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Optimal Outcomes of Labor and Birth in Water Compared to Standard Maternity Care

by

Jenna Cleave Shaw-Battista

### DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

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Nursing

in the

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of the

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by

Jenna Cleave Shaw-Battista

In memory of my grandmothers, Teodolinda Frate Apruzzese Battista, Adelina Macrelli Michele, Mary Rose Michele Battista, Kate Cleave Rowe, Helen Cleave Anderson Ward, and Joan Ward Shaw, RN.

Dedicated to my precious waterbaby, Sarah Cleave Novick, and my beloved husband, Jeffrey Benjamin Novick, for everything.

With gratitude to Sandra Cleave Shaw and Wendy Nyquist,

inspiring role models, beloved grandmothers and terrific cheerleaders.

I am also so grateful for all of my family and friends, unique and passionate individuals who lovingly use their many talents in the service of humanity, the earth and the divine.

Imagine you are a Midwife, assisting at someone else's birth.

Do good without show or fuss.

Facilitate what is happening, rather than what you think ought to be happening. If you must take the lead, lead so that the Mother is helped, yet still free and in charge. When the baby is born, the Mother will rightly say, "We did it ourselves."

Tau Te Ching, 2<sup>nd</sup> century BC, adapted by John Heider, 1985

#### ABSTRACT

Optimal Outcomes of Labor and Birth in Water Compared to Standard Maternity Care

BACKGROUND: Eleven randomized controlled trials have demonstrated that warm water immersion during labor (WL) safely and effectively reduces obstetric pain. Data are less conclusive regarding underwater birth (WB), although excellent outcomes have been reported for 25,000 cases. This study was designed to address the lack of literature about inpatient WB in the United States, despite availability in 300 hospitals.

METHODS: A retrospective cohort study of 13,394 births was conducted at a California community hospital during the first ten years intrapartum immersion was available; 624 WL (4.7%) and 675 WB (5.0%) were identified. Logistic regression and analyses of variance were used to compare perinatal optimality (Optimality Index-United States ratings), care processes and outcomes among three study groups (WL, WB, and standard care), after controlling for medical and obstetric risk factors.

RESULTS: Nurse-midwives were the provider type most likely to furnish hydrotherapy (93.6%). WL and WB were most common among English-speaking, nulliparous women with a college or graduate education. Hydrotherapy was associated with specific midwives and labor nurses. Use of pharmacological pain relief methods was five times greater in the non-immersion group than the WB group (OR=5.7, 99% CI= 4.0-6.2, p<.0001). Severe perineal laceration was decreased in the WB group relative to the standard care group (p<.0001), although obstetric laceration repair (p<.0001) and periurethral laceration (p<.0001) were increased. WB was also associated with decreased labor augmentation (p<.0001), fewer prophylactic and therapeutic antibiotics (p<.0001), and intermittent versus continuous fetal monitoring (p<.0001) compared to the non-immersion and WL groups. There were no other differences in maternal or neonatal parameters including method of delivery, Apgar scores and nursery admission.

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CONCLUSIONS: WB was associated with optimal perinatal outcomes and reductions of intrapartum medications and technologic care processes. Although increased periurethral laceration and laceration repair were associated with WB, this was balanced by decreased severe perineal laceration. Data support the use of hydrotherapy during labor and birth by healthy women who self-select with informed consent. Findings highlight the impact that midwives and nurses have on women's decision-making for pain relief during childbirth.

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#### CHAPTER 1

#### Introduction

This dissertation provides background information and a detailed description of research designed to address gaps in the literature regarding warm water immersion for pain relief during labor and birth in inpatient United States (US) settings. The first chapter outlines the research problem and significance of the study. The second chapter will review the theoretical basis for intrapartum hydrotherapy (IPH); namely physiology, pain and feminist theories. Chapter three will provide a review of published IPH research literature. The fourth chapter will describe the retrospective cohort study design and methods, informed by the preceding chapter and a review of approaches to perinatal outcomes research. Study findings are presented in the fifth chapter followed by a discussion of implications for clinicians, policy and research in the sixth chapter.

The purpose of the study was to examine outcomes of labor and birth in water during the first ten years that the practice was offered at a US community hospital. The study was designed to overcome some limitations of prior IPH research, thereby increasing the quality of data with which to evaluate the practice. Study aims also included increased knowledge of safe and efficacious non-pharmacologic intrapartum pain relief and comfort measures, in order to increase evidence-based care practices available to childbearing women.

