coalition of large national employers and public payers, including several state Medicaid agencies, understands that maternity care is in need of significant payment reform, both to remove the perverse incentives for unnecessary intervention in labor and delivery and to increase incentives for better adherence to rigorous clinical guidelines. To help purchasers work with health plans towards this goal, CPR created its Maternity Care Payment Reform Toolkit, available to all stakeholders

The Center for Healthcare Quality and Payment Reform (CHQPR) has been working since 2009 to educate physicians, hospitals, health plans, employers, consumers, and policy makers about the barriers to higher quality, more affordable health care created by current health care payment and delivery systems and ways to overcome those barriers. CHQPR understands that one of the best opportunities for making health care more affordable and improving the health status of the public is through improving the way maternity care is delivered in America. More information and resources about ways to improve payment and delivery of maternity care are available on the CHQPR website.

The MarketScan Commercial and Medicaid databases provided a unique opportunity to understand levels of charges and payments for maternal and newborn care in 2010. This report offers detailed breakdowns by Commercial and Medicaid payers, primary insurer versus secondary insurer and out-of-pocket payment sources, vaginal and cesarean birth, type of service, and phase of care. Special analyses investigate variation in maternal charges and payments across five selected states, costs of care for newborns with stays in neonatal intensive care units, and the increase in payments for maternal care from 2004 to 2010.

We hope you find this information helpful, and we invite you to join us in working to improve how we pay for and deliver maternity care in the United States.

Maureen P. Corry **Executive Director** Childbirth Connection Suzanne F. Delbanco **Executive Director** 

Suganoe J. Delbaner

Catalyst for Payment Reform

Harold D. Miller **Executive Director** 

Center for Healthcare Quality and Payment Reform

#### **EXECUTIVE SUMMARY**

Childbirth is a major life and population event. In the United States, about four million women gave birth each year. Although childbirth is a common occurrence that has great impact on the healthcare system, our knowledge regarding the cost of childbirth is limited. This study updated a 2007 Thomson Healthcare report of maternity costs using the mothers' medical and drug claim records<sup>1</sup> and estimated the costs of the first three months of a newborn's life with newborn claim records (newborn costs) identified in the *MarketScan*® Commercial and Medicaid databases.

In this study, "cost" is measured by the amount that employers (for beneficiaries of Commercial, employer-sponsored insurance) or Medicaid managed care plans and Medicaid programs (for Medicaid beneficiaries) and others pay hospitals, clinicians, and other service providers, i.e., the cost of care to the organizations and individuals that *pay* for the care, not the costs incurred by organizations and individuals who provide care. The latter may be less or more than the former, but data are not available to determine which is the case. Actual payments for maternity and other health care are typically discounted considerably relative to the amount charged by the various service providers.

Babies are born either vaginally or by cesarean section. The study looked separately at costs for each of these methods of birth, since past studies have shown (and this study confirmed) that the costs differ significantly between the two methods. Since there is wide variation in the rate of cesarean section across states, across regions within states, and across hospitals and physicians within a region, it is more meaningful to describe the costs of each delivery method separately than to provide a single estimate of the cost of birth. Further analyses were conducted for source of payment (including out-of-pocket payments), type of service, phase of care, cost variation across selected states (maternal only), and neonatal intensive care unit costs.

#### TOTAL PAYMENTS FOR MATERNAL AND NEWBORN CARE

The study found that among women and newborns with employer-provided Commercial health insurance, average total charges for care with vaginal and cesarean births were \$32,093 and \$51,125, respectively. Average total Commercial insurer payments for all maternal and newborn care with vaginal and cesarean childbirths were \$18,329 and \$27,866, respectively. In Medicaid, average total maternal and newborn care charges for care with vaginal and cesarean births were \$29,800 and \$50,373, respectively. Medicaid payments for all maternal and newborn care involving vaginal and cesarean childbirths were \$9,131 and \$13,590, respectively. Both Commercial and Medicaid payers paid approximately 50% more for cesarean than vaginal births. For both types of birth, Commercial payers paid approximately 100% more than Medicaid.

The study examined the source of payments, which were the primary payer (employer-provided Commercial insurance or Medicaid), a secondary insurer such as a union, and out-of-pocket costs. Among total maternal-newborn payments for beneficiaries with Commercial insurance and vaginal births, on average the primary insurer paid the largest proportion of costs (\$15,931 or 87%), out-of-pocket costs averaged \$2,244 (12%), and secondary insurers covered a small portion (\$153 or 1%). Among total maternal-newborn payments for beneficiaries with Commercial insurance and cesarean births, on average the primary insurer paid \$24,949 (90%), out-of-pocket costs were \$2,669 (10%), and secondary insurers paid \$267 (1%) (numbers exceed 100% due to rounding). For both vaginal and cesarean births covered by Medicaid, Medicaid paid nearly all costs for vaginal (\$9,002 or 99%) and cesarean (\$13,327 or 98%) births.

Among total average Commercial payments for maternal-newborn care with vaginal births (\$18,329), 59% went to facilities and 25% to maternity care providers, followed in descending order by payments for anesthesiology, radiology/imaging, laboratory, and pharmacy services. Among total average Commercial payments for maternal-newborn care with cesarean births (\$27,866), 66% went to facilities and 21% to maternity care providers, followed in descending order by payments for anesthesiology, radiology/imaging, pharmacy, and laboratory services. Among total average Medicaid payments for maternal-newborn care with vaginal births (\$9,131), 59% went to facilities and 23% to maternity care providers, while among total Medicaid payments for cesarean births (\$13,590), 65% went to facilities and 20% to maternity care providers. For both types of birth, remaining Medicaid payments covered in descending order pharmacy, radiology/imaging, laboratory, and anesthesia services.

When examined by phase of care — prenatal, the intrapartum hospital stay for both women and newborns, and the care provided to them after the discharge from the birth hospitalization — 2010 payments were heavily concentrated in the intrapartum hospital stay. Our figures slightly overestimate payments for the intrapartum phase and slightly underestimate payments for care after discharge, as modest newborn payments for care after discharge are included in the intrapartum

<sup>&</sup>lt;sup>1</sup> Thomson Healthcare. *The Healthcare Costs of Having a Baby*. May 2007. http://www.kff.org/womenshealth/upload/whp061207othc.pdf.

phase figures in this report. Commercially-insured intrapartum care involved 81% of maternal-newborn payments in vaginal births and 86% of maternal-newborn payments in cesarean births. In Medicaid, intrapartum payments were 70% of payments for vaginal births and 76% of payments for cesarean births.

#### PAYMENTS FOR MATERNAL CARE

The study separately analyzed maternal payments for maternity care and found that among women with employer-provided Commercial insurance, average payments in 2010 for all maternal care with vaginal and cesarean childbirths were \$12,520 and \$16,673, respectively. Since 2004, when a similar analysis was carried out, Commercial payments for maternal care with both vaginal and cesarean births increased by over 50%. In Medicaid, payments for all maternal care with vaginal and cesarean childbirths were \$6,117 and \$7,983, respectively. (No comparable 2004 Medicaid analysis is available.)

The study analyzed average maternal payments by payment source: the Commercial insurer or Medicaid, out-of-pocket payments, and payments from another party such as a union. In women with employer-provided Commercial insurance, the insurer covered the great majority of payments for vaginal (86%) and cesarean (87%) births, Nonetheless, women paid \$1,686 and \$1,948 for vaginal and cesarean births, respectively, a nearly fourfold increase in out-of-pocket costs in both cases since 2004. Medicaid paid virtually all maternal care payments for women covered by Medicaid.

A further analysis explored total maternal payments by type of service. For women with employer-provided Commercial insurance and vaginal births, the most costly types of services were facility (54% of maternal payments) and maternity care provider (23%) payments, with smaller percentages for, in descending order, anesthesiology, radiology/imaging, laboratory, and pharmacy services. For women with employer-provided Commercial insurance and cesarean births, total costs were higher, with a larger proportion of payments going to facilities (60%), a smaller proportion to maternity care providers (20%), and remaining payments, in order, for anesthesiology, radiology/imaging, pharmacy, and laboratory. For women with Medicaid coverage and vaginal births, facility (51%) and maternity care provider (24%) payments also predominated, followed in order by pharmacy, radiology/imaging, laboratory, and anesthesiology payments. For Medicaid beneficiaries with cesarean births, payments went in descending order to facility (55%) and maternity care provider (21%), followed by pharmacy, radiology/imaging, laboratory, and anesthesiology fees.

Maternal payments can be divided into three phases: payments for a woman's prenatal care (before labor and birth processes begin), payments for a woman's intrapartum care (labor, birth, and the rest of her hospital stay), and payments for a woman's postpartum care after hospital discharge. The analysis found:

- Maternal payments in 2010 were concentrated in the intrapartum hospital stay for Commercial beneficiaries and, to a
  lesser extent, for Medicaid beneficiaries. Average Commercial intrapartum payments were \$9,048 for vaginal births
  (72% of all maternal care payments) and \$12,739 for cesarean births (76% of maternal payments). Average Medicaid
  intrapartum payments were \$3,347 for vaginal births (55% of maternal payments) and \$4,655 for cesarean births (58%
  of maternal payments).
- Average maternal prenatal payments in 2010 far exceeded average postpartum payments. Among Commercial vaginal births, prenatal payments were \$3,180 (25% of all maternal payments), in contrast to postpartum payments of \$293 (2% of maternal payments). Among Commercial cesarean births, prenatal payments were \$3,580 (21% of maternal payments), in contrast to postpartum payments of \$354 (2% of maternal payments). Among Medicaid vaginal births, prenatal payments were \$2,405 (39% of maternal costs), in contrast to postpartum payments of \$365 (6% of maternal costs). Among Medicaid cesarean births, prenatal payments were \$2,859 (36% of maternal payments), in contrast to postpartum payments of \$469 (6% of maternal payments).

An analysis of variation in five selected states in average total maternal care costs for women with employer-provided Commercial insurance in 2010 found a large spread:

- In Louisiana, maternal payments were \$10,318 for vaginal births and \$13,943 for cesarean births.
- In Illinois, maternal payments were \$11,692 for vaginal births and \$15,602 for cesarean births.
- In Minnesota, maternal payments were \$12,130 for vaginal births and \$17,109 for cesarean births.
- In California, maternal payments were \$15,259 for vaginal births and \$21,307 for cesarean births.
- In Massachusetts, maternal payments were \$16,888 for vaginal births and \$20,620 for cesarean births.

#### PAYMENTS FOR NEWBORN CARE

The study separately analyzed newborn care payments, measured as payments for the hospital stay plus subsequent care to age three months. Total newborn Commercial payments were \$5,809 for vaginal births and \$11,193 for cesarean births. Total newborn Medicaid payments were \$3,014 for vaginal births and \$5,607 for cesarean births.

The study analyzed average newborn payments by payment source: the Commercial insurer or Medicaid, out-of-pocket payments, and a supplementary insurer. In newborns with employer-provided Commercial insurance, the insurer covered the great majority of payments for vaginal (90%) and cesarean (93%) births. Average out-of-pocket costs for newborn care were \$558 and \$721 for vaginal and cesarean births, respectively. Medicaid paid virtually all newborn care payments for newborns covered by Medicaid: 98% of vaginal birth payments and 97% of cesarean birth payments.

When analyzed by type of service, virtually all newborn payments were for facilities and professional fees. 2010 payments for newborns with employer-provided Commercial insurance and vaginal births were for facility (71%) and professional (28%) fees, with less than 2% on average for combined radiology/imaging, pharmacy, and laboratory fees. Commercial payments for newborns with cesarean births were for facility (75%) and professional (23%) fees, with 1% for combined pharmacy, radiology/imaging, and laboratory fees. Medicaid payments for newborns with vaginal births were for facility (77%) and professional (20%) fees, with less than 3% for combined pharmacy, radiology/imaging, and laboratory fees. Medicaid payments for newborns with cesarean births were for facility (79%) and professional (19%) fees, with less than 3% for combined pharmacy, radiology/imaging, and laboratory fees.

While we do not provide separate figures for newborn hospital and ambulatory costs, as with maternal payments those newborn payments are concentrated in the hospital phase of care.

Predictably, an analysis of newborns with stays in neonatal intensive care units (NICUs) found steeply increased average payment levels relative to payments for all newborns. For newborns with Commercial insurance, vaginal births, and NICU care, insurers paid \$30,875, out-of-pocket costs were \$1,241, and others (e.g., unions) paid \$468. For similar newborns with cesarean births, insurers paid \$45,496, out-of-pocket costs were \$1,351, and others paid \$735. Medicaid paid \$13,875 for newborns with vaginal births and NICU care and \$19,971 for newborns with cesarean births and NICU care. Modest other sources of payment for Medicaid were not separately identified.

#### **KEY FINDINGS**

The *MarketScan* databases provide a unique opportunity to understand recent, 2010, average payments for maternal and newborn care by Commercial insurers and Medicaid. Key findings are as follows:

- Average total payments for maternal and newborn care with cesarean births were about 50% higher than average payments with vaginal births for both Commercial payers (\$27,866 vs. \$18,329) and Medicaid (\$13,590 vs. \$9,131).
- Commercial payers paid an extra \$1,464 to clinicians and \$7,518 to facilities for cesarean versus vaginal births.
- Average total payments for maternal-newborn care by Commercial payers were about 100% higher than average Medicaid payments for both vaginal births (\$18,239 vs. \$9,131) and cesarean births (\$27,866 vs. \$13,590).
- Across the prenatal, childbirth hospitalization, and postpartum phases of care, average inpatient maternal-newborn payments predominated (from 70% to 86% of all payments) for both types of payers and both types of birth.
- Across the prenatal, childbirth hospitalization, and postpartum phases of care, average maternal payments to maternity care providers were concentrated in the hospitalization phase (from 70% to 84% of all maternity care provider payments, depending on type of payer and type of birth).
- Facility fees (from 59% to 66% on average) and professional service fees (from 20% to 25%) predominated over anesthesiology, laboratory, radiology, and pharmacy fees for both types of payers and both types of birth.
- For both Commercial and Medicaid payers, average total for maternal care payments were about twice as great as average total newborn care payments with vaginal births, and between 40% and 50% higher with cesarean births.
- Across five selected states, average Commercial insurer payments for all maternal care ranged from \$10,318
  (Louisiana) to \$16,888 (Massachusetts) with vaginal births and from \$13,943 (Louisiana) to \$21,307 (California) with cesarean births.
- Average payments for babies with stays in neonatal intensive care unit nurseries far exceeded average payments for all newborns (from 3.7- to 5.6-fold) for both types of payers and both types of birth.
- From 2004 to 2010, average Commercial insurer payments for all maternal care increased by 49% for vaginal births and 41% for cesarean births.
- From 2004 to 2010, average out-of-pocket payments for all maternal care covered by Commercial insurers increased nearly fourfold for both vaginal (from \$463 to \$1,686) and cesarean (from \$523 to \$1,948) births.

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# Delivering High-Quality, High-Value Care to Childbearing Women and Babies: Policymakers Can Make a Difference

#### **FEBRUARY 2015**

Policymakers can help promote safe, healthy childbirth experiences for women and babies in the United States with wiser use of resources. Our nation lags behind many others, with worse maternal-newborn care and health, at greater cost. Improvement is essential, as this care impacts the entire population during a crucial window of development and fully 85 percent of women give birth once or more in their lifetime. Improvement can also play a major role in controlling health care costs. In 2012, maternal-newborn care accounted for 22 percent of hospital discharges and \$34.6 billion in hospital payments alone. Six of the ten most common hospital procedures and the most common operating room procedure – cesarean delivery – are carried out in childbearing women and newborns. However, a technology-intensive approach is often unwarranted for this largely healthy population. With Medicaid as the primary payer for 45 percent of childbearing women and 47 percent of newborns, government has a major stake in, and responsibility for, the quality and value of maternal-newborn care.

A new report from Childbirth Connection Programs at the National Partnership for Women & Families identifies abundant opportunities to create a high-quality, high-value maternity care system. Hormonal Physiology of Childbearing: Evidence and Implications for Women, Babies, and Maternity Care (www.ChildbirthConnection.org/HormonalPhysiology) reveals many health benefits of the innate processes of labor, birth, breastfeeding and attachment that — with supportive care — occur naturally in women and babies. For those without a clear need, the report finds, many modern medical "advances" that are widely used in this primarily healthy population are a poor substitute for the body's own — too often untapped — beneficial processes. Costly overused interventions such as labor induction and cesarean section interfere with these benefits and should only be used when clearly indicated. Beneficial practices such as labor support and skin-to-skin mother-baby contact after birth support healthy childbirth processes and are underused; increasing their use offers important opportunities for gains.

To improve the health of mothers and babies, eliminate waste, and use heath care resources wisely, policymakers should:

- **1.** Encourage use of innovative maternity care payment and delivery systems that foster appropriate care for healthy women and babies, healthy outcomes, and high-value care, including within accountable care organizations, maternity care homes, and integrated delivery systems.
- **2.** Increase access to caregivers and care settings that most reliably support physiologic childbearing:



- ▶ *Midwives*. Ways to increase access include: increase the supply of midwives, enable midwives to practice to the fullest extent of their scope of practice, and encourage pregnant women to use midwifery care.
- ▶ Freestanding birth centers. Ways to increase access include: support the development of freestanding birth centers, remove reimbursement and other barriers to birth center sustainability, and encourage pregnant women to use birth centers.
- ▶ *Birth doulas*. Ways to increase access include: create reimbursement mechanisms for birth doula care, support community-based doula programs, and encourage pregnant women to use doulas.
- **3.** Support quality collaboratives and other maternity care quality improvement initiatives to foster care that supports physiologic processes in healthy women and newborns and, whenever safe, in those with special needs (e.g., routine skin-to-skin mother-baby contact after cesarean birth). (The Quality Care for Moms and Babies Act, S. 466, includes support for maternity care quality collaboratives.)
- **4.** Leverage The Joint Commission's Cesarean Delivery (PC-03) and Exclusive Breast Milk Feeding (PC-05) facility-level performance measures for quality improvement and public reporting, and similarly apply these to clinician-group and health plan care. (S. 466 includes support for maternity care quality measurement.)
- **5.** Develop and implement experience of care, outcome, and woman-reported quality measures to foster care environments and practices that support the innate capacities of childbearing women and newborns. (S. 466 includes support for maternity care quality measurement.)
- **6.** Develop and publicize the availability of user-friendly web portals to enable pregnant women to consider meaningful, broadly applicable, and up-to-date performance results when choosing health plans, maternity care providers, and birth settings.
- **7.** To promote breastfeeding, provide incentives for all facilities to secure and maintain the Baby-Friendly Hospital Initiative designation.
- **8.** Support a public education campaign to inform women, the general public, journalists and others about the value of physiologic childbearing processes for healthy women and newborns, and steps women can take to experience such processes.
- **9.** Support pilot projects to develop and implement model health professions education curricula to ensure that all members of teams caring for childbearing women and newborns have foundational knowledge about physiologic processes around the time of birth, how to foster these processes, and impacts of common maternity care practices on them.
- **10.** Fund research to fill knowledge gaps about the hormonal physiology of childbearing and the impact of common maternity care interventions on physiologic processes over the short, medium, and longer terms. Of special interest are 1) clarifying impacts of common perinatal interventions on breastfeeding, maternal behaviors and mother-baby attachment, and maternal mood states, and 2) understanding their possible long-term epigenetic effects.

The National Partnership for Women & Families is a nonprofit, nonpartisan advocacy group dedicated to promoting fairness in the workplace, access to quality health care and policies that help women and men meet the dual demands of work and family. More information is available at www.NationalPartnership.org.

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#### **HEALTH AFFAIRS BLOG**

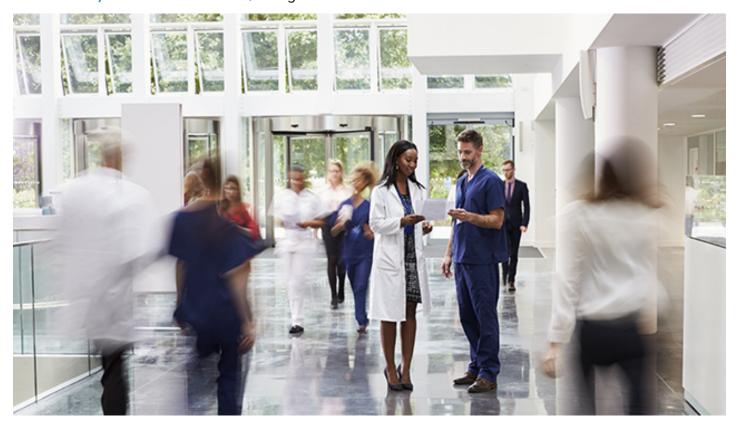
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## The New State Medical Board: Life In The Antitrust Shadow

Eli Y. Adashi, Barak D. Richman, Reuben C. Baker

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For the better part of the twentieth century, state medical boards (SMBs) strove to protect the US public by licensing, disciplining, and regulating health care professionals. For much of this time, however, SMBs, along with the corresponding state medical society, have also engaged in vigorous economic advocacy on behalf of their members. It

was this facet of the medical enterprise that drew the attention of federal antitrust overseers. Decades of legal battles over alleged anticompetitive practices followed. None proved more significant than the recent *North Carolina State Board of Dental Examiners v. Federal Trade Commission*. It was here that the Supreme Court of the United States (SCOTUS) concluded that SMBs made up of "active market participants" may not claim immunity from antitrust laws unless they are "actively supervised by the State." The implications of this and subsequent verdicts to present-day SMBs cannot be overestimated. In this communication, we describe the evolution of the SMBs, trace their exposure to federal antitrust liability, examine the erosion of their economic brief, and discuss the legal boundaries of their state-given authority.

#### The State Medical Boards Of Yore

As byproducts of the Progressive Era, SMBs came to be during the latter half of the nineteenth century. It was 1859 when the first SMB was constituted by the North Carolina state legislature. By 1901, every state of the union (and the District of Columbia) has seen to the enactment of a medical practice act. The derivative SMBs were to oversee the attendant regulatory framework and update it as necessary. Representation of state medical societies with the House of Delegates of the American Medical Association (AMA) followed before too long. It is through this position of leadership that state medical societies came to constitute the local custodians of the AMA Code of Medical Ethics. In time, SMBs and the relevant state medical societies have also come to be regulators of physician supply, guarantors of hospital privileges, allocators of consultation requests, and purveyors of patient referrals. Additional pursuits comprised furnishing malpractice insurance, distributing teaching positions, and establishing specialty ratings. At the height of their power, SMBs and their partner state medical societies appeared to be acting as a medical monopoly for physicians, by physicians.

#### Health Care Competition Enforced

Increasingly, SMBs and their partner state medical societies came to be viewed by federal regulators less as professional standard bearers and more as protectors of a lucrative professional monopoly. In so doing, the local medical establishment focused less on assuring the quality of its own members and more on promoting their economic interests, becoming arbiters of fee schedules, resisting entry from alternative providers, and taking other measures that stifle competition in the health care market. Eventually, the conduct of the AMA, its cognate state medical societies, and the SMBs became the subject of growing federal attention. Legal antitrust action by the Department of Justice (DOJ) or by the Federal Trade Commission (FTC) was just a matter of time. It was 1938

when the DOJ finally sought and secured an indictment against the AMA and the Medical Society for the District of Columbia for allegedly conspiring to restrict competition. The alleged violation of the Sherman Antitrust Act detailed how the Medical Society orchestrated an illegal boycott against a prepaid risk-sharing nonprofit health plan (Group Health), which presented an economic challenge to AMA physicians. In the ensuing litigation (American Medical Ass'n v. United States. Medical Society of the District of Columbia v. Same), several courts, including SCOTUS, found for the government. These and other subsequent lessons garnered through decades of antitrust litigation in the health care arena found their way into a 2004 joint FTC/DOJ report titled "Improving Health Care: A Dose of Competition." That report, crafted by policy makers who were deeply distressed by a lack of competition in many areas of the health sector, identified SMBs as a significant source of anticompetitive harm. The report proffered certain reforms to SMBs that would sustain their role as quality assurers while mitigating the market harm they inflicted, and it warned that SMB reform is an important factor in making health care more affordable and encouraging valuable innovations to the delivery system. In charging the health care arena, heretofore rife with restraint of trade, to embrace the principles of free market competition, the federal government singled out the harmful practices continued by SMBs.

#### The "State Action" Doctrine

By the late '70s and '80s, with an eye toward skirting further antitrust scrutiny, SMBs took to invoking the "state action" doctrine according to which only private, but not state, economic actors are subject to antitrust laws. Claiming to be an integral, indeed inseparable part of state government, SMBs have, until recently, been shielded from antitrust enforcement. In so doing, SMBs retained the freedom to engage in pursuits otherwise deemed restrictive to economic competition. Seeking to break the ongoing enforcement logjam, the FTC convened a State Action Task Force to reassess and clarify the state action doctrine. In 2003, the Task Force concluded that "overbroad interpretations of the state action doctrine could potentially impede national competition policy goals." The Task Force further concluded that the FTC would do well to litigate additional cases wherein the state action doctrine is being used to shield alleged anticompetitive practices.

#### The "State Action" Doctrine Revisited

Acting on the recommendations of the State Action Task Force, the FTC filed an administrative complaint in 2010 against the North Carolina Board of Dental Examiners (NCBDE). At issue were cease-and-desist letters sent by the NCBDE to non-dentists

engaged in teeth whitening even though the North Carolina Dental Practice Act does not categorize teeth whitening as "the practice of dentistry." In its administrative complaint, the FTC alleged that the "concerted action [by the NCBDE] to exclude non-dentists from the market for teeth whitening" constituted an "unfair method of competition." A motion to dismiss by invoking the state action doctrine was denied by an administrative law judge and sustained by the FTC since the NCBDE was not "actively supervised by the State to claim immunity." Similar conclusions were reached by several courts, including SCOTUS. Writing for the majority in 2015, Justice Anthony M. Kennedy rejected the NCBDE claim of immunity noting that "a state board on which a controlling number of decisionmakers are active market participants in the occupation the board regulates" must satisfy strict requirements if it is to invoke the state action doctrine. Seeking to amplify and explicate the findings of the court, the FTC in 2015 issued "Guidance on Active Supervision of State Regulatory Boards Controlled by Market Participants." Leaving little room for ambiguity, the FTC carefully offered guidance regarding the requirements it deemed that SMBs must meet in seeking to claim state action immunity from antitrust litigation. In essence, those requirements emphasized the need for politically accountable officers to oversee and have the ready capacity to intervene in anticompetitive SMB actions.

#### The Case Of The Texas Medical Board

The significance of the precedent set by *North Carolina State Board of Dental Examiners v. Federal Trade Commission* was soon to become evident in a familiar context. It was in 2011 that the Texas Medical Board (TMB) informed Teladoc, Inc., a Texas-based telehealth services provider, that, by prescribing medication without conducting a "face-to-face" examination, it was in violation of state regulations. A protracted legal battle ensued until Teladoc just months after the US Supreme Court issued its decision in *NC Dental Examiners*, countersued the TMB for antitrust violation. In the ensuing case, *Teladoc, Inc. v. Texas Medical Board*, in which the FTC intervened on behalf of Teladoc, the telemedicine company sought relief in state and US District courts. Citing failure to meet the "active supervision requirement" of state action immunity, the courts found in favor of Teladoc, while invalidating the TMB claim. Further legal proceedings at a US Court of Appeals were voluntarily terminated by TMB in expectation of the enactment of the Telemedicine and Telehealth Services bill by the Texas legislature, which when enacted, had eliminated the "face-to-face" requirement that had been the centerpiece of the TMB grievance.

#### The New State Medical Boards

Living in the antitrust shadow, SMBs, no longer shielded by the state action doctrine, would do well to refrain from impeding competition. The views of the FTC and of the DOJ with respect to such forays have been made amply clear. Their joint call to uphold the principles of free market competition must not go unheeded.

Some SMBs appear to have received the message. The Texas Medical Board has, for the most part, abandoned its fight against Teladoc, and other SMBs—perhaps in response to Texas' failure—have been less resistant to telemedicine providers. Some states also appear poised to expand nurse practitioner authority, and although SMBs remain opposed to such liberalization, many recognize that the political and economic tides are pushing against their traditional authorities.

However, SMBs continue to maintain unnecessary restrictions on good medicine. Many continue to resist ceding authority to non-physicians, undermine cross-state reciprocity compacts while jealously controlling their exclusive state licensure regimes, and use their regulatory authority to impede innovation. As health care costs continue to outpace inflation, the urgency to remove SMB-sustained inefficiencies remains pressing. The FTC deserves enormous credit for both identifying the economic harm inflicted by SMBs and for targeting SMBs with its limited litigation resources, but it cannot become complacent. State attorneys general should also enforce state consumer protection laws to counter SMB abuses, and Congress would do well to consider reforms to obsolete elements of state-based licensure fiefdoms. And we should celebrate the repeated and unambiguous affirmation of competition principles by the courts, which have a spotty record in enforcing the antitrust laws. Continued success in federal courts will require a continued justification and prioritization of competition in health care markets.

Perhaps most importantly, the medical profession ought to reconsider the role of its SMBs. Embracing and fostering robust competition in health care markets is the only route to assuring that the new SMB has indeed arrived, and this can only happen from within. Physicians can recognize SMB abuses better than any outsider, and they recognize how SMBs have impeded dire reforms of the practice of medicine. At the same time, physicians know how SMBs might be agents of necessary change. SMBs could not only embrace the value and rigors of competition, but they also might provide useful leadership in encouraging physicians to pursue reform. In short, the new SMB could be one that abandons its role as an ossified gatekeeper and crafts a visionary role for expanding consumer welfare and professional dynamism.

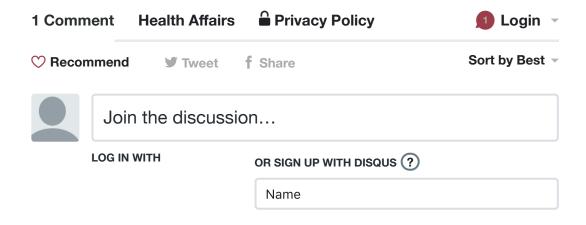
#### **Authors' Note**

Professor Adashi serves as co-chair of the Safety Advisory Board of Ohana Biosciences, Inc.