#### **Operational Definitions**

IPH is the therapeutic use of water for pain relief and relaxation by childbearing women. Hydrotherapy can be provided in a shower, as well as a bath tub, pool or any body of water available for maternal immersion. In contrast, the term intrapartum immersion (IPI) is only used to signify hydrotherapy via submersion. For the purpose of this dissertation, hydrotherapy and IPI will be used interchangeably to identify maternal immersion during labor or birth.

Other terms that will be used are water birth (WB) and water labor (WL). WB occurs when a newborn emerges from its mother underwater. For this research, WB was defined as emergence of the presenting part in water. In instances where shoulder dystocia occurred in water and women exited the tub prior to resolution, births were considered to have occurred in water. WB may or may not include immersion during the third stage of labor, or underwater delivery of the placenta. Women who birthed in water, generally also labored in water. WL is defined as immersion during the first and/or second stage of labor, but not during the moment of birth.

#### Background

For most women, pain is both anticipated and experienced during childbirth (Goodman, Mackey, & Tavakoli, 2004; Green, Coupland, & Kitzinger, 1990). In addition to clinical factors, psychosocial variables contribute to differences in the degree and character of pain and coping experienced by childbearing women (Brownridge, 1995; Melzack, 1980, 1993; Melzack & Belanger, 1989; Melzack, Belanger, & Lacroix, 1991; Melzack, Kinch, Dobkin, Lebrun, & Taenzer, 1984; Melzack & Schaffelberg, 1987). Psychosocial factors include confidence and preparedness, fear and anxiety, personal history of pain and abuse, and cultural identities (Brownridge, 1995; CNM Data Group, 1998; Melzack, 1980, 1993; Melzack et al., 1984; Trout, 2004). Evidence supports addressing these non-clinical determinants of the experience of labor pain with prenatal interventions, as well as the creation of a supportive and therapeutic environment for labor and birth (Enkin et al., 2000; Melzack et al., 1984). Further, 11 randomized controlled trials (RCT) have conclusively demonstrated the pain relieving effect of IPI (Cluett & Burns, 2009). Despite these data, labor support provided to most childbearing women is minimal and pharmacologic pain relief methods are the norm (Declerg, Sakala, Corry, & Applebaum, 2006; Hodnett, 2002; Hodnett et al., 2002). Among more than 1500 US women queried about their experiences with childbirth in 2005, 76%

received epidural analgesia, 47% received pain medications other than epidural analgesia and general anesthesia, and just 6% utilized IPI (Declerq et al., 2006).

Given the predominance of epidural analgesia and its excellent pain relief, one might assume that its use is accompanied by improved psychosocial outcomes, including maternal satisfaction with the experience of childbirth (Anim-Somuah, Smyth, & Howell, 2005). While this is true to a degree, factors other than absolute pain levels are stronger predictors of optimal outcomes (Anim-Somuah et al., 2005; Goodman et al., 2004). A sentinel study of childbearing women by Morgan and colleagues (1982) observed that low levels of pain were not well correlated with high levels of satisfaction. This finding has subsequently been reported by others, including randomized controlled trails (RCTs) of epidural and non-epidural pain relief methods (Anim-Somuah et al., 2005; Goodman et al., 2004; McCrea & Wright, 1999; Morgan, Bulpitt, Clifton, & Lewis, 1982).

Investigation of these relationships has been limited thus far. However, it appears that medical intervention, regardless of effect on pain, may result in decreased maternal satisfaction with childbirth if accompanied by a perception of loss of control (Downe, 2004; Goodman et al., 2004; Green & Baston, 2003; Green et al., 1990). Obstetric intervention may also result in lower levels of emotional well-being in the postpartum period, particularly when women do not feel involved in decision-making around intervention use (Downe, 2004; Goodman et al., 2004; Green & Baston, 2003; Green et al., 1990). Women may be increasingly opting for alternative childbirth practices, including IPI, to avoid a perceived loss of autonomy (Hall & Holloway, 1998; McCrea & Wright, 1999). Indeed, initial qualitative inquiries into the IPI phenomenon reveal that some women choose to labor and birth in water to avoid conventional obstetric care practices, including but not limited to pharmacologic pain relief methods (Hall & Holloway, 1998; Richmond, 2003b; Wu & Chung, 2003).