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#### Shirley • 2 months ago

A patient may travel to receive care from a physician licensed in another state. It would be essentially the same thing if states were to allow out-of-state telemedicine providers to offer services based on their home state license. This would be particularly valuable for specialty care and care in rural areas -- a windfall for patients. OR the federal government could pass a law to redefine the location of the practice of medicine, shifting it from the location of the patient to the location of the physician. See Svorny, Liberating Telemedicine, 2017.

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### issue brief

**Blair Dudley** MPH

## Promoting Midwifery and High Value Care in Medi-Cal



#### Introduction

The Pacific Business Group on Health (PBGH) interviewed California Medicaid (Medi-Cal) plans across managed care models and geographies to explore opportunities to promote Medi-Cal access to midwives and high value care strategies in maternity. PBGH evaluated payer contracting and reimbursement practices, network requirements, quality incentives, and value-based payment. In order to capture the full landscape of payer practices in maternity, PBGH also interviewed large commercial health plans. From these interviews, we have developed recommendations to promote access to and use of midwives and high value strategies in Medi-Cal.

From the *Listening to Mothers in California* survey, we learned that most women would want or would consider a midwife for a future pregnancy. Moreover, the main reason women who wanted a midwife did not have one was because they thought their insurance would not pay for a midwife. Clearly, insurance coverage is a key concern for women considering maternity care team and care location options. In addition, PBGH believes increasing midwifery utilization is a critical strategy to improve in maternal quality, affordability, and the patient experience.

During these interviews, we asked payers about their contracting and reimbursement practices for midwifery, separating out policies for Certified Nurse-Midwives (CNMs) and Licensed Midwives (LMs) when appropriate. CNMs are educated in both nursing and midwifery – they earn graduate degrees, complete a midwifery education program accredited by the Accreditation Commission for Midwifery Education (ACME), and pass a national certification examination administered by the American Midwifery Certification Board (AMCB) to receive the professional designation of CNM.<sup>2</sup> They are credentialed to practice with prescriptive authority in all 50 states. Licensed Midwives, LMs, are educated in the discipline of midwifery. They earn graduate degrees, meet health and science education requirements, complete a midwifery education program accredited by the Midwifery Education Accreditation Council), and LMs take a national certification exam which is equivalent but not identical to the test administered by the AMCB. CNMs practice most often in the hospital, while LMs rarely practice in the hospital. In California, CNMs must practice with physician supervision (which remains undefined in statute, and does not mean the physician is physically present).<sup>3</sup>

Our interviews included the following payers: Inland Empire Health Plan, Partnership Health Plan, CalOptima, community Health Group of San Diego, L.A. Care, Santa Clara Family Health Plan, Blue Shield of California, Health Net, United Health Care, Cigna, Aetna, and Anthem. These health plans represent the diversity of California's population and the wide range in health plan structures in terms of size, level of delegation, and level of concentration of maternal delivery volume in network. These differences in size (1,000 to 20,000 annual births) and concentration (3 to 72 labor and delivery hospitals), as well as competition with other area health plans, impacts the payer's overall ability to drive improvements locally and regionally. Additionally, most of the health plans have at least some portion of their business management delegated to contracted health systems, medical groups, and independent physician associations, which can significantly affect a plan's capacity to influence changes in care delivery and performance.

#### **Midwifery Contracting and Reimbursement Practices**

Health plans have several levers to promote access to and utilization of midwives, including network adequacy and contracting, consumer access, and reimbursement rates.

#### Key Health Plan Levers



#### **Network adequacy and contracting**

Ensuring midwives and birth centers are available in network



#### Reimbursement rates

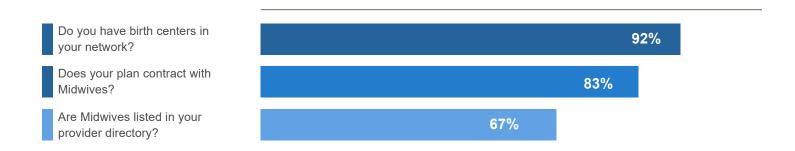
Competitive rates of reimbursement to support the practice of midwifery and the financial viability of birth centers



#### **Consumer access**

Ensuring midwives are visible to the consumer

With these levers in mind, we asked health plans if they contract with midwives and birth centers, if midwives are listed in the provider directory, and what the reimbursement rates are for midwives and birth centers (compared to reimbursement practices for an OBGYN and hospital birth).



Health Plan	Contracts with Midwives	Midwives Listed in Provider Directory	Contracts with Birth Centers
Aetna (commercial only)	•	•	•
Anthem	•	•	•
Blue Shield of California			•
CalOptima	•	•	•
Cigna (commercial only)	•	•	•
Community Health Group of San Diego	•	•	•
Health Net	•		•
Inland Empire	•	•	•
L.A. Care	•		•
Partnership Health Plan	•	•	•
Santa Clara Family Health Plan	•		
United Health Care	•	•	•

In our interviews, a few key themes emerged:

#### 1) Contracting

Availability of midwives in network is a necessary condition for women seeking a maternal care provider. Under Medi-Cal managed care, women must seek from networked providers for services to be covered. As a result, midwives must be part of the network to ensure access.

Almost all health plans contract directly with midwives, with Blue Shield of California as the exception. Medi-Cal plans are required to contract with at least one Certified Nurse-Midwife (CNM)/Licensed Midwife (LM) and at least one birth center if they are available in the plan's catchment area and willing to accept offered rates, in accordance with the All Plan Letter 18-022.4 However, health plans were largely unable to determine the exact number of nurse-midwives providing care in their network. Many of these plans noted that their delegated medical groups, community clinics or network hospitals may have nurse-midwives on staff, but the claims often come in under the physician's name, since billing midwifery services "incident to" a physician often means a higher reimbursement rate, or come in under the delegated entity. Thus, health plans are unable to determine how many midwives are effectively in network or attend births for their population.

Licensed Midwives can practice independently (not under physician supervision), which would mitigate these data issues. However, some health plans hesitate to contract with LMs due to concerns about variation in quality of care and lack of integration with OBs and hospitals when its needed. While many LMs have worked to decrease variation in practice and to establish relationships with hospitals and physicians, this perception remains.

#### 2) Consumer Access

Midwives need to be not only available in Medi-Cal networks, they also need to be a visible option to women seeking care. All the health plans interviewed that contract with midwives cite that these providers are visible to consumers in their online provider directories. This finding is encouraging, since these online directories serve as a menu of options for consumers. However, as plans do not have full information about the midwives delivering services in their network under delegated arrangements and/or in clinics and hospitals that employ midwives, it may be hard for consumers seeking midwife care to find it using these directories.

#### 3) Reimbursement and provider incentives

While we learned that most Medi-Cal plans contract with midwives and include midwives in their provider directories; the actual reimbursement for midwives evidenced a range of payer practices.

Several plans reported reimbursing at the same rate for midwives as physicians, noting that the actual rate varies by contract (100% or some slight variation of the Medi-Cal fee-for-service rate). However, other plans reported reimbursing midwives between 80% and 90% the rate of reimbursement for physicians.

Health plans consistently reported lower rates of reimbursement for birth centers compared to hospital births. Many of the plans noted that for birth center births, the professional fee is the same or similar, but the facility fee is less, since it is based on simply the APR-DRG and the per diem rate. Health plans reported that birth center reimbursement was anywhere from 30% to 50% less than hospital reimbursement.

#### **Network Requirements**

New regulations encourage change in the industry. The binding guidance of the All Plan Letter 18-022 ensures that at the very least, Medi-Cal plans must attempt to contract with Certified Nurse-Midwives, Licensed Midwives, and birth centers. While there is much room to improve and expand this basic network requirement, this APL was a significant victory for Medi-Cal families looking to access a midwife for their maternity care.

Health plan network requirements, such as provider performance on quality metrics, are key drivers of change. Studies have shown that areas with more midwives integrated into the health system evidence significantly higher rates of physiologic birth, less obstetric interventions, and fewer adverse neonatal outcomes.<sup>5</sup> However, a narrow provider network strategy is not always available to health plans facing network adequacy challenges in rural areas.

PBGH recommends that health plans work with purchasers to ensure high standards for network requirements. For example, Covered California requires that participating plans only contract with hospitals that meet certain quality and safety targets, including achieving the Healthy People 2020 NTSV (nulliparous term singleton vertex) or "low-risk" C-section target rate of 23.9%. Aligning contracting standards with nationally recognized targets sends a strong message to the provider community that purchasers, and consumers, demand high quality and refuse to pay in-network rates for anything less.

#### **Quality Measurement**

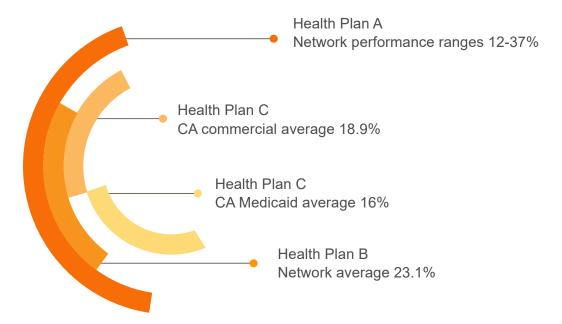
Another important strategy for health plans is to promote professional standards and drive improvement in their networks through quality measurement and data transparency. Public reporting promotes healthy competition among providers and educates consumers on their care options.

Health plans can take leadership and leverage change through hospitals. Inland Empire Health Plan and Partnership Health plan heavily incentivize their network hospitals to participate in the California Maternal Quality Care Collaborative (CMQCC) and to submit data to the Maternal Data Center. Significant financial incentives are tied to hospitals' performance on CMQCC metrics such as NTSV C-section rate. Other plans, such as Health Net and Blue Shield of California, are following suit and starting to include quality incentives for performance on the NTSV C-section metric in their contracts. Health plans can leverage hospital participation in CMQCC to create powerful incentives for improvement on NTSV C-section and other key maternity metrics.

Health plans can leverage hospital participation in CMQCC to create powerful incentives for improvement on NTSV C-section and other key maternity metrics.

The newly published %CNM deliveries metric on CalHospitalCompare could be a new opportunity for plans to promote and incentivize midwifery utilization in their networks. This %CNM deliveries metric first needs a target, and second, any incentives for achievement must be substantial enough to influence the bottom line for hospitals and providers.

C-section rates have been on the rise in the U.S. over the past several decades, and many payers are taking steps to monitor performance. Several managed Medi-Cal plans – Inland Empire, CalOptima, and Partnership Health Plan – as well as the national health plan United Health Care are tracking variation in NTSV C-section rates across their networks. NTSV C-section rates are difficult to calculate from claims data, which creates a barrier for many health plans. The availability of this data has been a major driver of improvement on the NTSV C-section metric in California. While NTSV C-section rates are typically calculated at the hospital level, hospital participants of the California Maternal Quality Care Collaborative (CMQCC) can see provider-level performance and have used this to support efforts to reduce variation and improve performance. Since CNM-attended births tend to have fewer interventions such as C-sections<sup>6</sup>, PBGH recommends increasing midwifery utilization and physician-midwife collaboration.



Other payers have decided to track a non-risk-adjusted C-section rate for hospitals in their networks. For example, Cigna has constructed an index measuring primary Cesarian delivery rates using the Agency for Healthcare Research and Quality methodology (AHRQ IQI #33 specifications.) While the Joint Commission and AHRQ measures are commonly used to define low-risk C-sections, the Society for Maternal Fetal Medicine recommends another metric – the SMFM definition. This claims-based metric is appealing because it does not rely on hospital resources for data collection. Aetna utilizes this SMFM definition to track C-sections across their networks. The lack of consistency in C-section measurement creates a barrier for measurement and improvement, since most providers contract with many health plans.

Payers also measure performance through claims at the provider level. Health plans consistently reported tracking performance on perinatal care measures that are part of the Healthcare Effectiveness Data and Information Set (HEDIS), such as timely visits for Prenatal and Postpartum Care and the proposed new measures of Prenatal and Postpartum Depression Screening and Follow-up. Payers are tracking general population health metrics such as Tdap (influenza and diphtheria and pertussis) vaccinations, chlamydia screening, blood pressure screening, diabetes screening (gestational and postpartum), Hepatitis B screening, and smoking cessation. Many of these are required measures that are part of the managed care accountability set (MCAS)<sup>8</sup> that Medicaid managed care plans are evaluated annually. In addition, historically some measures, including timely prenatal care, have been tied to auto-assignment in counties with multiple plans. This results in higher performing plans receiving a higher percentage of those members who enroll in managed care but do not select a plan.<sup>9</sup>

Payers are also responding to population-specific quality improvement needs through physician quality measurement. For example, Los Angeles County experienced a rise in syphilis and congenital syphilis rates in 2018,<sup>10</sup> and in response, L.A. Care partnered with the LA County Department of Public Health to increase syphilis and sexually transmitted disease screening rates in the third trimester. This effort demonstrates that while tracking performance and comparing targets at the national level is important, health plans are uniquely positioned to respond to local concerns. (BRIGHT SPOT– ask LA Care to present best practice)

However, attribution for maternity-related quality measures (other than NTSV C-section) is complicated in Medi-Cal managed care, as patients are assigned to a primary care physician but not to a specific maternity provider. Under Medi-Cal fee-for-service, most plans will see who the designated provider is using global obstetric CPT codes, but under capitated or delegated arrangements, it may be harder to ascertain.

#### **Maternal Mental Health**

Health plans are increasingly turning their attention to behavioral health in maternity care in response to both consumer advocacy efforts and new policy regulations. California Assembly Bill 2193, which went into effect on July 1, 2019, requires obstetric providers to confirm screening for maternal depression. This new law shines light on an important issue, but implementation of the policy has been varied. Many plans had already included maternal depression screening in their provider performance tracking programs, aligning with the US Preventative Services Task Force recommendation "that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions." Some payers, such as Partnership, Inland Empire, and Cigna have attached incentives to performance on perinatal depression screening. Many other plans, such as CalOptima and Health Net, are developing robust data tracking and incentive programs to focus on perinatal mood and anxiety disorders in 2020.

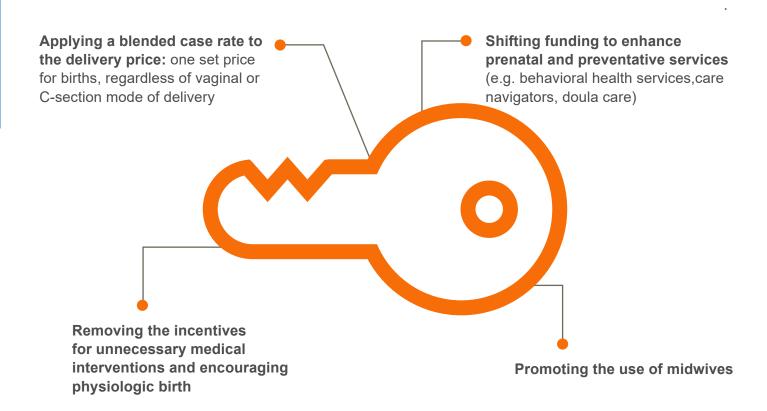
Other plans are developing care management resources to support providers in their ability to screen, treat, and refer patients to treatment. The Aetna Maternity Program has an embedded behavioral health specialist to actively manage members with perinatal mood and anxiety disorders. This strategy is appealing to health plans with extensive resources and a large geographical or national presence; however, building a care management team is a challenge to smaller local health plans who already have difficulty identifying behavioral health specialists in their area.