WB was first described by a French physician two centuries ago (Embry, 1805). Most of the contemporary IPI literature also originated in Europe, where the practice is widespread and growing. In the United Kingdom (UK), the 1992 Winterton report directed providers to make IPI available to women in all maternity facilities (House of Commons Health Committee, 1992). In the year following this report, the number of women who labored in water in England and Wales increased 70% while the occurrence of WB increased by 63% (Alderice et al., 1995a, 1995b). By 1993 89% of maternity units in England and Wales were providing the option of both WL and WB (Alderice et al., 1995a, 1995b). Among German speaking obstetrical units queried in 1998, 25% offered the option of WB and one-quarter of these had introduced the practice within the previous twelve months (Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve, & Hosli, 2006). European authors currently report WB rates ranging from 1% to 71% in institutional settings where the option is offered (Baxter, 2006; Chinze M. Otigbah Research Registrar, Dhanjal, Harmsworth, & Chard, 2000; Eldering & Selke, 1996; Geissbühler & Eberhard, 2000; Geissbühler, Stein, & Eberhard, 2004; Nightingale, 1996; Ponette, 1995; Schrocksnadel, Kunczicky, Meier, Brezinka, & Oberaigner, 2003; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006).

European incidence of WB will likely continue to rise following the 2007 release of revised evidence-based guidelines for maternity care in the UK which instruct obstetric providers to recommend IPI as a safe and efficacious pain relief method for healthy childbearing women in the first stage of labor, but conclude there is insufficient evidence to either endorse or prohibit WB (National Collaborating Centre for Women's and Children's Health, 2007). A recent joint statement by the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives recognized the limitations of WB research but commented that available data is arguably reassuring despite documenting the potential for rare but serious neonatal complications (Alfirevic &

Gould, 2006). Further, they asserted that childbearing women have the right to make an informed choice to give birth in water and be attended by providers who can facilitate and are experienced with the practice (Alfirevic & Gould, 2006).

This public policy endorsement of IPI differs from the reception received by the practice in the US. Neither the American College of Nurse-Midwives (ACNM) nor the American College of Obstetricians and Gynecologists have position statements on IPI (ACNM Department of Professional Services, 2006). The American Academy of Pediatrics' Committee on Fetus and Newborn issued commentary advising that neither the fetal safety nor benefit of underwater delivery has been demonstrated, and that WB is an experimental procedure which should only take place in the context of a RCT (Batton et al., 2005). This pediatric position may provide a disincentive for providers and institutions to incorporate or continue the provision of IPI in the US.

Although the current rate of IPI utilization in the US is unknown, it is certainly less than that of Europe. In the absence of a national health system or standardized maternity data collection beyond major morbidity and mortality, the incidence is difficult to ascertain. To date, few national studies of childbearing women and pain relief methods have been performed (CNM Data Group, 1998; Declerq et al., 2006). One study reviewed pain management methods utilized by women attended by nurse-midwives in nine US hospitals in 1996, and found that 14.9% (n=622) used hydrotherapy (CNM Data Group, 1998). In a subsequent survey of 1,573 US women who birthed in 2005 with any type of maternity care provider, 6% reported utilizing IPI in a tub or pool (Declerq et al., 2006). It is unknown how many of the respondents in either study both labored and birthed in water. Best estimates of US WB prevalence arise from unsystematic surveys of obstetric facilities. Cohen (1996) reported that 44 hospitals, and 35 birth centers unaffiliated with hospitals, were the site of at least one WB in the US between 1989 and 1996. By 2009, at least 300 US hospitals had witnessed WB

(Mackey, 2001; Harper, 2009).

Nine additional data-based articles about IPI in the US have been published. Among these were two case reports (Hagadorn, Guthrie, Atkins, Wright-DeVine, & Hamilton, 1997; Parker & Boles, 1997), two rigorous studies of maternal outcomes following a period of immersion during labor but not birth (Robertson Huang, Croughan-Minihane, & Kilpatrick, 1998; Schorn McAllister, & Blanco, 1993), one description of maternal movement and positioning observed during WL (Stark, Rudell, & Haus, 2008), one brief report on the demographics of women who had WB at an Oregon university hospital (Mack, Pechovnik, Andronici, Tallman, & Lowe, 2005), and two authors who provided minimal descriptive statistics from an independent birth center in southern California where IPI was common (Church, 1989; Rosenthal, 1991, 1996). In contrast to US literature, 78 international data-based publications were located, including 49 that described both labor and birth in water. These studies will be discussed in chapter three.