The largest barrier for both referring providers and patients is the lack of access to behavioral health specialists. For managed Medi-Cal plans, specialty mental health benefits and substance use are administered by the county, while mild to moderate mental health benefits are part of the plan's responsibility. Due to provider shortages, often patients with acute symptoms are addressed in a timely manner, while patients with mild-to-moderate conditions experience a long waiting period. This fragmented structure creates major challenges for data collection, provider communication, and consistency in care delivery.<sup>12</sup>

Despite public attention, utilization of mental health benefits during pregnancy and the postpartum period was reportedly very low compared to other populations (this was true for both the California managed Medi-Cal plans and the national commercial plans interviewed.) This surprisingly low utilization highlights the need for health plans, purchasers, and community organizations to develop consumer engagement strategies to educate individuals on the benefits of early and aggressive screening and treatment.

#### **Bundled Payment & Learnings from Commercial Payers**

An emerging trend in value-based care is episode-based bundled payment, and several commercial health plans, including Cigna and United, have created bundled payments for maternity. Although there is no consumer cost-sharing in Medi-Cal, some of the learnings from bundled payment in the commercial space could translate into the public space. The bundled payment strategy encourages payer/provider collaboration, resulting in many key benefits:



The Department of Health Care services is encouraging value-based payment in Medi-Cal for maternity, and several Medi-Cal health plans are using or considering a blended case rate. PBGH recommends this strategy as a preliminary step to implementing a maternity bundled payment model. In addition, many Medi-Cal plans would consider developing a maternity bundle. The biggest challenge is that contracting is not standard throughout the state, and each provider organization and hospital contract and network is unique. Moreover, the delegated arrangements within plans adds another layer of complexity. Although a bundled payment strategy offers several benefits, significant on-the-ground effort would be needed to tackle the existing contract layers to develop, implement, scale, and spread a maternity bundle in Medi-Cal.

#### **Challenges and Recommendations**

Our findings indicate wide variation in contracting practices and reimbursement policies for midwives amongst managed Medi-Cal plans, and several plans have acknowledged that this topic is not a priority.

These plans consistently referenced a few challenges, including the level of delegation within their networks and the ability to credential providers or ensure providers are meeting professional standards. Many of the plans we interviewed are highly delegated, thus, they have less insight into the contracting decisions made by delegated groups. However, they could still require contractually the inclusion of midwives in their network. For Medi-Cal, the supervising physician needs to be a Medi-Cal participating and credentialed provider. In some cases, the midwife groups have found a supervising physician but not one who is willing to contract with a Medi-Cal Plan. Essentially, the physician supervision requirement creates a barrier for Medi-Cal consumer access to CNMs while having no added effect on quality or safety, and variation (or perceived variation) in professional standards pose a challenge to health plans contracting with LMs.

However, the implementation of quality measurement with significant incentives, and the move toward value-based payment are essential tools to promote not only midwifery but also high value care in general. Implementing a blended case rate and having one set price for both vaginal and C-section modes of delivery reduces the financial incentive for unnecessary interventions such as C-sections and improves outcomes by having the entire care team working collaboratively under a shared budget and common quality goals. Moreover, PBGH recommends that purchasers explore prospective bundled payment methodologies - setting a price target and paying for the entire episode upfront. This brings the whole team together to plan how they will deliver care most effectively, rather than having them continue in a "fee-for-service" model in which each provider on the team bills separately. This makes the cost of maternity care for both purchasers and patients more predictable – with fewer surprises.

Given the existing barriers, we recommend a few ways **health plans** could promote midwifery utilization, including:

- Equalizing reimbursement rates for midwives with obstetricians
- Increasing reimbursement rates for birth center births (the facility fee)
- Developing quality performance incentives encouraging midwifery utilization general quality metrics such as NTSV C-section rates, or more specific quality metrics such as %CNM deliveries, or requiring a certain proportion increase in CNM deliveries over a designated period of time – both for hospitals and for delegated groups
- Support the full practice authority for Certified Nurse Midwives (CNMs) and Licensed Midwives (LMs), to the full extent of their training and licensure
- Offering the equivalent of PPS-wraparound payment for FQHC-employed CNMs who do deliveries (since, if an FQHC employs a CNM, they are incentivized to have that CNM only do prenatal care because they cannot get a top-up payment if they deliver services off-site)

Given that about 40% of Medi-Cal births happen under fee-for-service Medi-Cal<sup>13</sup>, we recommend a few levers available to the Department of Health Care Services (DHCS) to promote midwifery, both as a purchaser governing plan behavior (e.g. All Plan Letters, quality measures, etc.), and as the plan for fee-for-service Medi-Cal births:

- Including NTSV C-section rate in EAS External Accountability (EAS) measure set and measuring disparities
- Equalizing reimbursement rates for midwives with obstetricians
- Increasing reimbursement rates for birth center births (the facility fee)
- Increasing network adequacy requirements for CNMs and LMs and accredited birth centers beyond just one per region (consider current physician network adequacy standards when determining midwifery network adequacy standards)

Although our analysis focuses on recommendations for Medi-Cal plans, we are exploring ways in which Medi-Cal plans and commercial plans can work together in a market. Commercial plans could implement tactics which are not available to Medi-Cal, such as benefit design incentives. A few commercial plans indicated that although such benefit design does not currently exist to steer consumers to midwives, there may be some opportunity to promote midwives, particularly within accountable care organizations (ACOs) where there is already shared risk. In addition, commercial plans could test certain innovations such as paying for a laborist to provide backup to midwives and to the regular nursing staff, and considering requiring hospitals to provide physician back-up for midwives. Finally, PBGH recommends that both Medi-Cal and commercial plans consider multi-payer solutions to promote midwifery integration.

PBGH's Transform Maternity Care program is dedicated to promoting high value maternity care for all. We believe that increasing midwifery utilization will improve maternal quality, affordability, and the patient experience in California and the U.S. Since there are a number of operational, cultural, and financial considerations regarding midwifery expansion, PBGH has developed several resources (available to download on our website: pbgh.org/midwifery) to support providers on this journey.

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- Santa Clara Family Health Plan
- Blue Shield of California
- Health Net
- United Health Care
- Cigna
- Aetna
- Anthem

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- Cristina Almeida, MD, MPH,
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- Kathleen Belzer, CNM, President of the California Nurse Midwives Association
- Amy Chen, JD; Senior Staff Attorney, National Health Law Program
- Cindy Haag, LM, CPM;
   Director of Pacifica Maternity
- Lance Lang, MD FAAFP,
   Chief Medical Officer, Covered California
- Elliott K. Main, MD, Medical Director, California Maternal Quality Care Collaborative, Clinical Professor of Obstetrics and Gynecology, Stanford University School of Medicine
- Holly Smith, MPH, MSN, CNM
- Stephanie Teleki, PhD, MPH,
   Director of Learning and Impact, California
   Health Care Foundation
- Jennifer Wong, MPH, Project Manager, Integrated Healthcare Association

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# Complaints, Investigations, Discipline Analysis

# What's in this section on Complaints, Investigations, Discipline:

- Overview
- Survey of DEMs about the process
- Voluntary Advisory Board fact sheet
- Crusade Against Homebirth article
- Washington State Quality Management Program example
- New Mexico Midwifery Board example



### Complaints, Investigation, Discipline

Survey of Colorado DEMs about the Complaint, Investigation, and Disciplinary Process

There is a sense among Colorado's Direct Entry Midwives that the complaint/investigation process could benefit from a critical analysis and overhaul.

Elephant Circle recently surveyed direct entry midwives in Colorado (n=36) about their experiences with the complaint/investigation process. The responses come from midwives in both urban and rural areas, all but four respondents are currently practicing, and 21 have received a complaint. Just over half of these complaints were ultimately dismissed, though 80% of the complaints were investigated. The results from that survey supported anecdotal evidence we have collected over the past 10 years.

This survey highlighted several issues with the current complaint/investigation process.

Midwives felt the process lacked good communication, was not timely, and did not feel fair.

- About 50% of midwives received notice of the complaint within 3-12 months after the event, and the majority of complaints (60%) were resolved between 6-24 months after the event. One complaint took more than 24 months; only 14% of complaints were resolved in less than 6 months.
- Only 13% felt the communication about the complaint process was timely.
- More than half of the respondents (57%) did not think the process was fair.

A lack of understanding about the differences between the midwifery, community birth model of care and the obstetric/pediatric/hospital model of care contributes to complaints.

- Consumers are not the primary source of complaints; only two complaints were known to be filed by a client.
- In contrast, 33% of the respondent's complaints were from an unknown origin, and 33% were filed by either medical professionals or a hospital.
- The origin of the other known complaints included other midwives (4), DORA (1), or non-clinical third parties (2).
- A number of filed complaints reprimanded midwives for not following OB practice protocols, which is not the midwifery scope of practice.

It is not uncommon for complaints to be initiated when a DEM client seeks a
higher level of care, which speaks to the current lack of integration of DEMs into
the Colorado maternity care landscape, and a failure on the part of medical
providers to follow best-practices for transfers from home to hospital.

Though the majority (80%) of midwives receiving complaints were not summarily suspended after the complaint, the use of this measure has increased dramatically in the past few years.

• There have been 3 midwives suspended upon complaint in the last 2 years.

### The process can be very expensive for midwives

- Seventy percent of the midwives who received a complaint obtained legal representation.
- The total cost of navigating the complaint process (including attorney/court fees, lost income, refunds to clients) ranged from \$800-30,000 with the average financial cost being \$7600.

To the midwife under investigation, the process did not appear to reflect larger Colorado midwifery community standards.

- Most (57%) did not know who reviewed their complaint, but felt their complaint
  was reviewed by midwifery professionals with different practice standards or
  professionals either unfamiliar with or outside the midwifery model of care.
- It is especially problematic when medical professionals and personnel who are unfamiliar with home birth and its scope of practice are a primary source of complaints and the play a role in the investigation process,
- US MERA (United States Midwifery Education, Regulation, and Accreditation), a
  national body that advocates for midwifery in the US states that, "Midwifery is a
  profession that is autonomous, separate, and distinct from nursing and medicine.
  Only midwives can exercise the full scope of midwifery practice and provide all
  the competencies within this scope."

Midwives subjected to the complaint and review process felt the process lacked transparency and accountability.

- Midwifery has a scope of practice which, by its nature means that there is variability between practitioners even when all are practicing safely and within the rules/regulations.
- The current system utilizes few individuals in the investigation/review process, which increases the bias that can come with variations in practice norms.
- A review board provides multiple practice perspectives, allowing for less bias due to practice variability.
- Most midwives were not privy to the investigation process, simply the outcome.
   When the outcome did not appear to reflect the practice standards of the larger midwifery community, there was no way to ask questions, provide alternatives or solicit more information.

 Some midwives felt as though the outcome reflected differences in opinion, rather than a demonstration of violating the rules, regulations, or standards of safe practice.

The DEM program has experienced a very high rate of program director turnover (none of whom have familiarity with the midwifery model of care or community birth) negatively affecting both the complaint/investigation process and ability of DEMs to receive accurate, timely guidance on rules and/or regulations.

- There is a sense that this period of program director instability has led to an
  increase in summary suspensions (4 in the last 2 years). Liberal use of this
  severe approach has significant implications for the viability of a midwife's
  practice and livelihood.
- Seven midwives reported that they had looked to DORA for guidance on a rule or regulation. Only 25% of those felt they had received clear guidance, 37% never received a response of any kind, and 68% did not receive a timely or accurate response.

### Written comments included several additional themes

- The process often makes midwives feel "guilty until proven innocent."
- When the volume of birth attended by DEMs competes with the local hospital, it is not uncommon for these hospitals/medical providers to place obstacles in the path of midwives providing good care. These barriers include clinical elements like refusing to accept transfer of care of clients exhibiting risk, refusing to collaborate in the provisional prenatal care like diagnostic ultrasounds, and also involve the complaint process. In one rural area of Colorado, a local hospital made multiple unfounded complaints over many years against a particular midwife who they viewed as "competition." The complaints only stopped when the hospital hired a new CEO.
- Midwives regularly encounter, deal with, and resolve complications during the course of labor, birth and early postpartum. There is a sense of vulnerability among Colorado midwives about the vagueness of Rule 1.5-H as it applies to transitory complications. This vulnerability stems from the general sense that medical providers who do not understand or support midwifery could easily use Rule 1.5H to generate a complaint about safe practice (eg., resolved complications during labor/birth or requiring a higher level of care and transfer to hospital). Rule 1.5H reads:

Once any of the conditions provided in paragraph G. are noted, the direct-entry midwife shall not resume care for the client until a qualified health care provider assesses the client and determines that the client is not exhibiting signs or symptoms of increased risk of medical, obstetrical, or neonatal complications, or problems during the completion of the pregnancy, labor, delivery, or the postpartum period, and is not exhibiting

signs and symptoms of increased risk that the infant may develop complications or problems during the first six weeks of life.



### **Volunteer Advisory Board for Direct-entry Midwifery**

DORA should be given the power to create a volunteer advisory board that does not cost the department any money, and consists of stakeholders including medical professionals, a majority of CPMs and a consumer.

- ≅ An advisory board would help decrease the confusion of the medical community about the midwifery standard of care, and would and increase collaboration (the board board process would necessarily involve MD-CPM-consumer collaboration)
- A board is usually the entity that determines the standard of care for a health profession, it is a model familiar to the medical community, and it is a trend in states that regulate direct entry midwives (New Mexico and Wyoming have midwifery boards for example).
- Midwifery is a profession that needs a board because of it's intersection with medicine, because it's historically been hotly contested, and because it involves sophisticated regulations.
- ≅ Consumers want a board because it's better governance, increases collaboration and transparency, increases consumer voice, and will result in better oversight.
- ≅ An advisory board would decrease costs to DORA incurred in pursuit of invalid complaints and to hire experts.¹

### Colorado Health Professions with and without boards:

Have a Board	Do not have a Board
Podiatrist	Acupuncturists
Chiropractor	Athletic Trainers
Dentists and Dental Hygienists	Massage Therapists
Doctors	Occupational Therapists
Nurses	Respiratory Therapists
Nurse Aides	Psychiatric Technicians
Nursing Home Administrators	Surgical Assistants and Technicians
Optometrists	
Physical Therapists	
Mental Health Professionals	

<sup>1</sup> The majority of complaints made to DORA against registered midwives are made by medical professionals and NOT consumers, and a majority of those complaints do not warrant discipline (data provided by DORA and on file with the Delivering Natural Care for Families coalition). The cost of the midwifery registry varies depending primarily on the cost of legal services which are employed during the disciplinary process. (see the 2010 DORA report, page 18).

## **COMMENTARY**

## **A Crusade Against Home Birth**

Melissa Cheyney, PhD, CPM, LDM, Paul Burcher, MD, PhD, and Saraswathi Vedam, MSN, FACNM, SciD (hc)

A recent study by Grunebaum et al examined the relationship between place of birth and adverse neonatal outcomes (Apgar of 0 at 5 minutes, and neonatal seizures or serious neurologic dysfunction—hereafter referred to as neonatal seizures) as reported in birth certificate data from 2007 to 2010 for term newborns (n = 13,891,274) (1). Outcomes were analyzed by four practitioner types: hospital physician, hospital midwife, freestanding birth center midwife, and home birth midwife. The authors claim that babies born at home and in freestanding birth centers were at a significantly higher risk of having a 5-minute Apgar score of 0 (RR = 10.55 and 3.56, respectively) and neonatal seizures or serious neurologic dysfunction (RR = 3.80 and 1.88). However, these findings must be interpreted with caution for several reasons.

Limitations of birth certificate data for epidemiologic analysis have been widely discussed in the literature, and include concerns about the completeness and accuracy of reporting of specific items on birth certificates, and the inability of birth certificates to provide longitudinal information (such as for planned home births that transfer to the hospital) or information on clinical intentions (2–4). The neonatal seizure variable, for example, is one of several medical variables unreliably reported on birth certificates (4–6). Two detailed studies comparing birth certificate data to medical records in New Jersey and Tennessee yielded sensitivity rates for neonatal seizures of 0.226 and 0.182, respectively (5,6). This means that approximately 80 percent of cases of neonatal seizures identified on medical records are not

reported on birth certificates. Data of this poor quality should not be used as the main outcome measure in any study.

Although reporting of data on 5-minute Apgar scores in broad categories (such as <7 or ≥7) is a bit better (7), no studies have examined the validity of reporting of 5-minute Apgar score = 0. However, there is substantial evidence that the reporting of this item on birth certificates is very problematic. Watterberg found that although large differences existed between home, birthing center, and hospital settings for reported Apgar scores of 0 and 10, these differences were greatly reduced for Apgar <4, and virtually eliminated for the combined category of Apgar 9 or 10 (8). There appear to be real differences between how physicians and home and birth center midwives perceive and report Apgar scores at the edges of the Apgar spectrum. Physicians are more likely to report fine gradations of either very low or very high Apgar scores, whereas home and birth center midwives are more likely to report Apgar scores of 0 or 10 more absolutely. Apgar score <4 is the more commonly used measure of early neonatal compromise, and has the added advantage of providing greater numbers of cases for analysis. The reported odds ratios for 5-minute Apgar score of 0 and neonatal seizures in the Grunebaum et al study are based on very small numbers of cases, and thus have limited generalizability or clinical relevance. It is also well-established that Apgar scores are poor predictors of neonatal outcomes (9), so even if these data could be improved, they

Melissa Cheyney, PhD, CPM, LDM, is an Associate Professor of medical anthropology in the Department of Anthropology at Oregon State University in Corvallis, Oregon, USA. She is also a certified professional midwife, the chair of the Board of Direct-Entry Midwifery for the State of Oregon, and the chair of the MANA Division of Research. Paul Burcher, MD, PhD is an Associate Professor of Bioethics and Obstetrics and Gynecology at Alden March Bioethics Institute at Albany Medical College, Albany, New York, USA. Saraswathi Vedam, RM, MSN, FACNM, SciD (h.c.), is an Associate Professor in the Faculty of Medicine at the University of British Columbia, Vancouver, BC, Canada, and principal investigator of the

Canadian Birth Place Study. She has been a clinician educator for 30 years in the United States and Canada.

Address correspondence to Melissa Cheyney, Department of Anthropology, Oregon State University, Waldo Hall 238, Corvallis, OR 97331, USA.

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would provide a poor proxy for adverse birth outcomes.

Also worrisome is the authors' assertion (based on the reported rate of Apgar = 0) that stillbirth is more common among home births. Stillbirths are not recorded on U.S. Certificates of Live Birth. The dataset that Grunebaum et al examined contains only records of infants born alive and does not include stillbirths. The CDC does produce a separate dataset on stillbirths (10), but the authors did not use this dataset in their analysis. When the 2007 to 2008 stillbirth data (the latest currently available) are analyzed using the same parameters as the Grunebaum study (singleton, term, birthweight 2,500+ grams), we find that the stillbirth rate for home births is 0.43 (stillbirths per 1,000 live births and stillbirths), and, for hospital births, 0.88 (10). These rates are based on relatively small numbers of cases (21 stillbirths for the home birth category) and are not meant to be definitive, but they do demonstrate that the results from the Appar score = 0 analysis do not coincide with results from stillbirth data.

We are concerned that Grunebaum et al may be unaware of the rigorous guidelines for the conduct of credible research on outcomes by planned place of birth, and of potential biases that may affect home birth research (11,12). They also appear to be unaware that international maternity research experts have applied these standards to the evaluation of research in this hotly contested area and concluded that the evidence on the safety of birth place in high resource countries is sufficient to recommend the integration of home birth services and home birth practitioners into regional health care systems (13). The Grunebaum et al article also conveniently ignores a large number of high-quality observational studies that use an intention-to-treat design to account for variance in maternal risk profiles and intrapartum transfers of care from home or birth center to the hospital (14-18), and find very low risks of poor neonatal outcomes for planned home births.

### Part of a Larger Trend

This article was not published in isolation, but is part of a larger effort by senior author Dr. Frank Chevernak from Cornell University, who has published at least six other articles critical of home birth in the past 2 years in major obstetrics, pediatrics, and ethics journals (19–24). A recent article published in *Pediatrics* is typical of Dr. Chevernak's work. In it, he claims to discuss the ethics of home birth, but his discussion runs counter to contemporary democratic principles of free choice and autonomy for the expectant mother, and to women's control over their own bodies. Demonstrating a remark-

able disregard for the importance of shared decision making and informed choice in maternity care, Chervenak and colleagues state that, "in a professional relationship, the physician's integrity justifiably limits the woman's rights by limiting the scope of clinically reasonable alternatives" (22, p35). They assert that the state of the science demands that pregnant women be counseled strongly against a planned home birth, that any clinician who attends a home birth should not be called a professional, and that he or she should be subject to regulatory sanctions. The difficult balance of maternal and fetal benefits and harms are also ignored in his commentaries. One wonders what motivates such a systematic crusade, but it appears to be neither science, nor a concern for women.

It should also be noted that Dr. Chevernak has gone on the record as vigorously opposing both the American College of Obstetrics and Gynecology's (24) and the American Academy of Pediatrics' (20) official policy statements on home birth, thus further marginalizing his opinions from the scientific mainstream. This type of unqualified and uncritical crusade against women who plan home births, the midwives who attend them, and the physicians who support and collaborate with them, puts mothers and babies at risk. Thus, we turn to a discussion of ethics.

### The Ethics of Home Birth

In a recent issue of the *Journal of Clinical Ethics*, two obstetricians, Drs. Howard Minkoff and Jeffrey Ecker, argued that in some circumstances physicians could ethically participate and collaborate with midwives who attend home births (25). Minkoff and Ecker provided an analysis of the available empirical evidence to argue that the safety of home birth is still not a settled issue, but that women can and do choose to deliver their babies at home, for reasons that are not irrational. We argue that physicians not only *can* collaborate with home birth midwives, but rather have a *duty* to seek out collaboration with the home birth community to further the safety of the home birth environment.

The authors of this commentary include an obstetrician (Burcher) and two midwives (Cheyney and Vedam) with 65 combined years of practice in home, birth center, and hospital settings, and thus we realize we are speaking heresy. However, the ethics of this position are actually straightforward. The most robust study establishing the safety of home birth is the observational study of over 500,000 births from The Netherlands by de Jonge et al. (14). de Jonge and colleagues' study found no differences in perinatal morbidity and mortality between planned hospital birth and planned home birth. This study suggests that home birth may

BIRTH 41:1 March 2014 3

be as safe as hospital birth given two important parameters: low-risk women and a *collaborative* medical environment.

Here is where obstetricians in the United States have failed both today and historically. During the 19th and early 20th centuries, physicians, for economic reasons and to increase the status of their profession, campaigned successfully to socially stigmatize midwifery, and, in many states, to make the ancient practice illegal (26). Yet, the evidence clearly shows that at the time this transition was occurring, physicians could not offer greater safety for women or their babies, even in the most medically complicated pregnancies (26). Rather than adopt a European model of physician–midwife cooperation, United States physicians chose to fight, and drive out their socially marginalized, and gender disadvantaged competitors, thus effectively eliminating a birth choice for many low-risk women.

Although we believe physicians may actually owe midwives the historical redress that renewed collaboration could provide, the more important argument is ahistorical. Obstetricians and midwives alike have a stated goal of improving maternal health, and a duty to collaborate is implied if we are truly open to helping all pregnant women—but real collaboration must flow both ways. There is much to do to improve the safety and humanism of hospital birth, and home birth midwives have a demonstrated expertise in how to safely reduce cesarean birth rates (27). In addition, home birth practitioners occasionally require expert consultation, and when that support is freely and respectfully given, home birth can be made safer and transfers of care less distressing. We suspect that it is women who will ultimately gain the most from renewed ties between the home and hospital birth communities. Still, the "birth is natural" and "birth is a medical event" paradigms have little overlap, and midwives and physicians will need to learn new language and new perspectives if they are going to be able to effectively communicate with one another (28). We need real dialogue rather than mutual recriminations. The history of the last 100 years will also need to be addressed.

### **Finding Common Ground**

As physicians and midwives, we are all committed to women's health, and safe childbirth is a crucial component of this. Given that women in the United States, despite significant cautionary recommendations by professional associations (29,30), are choosing home birth in increasing numbers (31), we must find ways to work together to improve the safety of home birth in this country. If 200 years of opposition have failed to extinguish home birth, then perhaps it is time for hospital

practitioners to embrace (metaphorically) their home birth colleagues, and to re-establish ties between our professions toward greater safety for all. The wholesale crusade against home birth championed by Chervenak and colleagues takes us in the wrong direction.

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4 BIRTH 41:1 March 2014

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### Washington State Example:

### MAWS Quality Management Program: Incident & Peer Reviews

Regular engagement in reflective self and peer evaluation is a public demonstration of the midwifery profession's commitment to providing safe, responsible, family-centered maternity care. The Quality Management Program (QMP) is state sanctioned and legally protected by WAC 246-834-360. It was established by MAWS in 2003 with the aim of furthering the autonomy of the midwifery profession and improving practice and outcomes, and is administered by the QMP committee. The protected space of Peer Review and Incident Review enables midwives to freely discuss clinical cases with their peers, safe from subpoena or legal inquiry.

The two branches of the QMP program provide mechanisms for quality improvement:

- a) Peer Review which each midwife must complete every two years with at least three other professional MAWS members (professional MAWS members must be WA State Licensed Midwives), and
- **b) Incident Review** which is organized by the QMP committee and is conducted by a specially convened panel whenever an outcome occurs which meets "Sentinel Event" criteria (see below).

The Quality Management Program (QMP) exists to:

- Help midwives improve their practice
- Help improve future outcomes
- Create a safe forum for discussion of clinical cases.
- Generate ideas directly from the membership for continuing education

# As of 2019, MAWS is pleased to announce two changes to Peer Review and Incident Review which will streamline both processes.

 Midwives need no longer get prior approval from the Peer Review Coordinator before conducting Peer Review. Instead, the Peer Review leader will verify participants' current MAWS membership status through Wild Apricot [online membership system] and attest to this in the Aggregate Data Form (see below). Midwives whose memberships have lapsed can renew through Wild Apricot

- [online membership system], effective immediately, and then proceed with Peer Review.
- 2. All QMP documents including both Peer Review and Incident Review should be faxed through the secure fax number: 1-206-691-8203. Documents received through USPS to the following address: MAWS attn QMP, 2120 N Oakes St, Tacoma, WA 98406 will still be received, but there may be delays in processing.

There is one more upcoming change to Peer Review. In accordance with the wishes of the majority of MAWS members, the QMP along with the MAWS Board of Directors is in the process of updating the legal document outlining Peer Review to allow for the inclusion of student-midwives. The membership will be notified as soon as the changes are finalized.

### **Responsibilities of MAWS Professional Members**

As MAWS members, we all have a shared responsibility to:

- Agree to participate as a panelist on an Incident Review Panel when called upon to do so
- Maintain strict confidentiality whenever participating in Peer Review or on an Incident Review Panel
- Turn in a <u>Self-Report</u> to the QMP within 14 days if any of the following "Sentinel Events" occur. If you are uncertain about whether a serious event meets criteria for an Incident Review, please submit one. You can view a <u>sample</u> <u>Self-Report form here.</u>

Sentinel Events:

- Maternal Mortality
- Perinatal Mortality
- Maternal shock or ICU admit
- Uterine rupture
- Maternal/neonatal seizure
- Uterine inversion
- NICU or Special care nursery admissions within 72 hours of birth (except for observation &/or congenital anomalies)

### Click here for Incident Review Instructions.

 Participate in a MAWS Peer Review: MAWS members are required to complete Peer Review of 5 charts every 2 years, in alignment with Washington State's new Peer Review requirement for licensure.

Click the button below for paperwork and instructions for filing Self-Reports and to organize a MAWS Peer Review.

### How to File a Complaint

MAWS is aware that some healthcare providers, consumers, or family members may have concerns about the care provided by a Licensed Midwife who is also a MAWS member. Any patient, client, family member, healthcare provider, allied birth professional, or facility may file a complaint against one of our midwives to the Quality Management Program (QMP). Click here to download the Complaint Form. Please be aware that a review of the event in question requires contacting the midwife and reviewing the chart notes, and therefore we cannot maintain client anonymity. The QMP upholds the highest standards of confidentiality and safety. Because of this very commitment to confidentiality, complainants will not receive any information about the results of such a review.

Once a complaint is received, the QMP Committee reviews the information and begins a review if the case meets criteria for investigation. Review panels are convened and the findings are reported back to the MAWS QMP committee. If any laws have been broken we are obligated to notify the Department of Health.

As a statewide midwifery organization, we appreciate your feedback in order to identify practice trends or any gaps in education. We organize annual <u>Continuing Education</u> <u>Conferences</u> for our members based partly on incident and peer review data. MAWS members are committed to the continuous improvement of maternity care services in Washington State.

### New Mexico Example:

## **16.11.3.13 ADVISORY BOARD:** The Division shall appoint a Licensed Midwifery Advisory Board

- A. The Boards activities will be:
- (1) Review complaints against Licensed Midwives as requested by the Division and make recommendations to the Division
- (2) Remain current in clinical practice and professional issues and advise the Division accordingly
  - (3) Recommend updates in the Standards and the Manual
  - (4) Conduct other relevant business as requested by the Division
- B. ADVISORY BOARD MEMBERSHIP: The Licensed Midwifery Advisory Board shall be composed of nine (9) members and one (1) ex-officio member; the membership shall be as follows:
- (1) Three (3) state licensed midwives, at least two of whom shall be actively practicing
  - (2) One state licensed certified nurse-midwife actively practicing midwifery
  - (3) Three (3) consumer members
  - (4) One (1) state licensed physician actively practicing obstetrics
  - (5) One (1) member from the Division; and
- (6) A representative of the Maternal and Child Health Bureau in the Public Health Division will be an ex-officio member of the Board
- C. ADVISORY BOARD PROCEDURES: Board members shall be appointed for staggered three year terms and not more than two consecutive terms, except for the member from the Division, who shall serve at the pleasure of the Division Director and who shall not be limited as to terms
- (1) Board members shall serve without compensation; they may submit for reimbursement for in-state travel and per diem for Division-called Board meetings according to Department of Finance and Administration Regulations
- (2) Any member failing to attend two (2) consecutive meetings without good cause and an excused absence prior to the meeting(s) shall be deemed to have resigned from the Board

[2-5-80...10-31-96; Recompiled 12/31/01].