#### Study Problem, Significance and Purpose

IPI is a non-pharmacologic obstetric pain relief method increasingly utilized in internationally. The current rate of IPI utilization is largely unknown but it appears to be rising and has become more widely available in institutions due to consumer demand (Alderice et al., 1995a, 1995b; Baxter, 2006; L. Brown, 1998; Cluett & Burns, 2009; Cohen, 1996; Geissbühler & Eberhard, 2000; Geissbühler et al., 2004; Mackey, 2001; McCandlish & Renfrew, 1993; Richmond, 2003b; Teschendorf & Evans, 2000; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006). Although existing research demonstrates efficacy and maternal and neonatal safety, case reports of adverse events and gaps in the literature compel further study and limit endorsement by some perinatal clinicians, particularly in the US (Batton et al., 2005; Cluett & Burns, 2009; Pinette, Wax, & Wilson, 2004; Schroeter, 2004; Schuman, 2006; Zimmermann, Huch, & Huch, 1993). To date, no rigorous outcome evaluations of WB in the US have been published.

Nonetheless, a significant number of US hospitals are currently providing IPI with the option of WB. Best estimates of US prevalence suggest there was a seven-fold increase in availability of hospital WB over the last two decades (Cohen, 1996; Mackey, 2001; Harper, 2009). Further, WB is occurring in the US despite lack of endorsement from obstetric or pediatric professional associations (Batton et al., 2005).

Since IPI is being utilized, it is imperative for both providers and consumers to understand what theoretical and demonstrable risks and benefits are associated with the practice. This study was undertaken to increase such understanding. In light of the discrepancies between European and US perceptions, the following questions must be asked: 1) "Are US women being denied universal access to an evidence-based obstetric pain relief method?" and 2) "Are European, Asian and Australian women and neonates being routinely subjected to an unproven or dangerous obstetric intervention?" Addressing these questions required a critical examination of the phenomenon of IPI and associated outcomes in US settings, as reported in this dissertation research. The following chapter presents a discussion of the theoretical basis for IPI and its study.

#### **CHAPTER 2**

#### Theoretical Basis for Intrapartum Immersion

#### Introduction

The primary purpose of this chapter is to describe theoretical frameworks that support the potential and demonstrable effects of IPI and related research. In addition to measures of maternal and neonatal morbidity and mortality, this study included the first application of the Optimality Index-United States to the phenomenon of IPI. This instrument is a conceptual departure from conventional perinatal outcomes research because both processes of care and outcomes are analyzed, and technologic intervention is considered sub-optimal. This concept will be discussed in detail in the fourth chapter.

There are many perspectives from which to examine IPI, but physiology and pain theory are the theoretical frameworks most applicable to the study of biophysical outcomes of WL and WB. Researchers rarely explicitly identify a theoretical framework for IPI, but authors often mention relevant physiology. Accordingly, the maternal and fetal physiologic responses to immersion, and the physiologic processes that occur during WB will be described. However, physiologic theory is insufficient given the unique psychosocial-physiologic experience of childbirth. In light of this, review of relevant physiology will be extended in a discussion of the Gate Control Theory of Pain and subsequent Neuromatrix Theory of Pain. Pain theories have not been applied to WB research to date, although they have been mentioned by several authors in discussions non-pharmacologic pain relief strategies for labor and delivery (Sagady, 1995; Simkin & Bolding, 2004; Trout, 2004; Zwelling, Johnson, & Allen, 2006). This dissertation research was also informed by feminism which provides a foundation for the models of care in which IPI is typically provided. Feminist tenets are also revealed in the OI-US instrument and concept of obstetric optimality.

Collectively these theoretical frameworks will provide for a deeper understanding of existing IPI literature discussed in the next chapter. Further, application of feminist, physiologic and pain theory perspectives will assist the provision and examination of IPI by clinicians and researchers alike. This chapter will conclude with recommendations for additional theoretical considerations in future research on WL and WB including theories of evolution, attachment, social support, and environmental psychology.