### EVENTS THAT REQUIRE REPORTING TO THE DEPARTMENT OF HEALTH

Licensed midwives practicing in New Mexico are required to report and submit for review any cases that fall into the event categories listed within this section. The listed

events trigger a required case review process by the New Mexico Department of Health's Maternal Health Program. It is the midwife's responsibility to report and provide any required documentation for all reportable cases of any client for whom the midwife provided care for during the perinatal period, whether the client's care was transferred or not. The outcomes of case review are confidential and not available in the public domain unless an action is taken against a midwife's license, in which case only the action against the license is in the public domain.

### A. IMMEDIATE REPORTING REQUIRED FOR MORTALITY EVENTS

- 1. Maternal death within 42 days of delivery (during 6 week postpartum period)
- 2. Neonatal death within 28 days of birth
- 3. IUFD or stillborn at 20 weeks gestation or more, or, if gestational age is unknown, when the fetus weighs greater than or equal to 350 grams
- 4. Immediate reporting is defined as within 48 hours of the event per the LM Rule, 16.11.3.12(I) NMAC (see Appendix B), "The licensed midwife must report within 48 hours to the Division any neonatal or maternal mortality in patients for whom she has cared in the perinatal period"

### B. REPORTABLE EVENT REPORTING PROCESS

- 1. Per above requirements for reporting timeframe, LM should contact the DOH Maternal Health Program by email or phone call.
- 2. LMs will be asked to provide: a. Name and date of birth of the client, date of incident including delivery and/or death, and any hospitals or outside entities involved in the care of the client b. Any and all client records for the case
- 3. DOH will be responsible for requesting records from hospitals or other applicable entities (i.e. Office of Medical Investigator).
- 4. All cases will be reviewed by the Department. a. If no input from the LM Advisory Board is needed, the case will be closed, and the LM will be notified via a USPS-posted letter b. If further input is needed, the case will be brought to the LM Advisory Board to be heard by the Department and Board in a closed session format at a regularly scheduled or special meeting c. Disciplinary action and proceedings will be conducted according to the LM Rule, 16.11.3.9 NMAC "Disciplinary Action" (see Appendix B)

# Suggested Changes to Improve Operations and Enhance the Public Interest

# What's in this Section of Suggested Changes to Improve Operations and Enhance the Public Interest:

- Overview
- Fact sheet on changing the language from "registered" to "licensed"
- Fact sheet on the definition of "direct-entry midwife" and "practice of direct-entry midwifery"
- Fact sheet clarifying that well-person care is within the scope of practice
- Fact sheet on expanding the ability of DEMs to obtain and administer certain drugs
- Fact sheet on vaginal birth after previous cesarean (VBAC) in Colorado
- Fact sheet on elimination of the "authorities"
- Fact sheet on vaccination access
- Examples of unnecessary or vague rules to eliminate or address
- Fact sheet on eliminating or revising the data collection process
- Fact sheet on CPMs and emergency planning
- Example of training of medical personnel on best practices for transfers

# Suggested Changes to Improve Operations and Enhance the Public Interest

The document "Principles for Model U.S. Midwifery Legislation and Regulation" can act as an informative tool for DORA use in ensuring it provides successful DEM program operations and that supports public safety.

Many of the issues DEMs face, and the public face when interfacing with a DEM, are related to misunderstandings of the practice, over-regulation, inconsistent data collection, and lack of integration in the health care system.

We provide several recommendations that we believe will preserve the autonomous practice of DEMs while providing provisions for public safety:

- Changing the language from "registered" to "licensed"
- Changing the definition of "direct-entry midwife" and "practice of direct-entry midwifery" so CPMs can practice in birth centers
- Clarify that well-person care is within the CPM's scope of practice
- Expand the ability of DEMs to obtain and administer certain drugs
- Continuation of VBAC with some modifications
- Elimination of the "authorities"
- Allowing midwives vaccines access
- Eliminate or clarify unnecessary or vague rules
- Eliminate or revise the data collection process
- Include CPMs in emergency planning
- Training of medical personnel on best practices for transfers



### Change the language from "registered" to "licensed"

There is unnecessary confusion about whether Colorado direct-entry midwives are licensed or registered. This should be addressed. The program is clearly a licensing program, not merely a registry, based on DORA's "types of regulations" definitions. The Direct-Entry Sunset Review from 2000 made this recommendation. It is past time for this change to be made. It should be made now, in 2020.

### Types of Regulation

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

### **Licensure**

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection — only those individuals who are properly licensed may use a particular title(s) — and practice exclusivity — only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

### Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

### Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

### **Title Protection**

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

### Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.



### Certified Professional Midwives as Clinical Staff in Colorado Birth Centers

- CPMs, (also known as Direct-Entry Midwives in statute and regulations), are recognized by
  the state of Colorado as independent providers of care during pregnancy, labor, birth, and
  the postpartum period. Because the definition in statute says "at home" DORA has
  interpreted this to mean they cannot be clinical staff in birth centers. But during the Birth
  Center Rulemaking in 2017 CDPHE indicated they would be happy to add CPMs as clinical
  staff in Colorado Birth Centers as soon as this definition is clarified.
- The CPM is the *only* midwifery credential that requires knowledge about and experience in out-of-hospital settings, making them uniquely qualified to work in birth centers.<sup>1</sup>
- It is common for CPMs to work in birth centers and they do in many other states. One-half of all birth centers in the United States employ or are owned by CPMs.<sup>2</sup>
- The American Congress of Obstetricians and Gynecologists recognize CPMs as one of the types of providers who are qualified to attend at the "birth center" level of care.<sup>3</sup>
- Including CPMs in Colorado birth centers will expand access for consumers and support the already exceptional quality of care consumers find in birth centers.
  - Consumers and birth center owners alike want these midwives to be able to work in birth centers.
- The direct-entry midwifery definition was written before the CPM credential existed and before birth-centers took their contemporary form; the "home" limitation is an anachronism.
- In 2013, a prospective cohort study of women receiving care in 79 midwifery-led birth centers in 33 US states from 2007 to 2010 was conducted.<sup>4</sup>
  - The study demonstrated the safety of birth centers and the consistency of their outcomes over time.
  - Emergent transfer was required in less than 2% of the patients.
  - Only 6% ended up having to transfer for a c-section.
  - There were no maternal deaths.
  - The intrapartum fetal mortality rate was .47/1000, and the neonatal mortality rate was .40/1000 excluding anomalies.
    - This coincides with the outcomes in planned homebirths with CPMs.5

<sup>&</sup>lt;sup>1</sup> North American Registry of Midwives, What is a CPM, http://narm.org/2016.

<sup>&</sup>lt;sup>2</sup> National Association of Certified Professional Midwives, CPMs: Playing a Leading Role in the Development of Birth Centers in the U.S. <a href="https://nacpm.org/cpms-playing-a-leading-role-in-the-development-of-birth-centers-in-the-u-s/">https://nacpm.org/cpms-playing-a-leading-role-in-the-development-of-birth-centers-in-the-u-s/</a>

<sup>&</sup>lt;sup>3</sup> American Congress of Obstetricians and Gynecologists, Levels of Care, Obstetric Care Consensus, Number 2, Februaty 2015, http://www.acog.org/Resources-And-Publications/Obstetric-Care-Consensus-Series/Levels-of-Maternal-Care

 $<sup>^4</sup>$  J Midwifery Womens Health. 2013 Jan-Feb;58(1):3-14. Epub 2013 Jan 30. Outcomes of care in birth centers: demonstration of a durable model. Stapleton SR1, Osborne C, Illuzzi J.

<sup>&</sup>lt;sup>5</sup> J Midwifery Womens Health. 2014 Jan-Feb;59(1):17-27. Epub 2014 Jan 30. Outcomes of care for 16,924 planned home births in the United States: the Midwives Alliance of North America Statistics Project. 2004 to 2009. Chevney M.



### Well-woman and Well-person Care

- Well-Woman and Well-person care can be used to categorize a variety of screening and treatments that promote the overall well-being and reproductive health of women and female bodied people from menarche through menopause and all the years in between.
  - Care includes: General physicals and bloodwork, fertility counseling, hormone balancing, family planning, STD testing and counseling, Pap smears and cervical health, breast exams and breast health, nutritional, herbal, and lifestyle counseling, sex education, menopausal support, the treatment of many common gynecological disorders, and supportive care for issues that require referral to a physician.
- Historically, midwives have provided well-person care in addition to perinatal care, especially to marginalized or vulnerable communities
- It is within the scope of skills and knowledge of Certified Professional Midwives (CPMs) to address these aspects of well-person care.
  - We have been trained and practiced these skills for NARM certification.
  - Well woman/well person care is included in the CPM scope of practice in several states (ie. NM, CA, WA, OR)
  - A majority of these skills are identical with those used with pregnant and postpartum clients. Direct-entry midwives already practice these skills within the scope of their regulations and rules.
  - The International Confederation of Midwives has set a precedence for midwifery competencies worldwide. These competencies include comprehensive assessments of sexual and reproductive health needs as well as regular health screenings and laboratory testing done by midwives (ICM Essential Competencies Updated 2019).
  - These skills are also a part of MANA's (Midwifery Alliance of North America) core competencies which establish the essential knowledge, clinical skills and critical thinking necessary for entry-level practice for

direct-entry midwifery in the United States<sup>1</sup>. The following list of well-woman skills is included in the MANA Core Competencies

"VI. Women's Health Care and Family Planning: The midwife provides care, support and information to women regarding their reproductive health and determines the need for consultation or referral by using a foundation of knowledge and skills that include but are not limited to:

- A. reproductive health care across the lifespan;
- B. evaluation of the woman's well-being, including relevant health history;
- C. anatomy and physiology of the female reproductive system and breasts;
- D. family planning and methods of contraception;
- E. decision making regarding timing of pregnancies and resources for counseling and referral;
- F. preconception and interconceptual care;
- G. well-woman gynecology as authorized by jurisdictional regulations"
- Providing well-person care would greatly benefit the community by increasing access to holistic, preventative, affordable and personalized reproductive health-care for those communities who may not seek it otherwise.
- Providing well-care diversifies work midwives can offer, offering additional streams of financial revenue. Many direct-entry midwives, especially rural midwives, are living below the poverty line. Balancing high-intensity birth work with low intensity well-person care and diversifying how midwives can make an income makes the profession of midwifery more sustainable. This change will simultaneously improve health outcomes in the wider community.

### Recommendation:

- We recommend our law reflect our scope of practice as reflected in national and international core competencies.
- We also recommend that direct-entry midwives be regulated with the least restrictive form of regulation, not restricting scope of practice unnecessarily.

<sup>&</sup>lt;sup>1</sup> https://mana.org/pdfs/MANACoreCompetenciesColor.pdf

- Our laws should allow well-care to be provided beyond pregnancy, birth, and six weeks postpartum period. This care would include:
  - Assess risk factors and at-risk behaviour
  - Order, perform, and interpret laboratory and/ or imaging screening tests



### **Direct Entry Midwives and Authorities**

Direct Entry Midwives in Colorado are regulated and registered through DORA. They then can choose to add, for additional money, authorities for medications, IVs, and suturing.

This system is not serving the public nor the midwife community.

- Use of medications, IVs and suturing are already included in the scope of practice direct-entry midwives must have to be licensed in Colorado.
- These are skills consumers want and need their midwives to have in the limited circumstances direct-entry midwives would use them.
- The existing system is confusing to the consumer. Consumers may not know that a Registered Direct-Entry Midwife does not automatically have the ability to use IVs, medications or to do suturing.
- Consumers should have access to midwives who can practice the skills they have and to the full scope of their education and training.

The existing system adds confusing variations between direct-entry midwives based on authorities.

- Authorities are an arbitrary distinction that is not based on educational and training requirements (both of which include these authorities as necessary skills).
- The variability of total licensing fee costs may influence a midwife's decision about which authorities to renew, rather than the level of skill and training they have, or that their clients may need.
  - For instance, in 2019 the license renewal fee was \$304; in 2016 it was \$1216. The unpredictability and the wide range makes it impractical from a business-planning perspective.
  - Lower-volume providers may be less likely to pay for these authorities based on the cost, but this doesn't make sense from a health and welfare perspective.
- This regulation is inconsistent: midwives must pay to renew medication and IV authority but not suturing authority.

This type of regulation is out of step with other states and other professions.

- Other states include these in scope of practice within regulations without issuing separate licenses and creating different categories of midwives.
- This regulatory practice is not consistent with other professions, and is biased against midwives.

We recommend that IV's, medications and suturing be added to the scope of the registration and no longer regulate these practices separately through authorities.

- This recommendation would streamline the registration system.
- These skills are already within the clinical scope of practice for all midwives in Colorado.
- Inclusion in the regulatory scope of practice (without additional licensing) is consistent with other states' rules and regulations, including neighboring New Mexico and Wyoming.



### **VBAC<sup>1</sup>** and Direct-Entry Midwives

Direct-entry midwives have provided Colorado families with the option to plan for a vaginal birth after cesarean (VBAC) at home since 2007. This long-standing, safe, and accessible option has served those desiring a VBAC in Colorado. Midwives and consumers alike desire to continue this availability of VBAC birth with a direct-entry midwife.

### Maintaining an option for VBAC is important for several reasons:

- The Center for Improving Value in Health Care (CIVHC) found that surgical births have increased about 50% from 1990-2012<sup>2</sup>.
  - The increase in surgical births has not improved the health of pregnant people or babies
  - Reducing the number of surgical births in Colorado by 10% (1708 procedures) would lower health care spending by \$6.5 million/year.
- Reducing unnecessary repeat c-sections has multiple benefits:
  - Consumers who choose VBAC reap important health benefits for themselves and their babies including faster postpartum recovery, improved breastfeeding, and reduced risk of chronic diseases.
  - VBACs are cost effective for families and insurance plans.

### **VBAC** in Colorado:

- 4 CCR 739-1, Rule 12, was established in 2007 and is devoted to VBAC including: provisions for informed consent, weighing risks and benefits, emergency transport plans, verification of incision type, number of previous births, and situations requiring referral to a physician.
  - The rule has been reviewed in previous rulemakings, and stakeholders have had several opportunities to weigh in as part of the rulemaking process.
  - DORA has NOT recommended that the law be amended.
  - DORA, as the governing regulatory body, is satisfied with the existing rules.

<sup>&</sup>lt;sup>1</sup> VBAC stands for vaginal birth after cesarean, and is used as shorthand for referring to the unique risks during childbirth that folks who had a cesarean section for a previous birth may face. A cesarean section is a surgical birth. There are increased risks for subsequent deliveries in both vaginal birth and in repeat cesarean surgery.

<sup>&</sup>lt;sup>2</sup> Center for Improving Value in Health Care, "Opportunities to Bend the Cost Curve: Reduce Cesarean Delivery Rates in Colorado," July 2014.

- Midwives and consumers are also satisfied with the existing rule with one recommendation for improvement - See section below regarding Operative Reports.
- According to the National Institute of Health (NIH), VBAC success rate, for those who attempt a VBAC, has remained high at 75% since the late 1980's.