#### Physiology

This discussion of physiologic theory will primarily address findings reported in IPI research literature. Physiologic explanations for such findings will be provided, beginning with practice safety. Common questions such as "Why doesn't the baby drown?" and "What about infection?" and will be addressed first, with a review of the physiology underlying a newborn's transition to extrauterine life. Discussion will then provide theoretical physiologic mechanisms by which benefits of IPI could occur. A review of the physiologic responses to immersion and the mechanical and biochemical processes involved in labor and birth will also be included. Limitations of these physiologic theory perspectives will be incorporated throughout.

#### Fetal Physiology and Transition to Extrauterine Life

*Fetal oxygenation and circulation.* While in utero, a fetus receives oxygen from its mother through the placenta where a fetal capillary bed feeds the umbilical vein (Cunningham et al., 2005). Fetal circulation differs from that of an adult, primarily because the fetus does not receive oxygen from the lungs. As such, fetal circulation does not require significant blood flow to the lungs to allow for gas exchange at the level of the alveoli. Fetal circulation allows only for minimal perfusion of lung tissues and fluid-filled bronchial and alveolar structures prior to the first breath of air after birth (Cunningham et al., 2005; Sagady, 1995).

*Fetal breathing movements.* While in utero, fetal "breathing" movements (FBM) can be intermittently observed and occur during at least 40% of both active and quiet sleep states in fetuses near term (Johnson, 1996). They are associated with normal fetal sleep cycles as well as fetal heart rate. Although commonly believed to be practice for eventual extrauterine breathing, FBM have a larger role in fetal lung development than anticipatory respiration.

During FBM the larynx and hypopharynx are completely obstructed during inspiration and partially obstructed during expiration, similar to mechanisms of obstructive sleep apnea (Fewell, Hislop, Kitterman, & Johnson, 1983; Fewell & Johnson, 1983; Johnson, 1996). This obstruction is due to inhibition of the uncoordinated inspiratory muscles involved in upper airway dilation, as well as fluid dynamics in the fetus and fetal environment (Johnson, 1996). FBM do not result in the intake of significant quantities of amniotic fluid largely due to the apneic and isometric qualities of movement in which weak positive pressures are generated during expiration and strong negative pressures occur during inspiration (Johnson, 1996). These factors are prominently involved in fetal lung development as evidenced by animal models in which fetal tracheostomy results in critical pulmonary hypoplasia after effectively reducing constant and dynamic subglottal pressures without altering FBM (Fewell et al., 1983; Fewell & Johnson, 1983; Johnson, 1996). The lung, of similar endoderm origin as the gastrointestinal tract, produces fluid with a pH of 6.3 which is closer to that of stomach content than the 7.2 pH of amniotic fluid (Johnson, 1996). This noticeable difference confirms that fetuses do not normally inhale significant quantities of amniotic fluid while in utero. Fluid found in the fetal lung is primarily produced there by pulmonary epithelial cells throughout the second half of pregnancy (Sagady, 1995). Overall, there is a net outflow or egress of fluid from the fetal lung, which is swallowed due to inhibited inspiratory muscles and valvular function of the larynx (Cunningham et al., 2005;

Johnson, 1996). Intake of fluid through swallowing mechanisms should be differentiated from inhalation through respiratory or gasping efforts, which will be discussed shortly.

In addition to fetal swallowing, fetal lung fluid volume is altered by hormonal mechanisms (Cunningham et al., 2005; Sagady, 1995). Fetal hypoxia and concomitant increased stress hormone production will decrease lung fluid production (Eldering & Selke, 1996). Catecholamines released during labor effectively alter pulmonary epithelial cell function from lung fluid production to lung fluid absorption (Sagady, 1995). In this way, most of the fluid remaining in the lungs after birth is reabsorbed into the bloodstream for later urinary and lymphatic elimination (Eldering & Selke, 1996). The reabsorption of lung fluid following birth generally occurs within six hours. This reabsorption is necessary for optimal respiratory function and crucial for expansion of the newborn's intravascular volume. Circulating blood volume must increase as the pulmonary circulatory system expands during the transition from maternal-fetal to independent circulation at birth (Eldering & Selke, 1996).

Hormonal and hypoxic effects on fetal breathing movements. Clinicians are primarily familiar with FBM observed on ultrasound during assessments of fetal wellbeing that also include gross motor movements and examination of fetal heart rate variability. Fetuses experiencing deprivation of oxygen will conserve expenditure by decreasing and eventually ceasing movement prior to demise, in addition to displaying decreased variability of the heart rate (Cunningham et al., 2005). However, there are several normal physiologic mechanisms by which FBM are inhibited as well (Johnson, 1996).