### Requested Rules Update:

- We suggest a provision be made for situations when previous records are unobtainable. The current regulations require obtaining records indicating the reason for the prior c-section and the operative report verifying a low transverse incision. If an operative report is unable to be obtained due to record retention limits, after every effort has been made, we request that a doctor's evaluation and agreement with trial of labor (TOLAC) may replace the operative records requirement.
  - Only 21/50 states in the USA require 10 years for record retention and 4 states have no requirement. Most require 5-7 years only. Colorado only requires hospitals to keep records for 10 years for adults and 10 years past the age of majority for children.
     <a href="https://www.healthit.gov/sites/default/files/appa7-1.pdf">https://www.healthit.gov/sites/default/files/appa7-1.pdf</a>
  - Operative reports from deliveries out-of-country may be impossible to obtain.
  - Reproductive years can span >30 years. It is not uncommon for people who had a traumatic birth to delay a second pregnancy.



### **Group B Strep Prophylaxis and Colorado Direct Entry Midwives**

Direct Entry Midwives have been working since registration in 1993 with clients who are Group B Strep positive during a pregnancy. Understanding the implications of Group B Strep is not new to direct entry midwives. They have been providing information to clients around this topic through informed choice. Midwives currently follow DORA's regulations which follow a risked-based assessment for Group B Strep and transfer to hospitals in labor if criteria is met for both pregnant clients and their newborns.

Approximately 10-30% of those pregnant are colonized with Group B Strep bacteria in their vagina and bowel. GBS is considered normal flora and most often is asymptomatic and causes no problems in adults (CDC 2010). It may be intermittent, transitory or persistent colonization. During birth, babies can be exposed to GBS as they travel through the birth canal. While most of the time the baby is not affected, in rare cases it can cause a newborn to become ill with infections such as sepsis, meningitis, pneumonia or rarely cause death (CDC, 2010). About 50% of babies who are exposed to GBS will become colonized by GBS. About 1% of the GBS-colonized newborns will get infected and become ill (CDC, 2010). According to the Meningitis Foundation of Canada, "Generally, mothers are immune to the types of GBS they carry and pass the antibodies to the baby during the last eight weeks of pregnancy. Consequently less than one percent of full term babies who do carry GBS develop severe infection." (Meningitis Foundation of Canada,

https://www.meningitis.ca/en/GroupBStrepDisease ) There are 2 types of GBS disease in the newborn. More than half of the cases of newborn infection occur in the first week of life ("early onset disease"), most starting within a few hours of birth and up to 7 days after birth. It is most likely to manifest at birth with the majority of infants symptomatic by 12-48 hours after birth (ACOG 2020). These babies present with a fast heart rate or fast breathing, lethargy or respiratory distress including high temperature or temperature instability, low oxygen saturations or poor nursing. The other type of GBS disease, and less common, occurs one week to 2-3 months after birth ("late-onset disease"). Only about half of late-onset GBS disease among newborns is from a mother, but with GBS colonization from other sources being hospital or community acquired. Intrapartum

antibiotic prophylaxis is not preventative of late-onset GBS disease (CDC, 2010). GBS infection is associated with stillbirth.

In the US, the standard of care during pregnancy is to be screened for Group B Strep at 36-37/6 weeks and to be treated with Group B Strep Prophylaxis. Administration of intrapartum antibiotic before delivery interrupts the transmission of Group B Strep colonization from the pregnant person to the fetus (AAP 2019). The preferred protocol currently for giving prophylactic antibiotics is to give Penicillin G by IV every 4 hours until delivery, unless the client is allergic to penicillin or a GBS culture reveals resistance and suggests an alternate antibiotic therapy (ACOG 2020). Those in labor who present at >37 weeks' gestation with unknown status should be administered GBS intrapartum antibiotic prophylaxis if risk factors develop (duration of rupture of membranes ≥18 hours or intrapartum temperature of ≥100.4°F [38°C]). Additionally, those in labor with known GBS colonization in a prior pregnancy may be offered intrapartum antibiotic prophylaxis if status is unknown at >37 weeks' gestation, given that such women have increased risk of colonization in the current pregnancy. Implementation of national guidelines for intrapartum antibiotic prophylaxis has resulted in a reduction in the incidence of GBS early onset disease of more than 80% from 1.8/1000 in 1990's to 0.23/1000 live births in 2015 (AAP recommendations 2019).

Testing positive in pregnancy for Group B Strep indicates the client has an additional risk factor, not a present infection, unless they have a urinary tract infection caused by Group B Strep. Risk factors for Group B Strep infection already require transport in the regulations for Direct Entry Midwives: Prolonged rupture of membranes, a fever of 100.4 degrees, or preterm labor. Additionally, if a person has a urinary tract infection, the direct entry midwife is required to consult and treat. The only risk factor not currently covered by our guidelines is a client who had a previously infected baby with Group B Strep being at greater risk of infection.

In the current Colorado Rules and regulations, there is no contraindication for working with a Group B Strep positive client as it is indirect risk. Rule 1:5:D Laboratory studies that should be obtained during pregnancy include: 4 ,"A culture for Group B Streptococci at 35 to 37 weeks, and, if the culture is positive, inform the client about antibiotic treatment options and recommend an appropriate health care provider." We propose this rule should be changed to: "culture for Group B Streptococci at 36/0-37/6" in keeping with the new ACOG guidelines (ACOG 2020). Rule 1:5 G. Rule 15. States, "Rupture of membranes for: a. Longer than 12 hours without labor for Group B Streptococci positive clients and unknown Group B Streptococci status; or b. Longer than 18 hours without labor for Group B Streptococci negative clients." We propose his

rule should be amended to: "a. Longer than 18 hours without labor for Group B Streptococci positive clients or clients with unknown status; or b. Longer than 24 hours without labor for Group B Streptococci negative clients" in order to keep with ACOG standards (ACOG 2020).

Those who are receiving care from a direct entry midwife are identified as the lowest risk population and are screened at every prenatal visit for additional risks. These clients should be able to choose standard protocols for Group B Strep as well as choose to decline this standard of care through an informed choice shared decision making model. Our current regulations do not require automatic transfer for Group B Strep positive status. However, they do not permit administration of Group B Strep prophylaxis, causing many to be faced with a difficult choice if they feel strongly about obtaining prophylactic antibiotic treatment for GBS. Also important to discuss with clients is the impact of antibiotic overuse; antibiotic prophylaxis in labor has been associated with changes in the gut microbiome of the baby and subsequent allergies, asthma and obesity (ACOG 2020). In light of the principles of autonomy, it is important that clients have the option to decline prophylactic treatment for themselves and their child.

18 of the 30 states that license direct entry midwives allow for Group B Strep Prophylaxis to be administered in labor and at home with a midwife for those who are Group B strep positive. For safety precautions they permit carrying Epinephrine and Benadryl.

Free standing birth centers in Colorado have been safely administering Group B Strep prophylaxis to a similar scope of low risk clients. They do not risk out for GBS positive patients nor those with a urinary tract infection with GBS.

Administering antibiotics in labor is a straightforward procedure. This procedure involves IV placement and injection skills, both skills that midwives are already adept at completing. Direct Entry Midwives have been safely administering IV's at home since the ruling permitting use in 2010. The midwife would simply place an IV with a luer lock in place, allowing for freedom of movement for the client and administer the antibiotics intermittently per guidelines during which they would reattach the tubing and small bag of antibiotics during treatment times. A vial of powdered 5 Million CFU of Penicillin G is reconstituted with a small amount of injected sterile saline and then drawn up and injected into an IV bag of 250 ml of normal saline, given wide open over 20-30 mins and then 2.5 million units of Penicillin G are given in similar fashion every 4 hours until delivery. Side effects are monitored, including blood pressure and pulse, respiration

rates, reactions to the skin and signs of shock to watch allergic reactions. Neither antepartum nor intrapartum oral or intramuscular regimens have been shown to be comparably effective in reducing Group B Strep early onset disease (ACOG 2020). The alternative treatment of chlorhexidine vaginal washes during labor have not decreased rates of neonatal sepsis according to meta-analyses of randomized controlled trials (ACOG 2020). Chlorhexidine vaginal washes have been used by direct entry midwives in the past with clients who were GBS positive as well as no treatment.

There are risks to administering antibiotics. Adverse reactions range in severity. If minor, it may present immediately or in a delayed response. It may be minor such as solely a rash or solely itching without other systemic symptoms. If severe, adverse reactions are noted immediately including itching with a rash, immediate hives or flushing, hypotension, respiratory distress or anaphylaxis. In treatment for severe reactions an epinephrine is administered, which is a simple injection. If a client must receive epinephrine, the client is treated for shock just as would be treated for postpartum hemorrhage and EMS is activated and client transported immediately. It is recommended for a pregnant person who is unsure of their allergy, but with a vague history of allergy to penicillin, be tested for Penicillin allergy prenatally (ACOG 2020). Overall, type I IgE-mediated allergic reactions (severe) occur in an estimated 0.7–4% of all treatment courses with penicillin, with the risk of anaphylaxis estimated at approximately 4/10,000–4/100,000 recipients (ACOG 2020). Therefore, the rate of antibiotic allergic reaction is rare and the potential benefits higher for those desiring the standard of care with Group B Strep antibiotic prophylactic treatment in labor.

It is recommended the State include in the Direct Entry Midwife list of prescriptive authority antibiotics for the treatment of Group B Strep prophylaxis per CDC guidelines. These guidelines are ever changing. Currently they recommend: Penicillin G, and main alternative for Penicillin allergy including: Ampicillin, Cefazolin, Clindamycin and Vancomycin. Cefazolin is recommended for those who report a penicillin allergy that indicates a low risk of anaphylaxis. For those with a high risk of anaphylaxis, Clindamycin or Vancomycin should be used if the GBS strain is susceptible. Epinephrine and Diphenhydramine should be included for safety measures against allergic reaction. Please see further description of each as follows and note these may change as the CDC sees fit to recommend.

Therefore we recommend a broad approach in rules and regulations to include a phrase noting "administration per CDC guidelines of Group B strep prophylaxis" rather listing specific drugs.

- Penicillin G Group B Strep Prophylaxis 5 million units initial dose, then 2.5-3 million units q 4 hours until birth IV in ≥ 100 mL Lactated ringer or Normal saline.
   Prophylactic treatment through the end of delivery.
- Ampicillin Sodium Group B Strep Prophylaxis only 2g initial dose, then 1g q 4
  hours until birth IV in ≥ 100 mL Normal saline Prophylactic treatment through end
  of delivery.
- Cefazolin Sodium Group B Strep Prophylaxis only 2g initial dose, then 1g q 8
  hours until birth IV in ≥ 100 mL Lactated Ringer or Normal Saline. Prophylactic
  treatment through the end of delivery. This antibiotic would be used if client has
  low risk allergy history to penicillin.
- Clindamycin Phosphate Group B Strep Prophylaxis only, if highly allergic to penicillin and strain is sensitive to clindamycin and erythromycin 900 mg q 8 hours IV in ≥ 100 mL lactated ringer or normal saline. Prophylactic treatment through the end of delivery.
- Vancomycin should be reserved for clients who are severely penicillin allergic with a strain that is not susceptible to Clindamycin through susceptibility testing. It should be based on weight and base renal function. With 20mg/kg given every 8 hours until delivery with a max dosage of 2g per single dose. Minimum infusion time of one hour or 500mg of normal saline over 30 mins with >1g.
- Epinephrine HCI 1:1000. Maternal treatment or post-exposure prevention of severe allergic reactions 0.3 mL premetered dose max of 3 doses as directed, max of 3 doses q 5 minutes or until EMS arrives; Administer first dose then immediately request EMS.
- Diphenhydramine treatment for post-exposure prevention of allergic reactions 25 mg- 50 mg orally as needed for rash or itching without systemic symptoms. This should not be used in place of Epinephrine.

### References:

ACOG Committee Opinion 797, February 2020:

https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co797.pdf?dmc=1&ts=20200309T2016276210

AAP. "Management of Infants at Risk for Group B Steptococcal Disease, Aug. 2019:

https://pediatrics.aappublications.org/content/144/2/e20191881

CDC 2010 Guidelines: <a href="https://www.cdc.gov/groupbstrep/guidelines/index.html">https://www.cdc.gov/groupbstrep/guidelines/index.html</a> Meningitis Foundation: <a href="https://www.meningitis.ca/en/GroupBStrepDisease">https://www.meningitis.ca/en/GroupBStrepDisease</a>



### **Vaccinations and Direct Entry Midwives**

Direct Entry Midwives provide direct care to clients, often to clients who might receive no care otherwise. Pregnancy is one of the few times people receive consistent health care. As a front-line health worker, Direct Entry Midwives (DEMs) should be able to provide essential public health measures such as vaccinations when requested by families. Allowing DEMs to offer vaccines reduces costs and barriers for people choosing out of hospital birth or out of hospital pre- and postnatal care. These injections are simple to perform. Ability to provide immunizations is considered a core competency by the International Confederation of Midwives. These medications are considered a standard of care and should be available to clients from their midwife.

New Mexico and Washington state both enable their DEMs to offer vaccinations including:

- Hepatitis B to the newborn at 24 hours
- Tdap
- Influenza

### Example of New Mexico Guidelines<sup>2</sup>:

- 1. Inactive Influenza Vaccine Prevent flu, make flu less severe if client is symptomatic or tests positive to flu, and to keep from spreading flu to family/others 0.5 mL IM Given as single dose to adult during influenza season (usually OctoberMay); can be given every season; can be given in any trimester.
- 2. Diphtheria, Tetanus, and Pertussis Vaccine (Tdap) Administered to pregnant woman to protect her newborn baby against pertussis 0.5 mL IM Pregnant

<sup>&</sup>lt;sup>1</sup> ICM Core Competencies, 2.b "Determine Health Status of Women," includes, "Assess status of immunizations and update as indicated," and 4.b "Provide Care to Healthy Newborn Infant," includes "Administer immunizations, carry out screening tests as indicated." Available at: <a href="https://www.internationalmidwives.org/assets/files/general-files/2018/10/icm-competencies---english-document\_final\_oct-2018.pdf">https://www.internationalmidwives.org/assets/files/general-files/2018/10/icm-competencies---english-document\_final\_oct-2018.pdf</a>

<sup>&</sup>lt;sup>2</sup> https://nmhealth.org/publication/view/guide/1725/

- women should receive a single dose of Tdap during every pregnancy, preferably at 27 through 36 weeks gestation. Tdap is recommended in the immediate postpartum period for new mothers who have not received Tdap during the pregnancy or whose vaccination status is unknown.
- 3. Hepatitis B Immune Globulin (HBIG) Postexposure prophylaxis for infants exposed to hepatitis B (i.e. mother is hepatitis B positive unknown to her since initial testing at first visit) 0.5 ml IM Should be administered to infant after physiologic stabilization of the infant and preferably within 12 hours of birth.
- 4. Hepatitis B Vaccine Prevention of hepatitis B infection in all infants; postexposure prophylaxis for infants exposed to hepatitis B (i.e. mother is hepatitis B positive) 0.5 ml of vaccine (10 ug) each IM The 1st dose should be given to infant within 1 day of birth and may be given concurrently with HBIG but at a separate site; the 2nd and 3rd doses should be given at 1 month and 6 months, respectively, after the 1st dose; these can be administered by pediatric care provider



#### Colorado's Vague or Unnecessary Rules

DORA should provide guidance that requires all rules coincide with nationally recognized scope of practice terms and definitions.

Below are examples of vague rules or rules that do not align with nationally recognized scope of practice:

- Colorado's rules for the spontaneous rupture of membranes in regards to labor management is 12 hours for GBS+ clients and 18 hours for GBS- clients while the midwifery consensus is greater than 24 hours without labor and 18 hours for GBS positive without labor. 4 CCR 739-1(5)(G)(15).
- 2. Our rule 4 CCR 739-1 (6) (B) represents an overreach of regulations by restricting the midwife to fully assess, if necessary, a client's status in order to offer informed decision making.
- 3. There is a lack of clarity about idiopathic thrombocytopenia of pregnancy (ITP, also called gestational thrombocytopenia) and no guidance in rules. In Colorado, labs define "low platelets" as 140 or 150 (depending on the lab). There is no medical treatment for this, but possible further testing. In Colorado, community birth centers (and medical providers such as MFM and obstetricians) refer or provide higher level of care if their 36 week ITP levels are below 100. Rule 4 CCR 739-1(5)(G)(9) refers to "laboratory results indicating need for medical treatment," a standard that is unclear. In Colorado, the community birth standard is that if ITP values are at or above 100, clients do not need to seek a higher level of care. "Gestational thrombocytopenia (GT), also called incidental thrombocytopenia of pregnancy, is a benign, self-limited condition that requires no additional evaluation or treatment mild thrombocytopenia (In 99 percent of women, the platelet count is ≥100,000 /microL.) GT requires no treatment and no change of normal prenatal care and management of delivery. No diagnostic testing is necessary because a platelet count >100,000/microL causes no risk for the mother or the fetus"Uptodate.com 2020.

- 4. Colorado's rules for diagnosing and managing anemia require a midwife to transfer care when there are iron levels not responding to over the counter iron therapy as measured by Hemoglobin below 11 grams or Hematocrit below 34% at term.C.R.S. 12-225-106 and 25-4-201. In Colorado, community midwives and medical professionals agree that a higher level of care is only necessary if Hemoglobin is below 10 g/dL or the Hematocrit is below 30% at term. Uptodate.com states that normal Hemoglobin and Hematocrit values during the third trimester are 9.5g/dL to 15.0 g/dL and 28.0-40.0%, respectively.
- 5. Colorado's rules restrict midwives from caring for someone with a positive antibody screen. C.R.S. 12-225-106 and 12-225-108(1)(a). In fact, it is Colorado community birth (in addition to the medical community) consensus that while a midwife should consult with a qualified licensed health care provider in the case of a positive antibody screen, they can continue care if the lab cannot identify a antibody type nor titre a level of an antibody. This rule should say "Identified antibody detected with a positive titre" rather than positive antibody screen.
- 6. Preterm Labor: Rule 1.4 A. 12. Preterm labor needs to be separated from neonatal death and a stillbirth associated with maternal health conditions as they are very different in assessment of risk. For example: history of a late preterm labor due to a car accident in a prior pregnancy is unlikely to cause a repeat of preterm labor. Late preterm history of delivery vs early preterm do not share the same risks. Restrictions for premature birth should have it's own section and be "delivery of an early preterm infant, <34 weeks, unless the client is under physician care and monitoring of the pregnancy until 37 weeks."
- 7. Note the following clause in Colorado's rule (1.5 H):

Once any of the conditions provided in paragraph G. are noted, the direct-entry midwife shall not resume care for the client until a qualified health care provider assesses the client and determines that the client is not exhibiting signs or symptoms of increased risk of medical, obstetrical, or neonatal complications, or problems during the completion of the pregnancy, labor, delivery, or the postpartum period, and is not exhibiting signs and symptoms of increased risk

that the infant may develop complications or problems during the first six weeks of life.

This rule is problematic as there are inherent risks with birth, and the midwifery model approaches these risks differently than the medical model of care. There is a sense of vulnerability among Colorado midwives about the vagueness of Rule 1.5-H as it applies to transitory or resolved complications. Currently medical providers (or others) who may not understand or support midwifery could easily use Rule 1.5H to generate a complaint about safe practice (eg., resolved complications during labor/birth or requiring a higher level of care and transfer to hospital). In fact, client outcomes and satisfaction increase when a community midwife continues to provide supportive care after referring for a higher level of care. This type of integration improves the continuity of care for clients and outcomes overall. Rule 1.5-H, as written, undermines integration, collaboration, and continuity of care.



#### Colorado's data collection program for direct-entry midwives

The Centers for Disease Control and Prevention defines perinatal mortality as a death occurring after 28 weeks of gestation through the first week of life.

- The major causes of perinatal deaths are congenital anomalies, low birth weight, maternal complications, complications of the placenta, cord and membranes, and infections.
- Rates of perinatal mortality in the United States have remained consistent at 6 deaths per 1000 births since 2011. While the overall perinatal mortality rates have remained steady, there are significant variations in these rates based on both maternal demographics and geographic location.
- The lowest perinatal mortality rate occurs among Asian and white women at 5 deaths per 1000, with the highest rate occurring among black women at 10.5 deaths per 1000.
- Rates are also higher for women younger than 20 or over the age of 35. Wyoming has the lowest overall perinatal mortality rate at 4.3 deaths per 1000 births, while Alabama has the highest rate at 8.3 deaths per 1000 births.
- The latest report shows Colorado's perinatal mortality rate at 5.5 deaths per 1000 births.

It is difficult to compare statistics from the Colorado Direct-Entry Midwives program to these state and national rates due to the way the program collects this data.

- Information collected does not conform to the CDC definition of perinatal mortality. Colorado data includes deaths occurring both earlier in pregnancy and later than one week after the birth.
- The relatively small number of births attended by registered midwives results in significant year to year variation in the rate of occurrence of rare events such as perinatal deaths.
- Over the last five years, the perinatal death rate based on program data is 9 deaths per 1000 births including births at home and those occurring in the hospital after transfer of care either before or during labor.

 However, it is nearly impossible to conclude if this number reflects an actual higher rate of perinatal loss under midwifery care or is a result of the variation in the data collected and the lack of verification of reported data.

We recommend that the Direct-Entry Midwives Program begin collecting perinatal mortality data consistent with the CDC definition, limited to losses after 28 weeks gestation during pregnancy and before 7 days following the birth.

- In order to have statistical data that would be meaningful to inform efforts to reduce perinatal losses, all data needs to be verified for accuracy and the causes of perinatal deaths must be included in these statistics.
- It is clear that such efforts are well beyond the capacity of the current 0.15 FTE position administering this program at DORA. Alternatively, the program could rely on data collected by the Department of Vital Statistics if the intended place of birth at onset of labor is added to birth records and linked to neonatal death records.
- While any avoidable loss is of grave concern, we would like to assess better data on perinatal losses to determine if and what efforts could prevent avoidable deaths.
- It is important to keep in perspective that according to Colorado Vital Statistics data, Direct-Entry Midwives were the primary provider involved or transferred care in 1.6% of perinatal deaths in Colorado in 2014-2018 attending 1.3% of Colorado birth (Based on RM perinatal loss data from DORA, and total Colorado infant mortality from perinatal causes data from Vital Statistics).
- There are some nationally available, reliable, well-validated data collection systems available that could be used to collect more accurate data.



#### **Community Birth and Pandemic Planning**

- Community Birth is the term for planned home and birth center births. During a pandemic out-of-hospital birth is essential to minimizing transmission, maintaining health, and efficiently utilizing medical resources.
- Even in normal times, home and hospital birth is a safe option for most pregnant people. 87% of service need can be delivered by midwives, when educated to international standards.1
  - o During a pandemic, when hospitals are overwhelmed with sick patients, healthy pregnant people may be all the more inclined to give birth out-of-
  - o During the SARS outbreak in 2003, parents made last-minute changes from a planned hospital birth to a planned home-birth to avoid the risk of hospitalbased SARS exposure.<sup>2</sup>
- Midwives are the most common community birth providers (though sometimes physicians also work in community birth). In the United States there are three midwifery credentials that all meet the educational requirements of the International Confederation of Midwives.
  - Those credentials are the Certified Nurse Midwife (CNM), the Certified Midwife (CM) and the Certified Professional Midwife (CPM). The CNM and the CM require graduate level education, the CPM is entry-level.
  - o The CPM is the *only* midwifery credential that requires knowledge about and experience in out-of-hospital settings, making them uniquely qualified Community Birth providers.<sup>3</sup>
- Despite their being the primary care providers for healthy birth all over the world, midwives in the United States remain not-well-integrated into the maternity care system. This impacts outcomes in normal times, and will expose the problems with lack of integration during a pandemic.4
  - o In a pandemic, this lack of integration means that low-risk, healthy pregnant people who do not need to birth in the hospital will have nowhere else to go and medical providers who could otherwise treat sick people will be needed to care for pregnant people.

<sup>&</sup>lt;sup>1</sup> UNFPA ICM, WHO: "The state of the world's midwifery 2014: A universal pathway. A women's right to health". 2014, New York: United Nations Population Fund.

<sup>&</sup>lt;sup>2</sup> Elena Cherney and Mark Heinzl, New disease curbs visits to hospitals in Toronto - Expectant mothers turning to midwifery for delivery, Wall Street Journal, April 3 2003. https://www.wsj.com/articles/SB104932780716267100

<sup>&</sup>lt;sup>3</sup> North American Registry of Midwives, What is a CPM, <a href="http://narm.org/">http://narm.org/</a> 2016.

<sup>&</sup>lt;sup>4</sup> National Academies of Science, Engineering, and Medicine. 2020 Birth Settings in America: Improving Outcomes, Quality, Access, and Choice. Washington, DC: The National Academies Press. https://doi.org/10.17226/25636. See also S. Vedam et al. Mapping integration of midwives across the United States: Impact on access, equity, and outcomes. PLoS ONE 13(2): e0192523. (2018) https://doi.org/10.1371/journal.pone.0192523



- Colorado's rate of community birth is 2.61% and this could potentially double despite workforce limits to accommodate the need during a pandemic, to 5.22% or an additional 1700 births out-of-hospital.
  - Colorado has licensed over 700 CNMs and 235 CPMs (but not all are currently active).
  - There are 7 birth centers currently operating in Colorado (though there are also 2 recently closed birth centers and others that could be opened).
- Barriers to Community Birth should be eliminated during a pandemic to increase Community Birth and relieve pressure on hospitals. In Colorado this may include:
  - Expediting, fast-tracking, renewing or providing provisional licenses for birth centers.
  - Waiving facility requirements for birth centers (like doorway widths, for example).
  - Allowing CPMs to staff birth centers (this was already on track to be addressed in 2021 legislation and has been discussed in birth center rulemakings).
  - o Removing barriers to reimbursement for CPMs by Medicaid and CHIP.<sup>5</sup>
  - Allowing previously licensed providers to become active whether through expedited renewals or waivers of some sort.
  - The interface between hospitals and community birth professionals when a laboring patient is in need of a higher level of care, could be improved through the modification of certain transfer requirements, and requiring certain transfer protocol from medical facilities.<sup>6</sup>
- Midwives who specialize in Community Birth should be involved in emergency planning for maternity care during a pandemic.
  - Community birth midwives have expertise in what is needed to make out-of-hospital birth successful and can provide essential insight and training to other providers and planners.

<sup>&</sup>lt;sup>5</sup> Until recently, Colorado CPMs were eligible for CHIP reimbursement and while CPMs are reimbursable by Medicaid in general, Colorado has not yet added them to the State Plan. See 42 USC sec 1396(a)(6) and 42 CFR 440.60.

<sup>&</sup>lt;sup>6</sup> See, The Birth Place Lab, Best Practice Guidelines for Interprofessional Collaboration: Community Midwives and Specialist Providers. Available at: <a href="https://www.birthplacelab.org/best-practice-guidelines-for-transfer-and-collaboration">https://www.birthplacelab.org/best-practice-guidelines-for-transfer-and-collaboration</a> and The Birth Place Lab, Best Practice Guidelines: Transfer from Planned Home Birth to Hospital. Available at: <a href="https://www.birthplacelab.org/best-practice-guidelines-for-transfer-and-collaboration/">https://www.birthplacelab.org/best-practice-guidelines-for-transfer-and-collaboration/</a>

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**Best Practices for Community Birth Transfers** 

# Transfer Tools for Midwives, EMS, and Hospital Providers

Transfers from home births and birth centers to hospitals happen regularly and are an important part of safe care for birthing people and babies. We know that approximately 10-20% of planned community births (homebirth and birth center births) transfer to the hospital when pain medication or labor augmentation is needed, or when complications arise.

Yet midwives, emergency services personnel, nurses, and receiving hospital providers don't receive training on how to work together as a care team. We often find ourselves trying to provide care in stressful emergency situations without the information or skills we need to do so effectively.

We're ready to change that and work together to improve care! This one-of-a-kind course:

- is a curriculum designed by and for midwives, emergency services personnel, nurses, and receiving hospital providers
- shares new collaborative methods for improving home birth and birth center to hospital transfers
- teaches communication skills critical to keep calm and clear during stressful situations
- includes clinical best practices
- models scenarios demonstrating these best practices for communication and care
- teaches creative tools for bridging relationships with other provider types
- includes everything you need to know about the other providers involved to support optimal care and smooth transfer across all settings of a community birth transfer

This course will help all provider types work together smoothly so we can improve outcomes and the experience of care for mothers and babies.

This course has been approved by MEAC for 4 hours of continuing education. The approval number for this course is M1920-17-1001DE, and this approval is current through October 1st, 2021.

This course has been approved by the NARM Bridge Program for Category III.

This course has been approved by ACNM for 4 hours of continuing education. The approval number for this course is 2019/085, and this approval is current through October 16th, 2021.

Other CE applications are in process.

This course is free for all volunteer EMS personnel! For a free enrollment, please email <a href="mailto:jesica@HiveCE.com">jesica@HiveCE.com</a> with: your name, your email, and the name of the organization you volunteer with (Example: Campbell County Volunteer Fire Department).

## **Course curriculum**

#### 01 1: Introduction

		1.1 111110			
	<b>1</b>	1.2 The Problem			
	Tx Tx	Readings			
	<b>□</b> 4	1.3 What is community birth?			
	<u>Tx</u>	Learn More About Community Birth			
02	2: Care Providers Involved In Community Birth				
03	3. Solutions for Smooth Transfer				
04	4. Best Practices for Communication During Community Birt				
	Transfers				
05	5. C	5. Clinical Best Practices During Community Birth Transfers			
06	6. C	hallenging Situations			
07	7. C	onclusion and Further Resources			
08	8· Þ	Post-Test and CE Certificates			
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#### **Instructor Bio:**

Silke Akerson

### Silke Akerson

Silke Akerson, CPM, LDM is a midwife and herbalist in Portland, Oregon. She has been i midwifery leadership and policy since 2010, and is currently the executive director of th collaboratively with emergency services personnel and receiving hospital providers on t passionate about continuing education for midwives and allied providers as ways of en continued growth for ourselves as practitioners.

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- (III) Efficiency and Effectiveness Analysis
- (IV) Economics and Competition Analysis
- (V) Complaints, Investigations, Discipline- Analysis
- (VI) Suggested Changes to Improve Operations and Enhance the Public Interest

March 2020