Although fetal heart rate variability is normally maintained until delivery, associated FBM all but cease approximately two days prior to the onset of labor, primarily as a result of hormonal inhibition (Johnson, 1996). Maternal prostaglandin E<sub>2</sub>, which suppresses respiration, rises prior to the onset of labor (Kitterman, Liggins,

Fewell, & Tooley, 1983). It is theorized that prior to labor onset prostaglandin E<sub>2</sub> and adenosine are released into fetal circulation through mechanisms involving the placental membranes which are not yet fully understood (McCoshen, Johnson, Dubin, & Ghodgaonkar, 1987). Adenosine and endorphins are known to exert effects on the specific parts of the brain implicated in suppression of FBM resulting from hypoxia (Johnson, 1996). Mild acute hypoxia generally inhibits FBM in utero, although it will trigger inhalation of air after birth, once transition from fetal circulation has been accomplished (Boddy, Dawes, Fisher, Pinter, & Robinson, 1974).

Suppression of FBM during parturition seems likely to be an adaptive and protective mechanism given its routine occurrence just prior to labor onset (Lagercrantz & Slotkin, 1986). FBM inhibition may serve a preparatory purpose such as conservation of energy prior to fetal requirements of labor and birth, or by readying the fetus for respiration through unknown mechanisms (Lagercrantz & Slotkin, 1986). From this perspective, mild hypoxic suppression of FBM may be viewed as an evolved response which fetuses routinely experience during physiologically normal labors and births (Lagercrantz & Slotkin, 1986; Simkin, 1986). Additionally, the hypoxic inhibition of FBM may be reinforced by endorphins produced by unmedicated women in labor, including those utilizing non-pharmacologic IPI for pain relief (Eldering & Selke, 1996). Hypoxic and hormonal suppression of lung fluid production may also be viewed as adaptive. During normal gestation, fetal lung fluid production contributes to pulmonary development and then intravascular volume following birth (Eldering & Selke, 1996). Regulation of lung fluid volume at term and during parturition likely ensures sufficient but not excessive quantities. Unfortunately, physiologic theory has not yet considered these evolutionary mechanisms in detail.

Another lapse in physiologic theoretical understanding is evident in observations of recurrent FBM in fetal lambs subjected to eight to twelve hours of prolonged "sub-

lethal" hypoxia (Johnson, 1996). In these observations, only fetal tachycardia indicated that continued hypoxemia was present. This indicates that there are instances in which FBM may not be suppressed by mild or moderate hypoxic states. It is unclear whether this gap in theory has implications for IPI given (a) observation in an animal model (b) inadequate researcher definition of "sub-lethal" hypoxia, and (c) minimal ingress of amniotic fluid and presumably, bathwater, due to the isometric nature of FBM previously reviewed.

Continued FBM seem unlikely to effect healthy fetuses birthed underwater if they are otherwise experiencing normal parturition. Several clinical researchers concur, including Selke, a neonatologist who reported observing FBM after WB when the newborn remained submerged, without clinical sequelae (Fewell et al., 1983; Fewell & Johnson, 1983; Harper, 1995; Johnson, 1996). In contrast, severe and prolonged hypoxia is known to trigger fetal gasping in utero which can result in amniotic fluid inhalation (Johnson, 1996). In the event of severe hypoxia during WB, it would be possible for newborns to inhale bathwater through this mechanism (Johnson, 1996). In light of this, published recommendations for IPI uniformly recommend clinically appropriate monitoring of fetal heart tones as indicators of fetal oxygenation and tolerance of labor, and intervention in the event of non-reassuring findings as would occur during conventional labor and delivery.

In summary, physiologic theory demonstrates that when fetuses are subject to normal hormonal conditions and mild hypoxia during physiologic childbirth, FBM are suppressed. This suppression is likely an adaptive and protective mechanism which is not yet fully explicated. In fetal lambs, prolonged sub-lethal hypoxia was not observed to inhibit FBM for reasons still unknown. The clinical significance of this finding for IPI is not yet determined, particularly given that FBM do not result in significant intake of surrounding amniotic fluid or, presumably, bathwater. Mechanisms of intake through

FBM are generally confined to swallowing rather than inhalation through inspiratory effort. To the contrary, severe and prolonged hypoxia will result in fetal gasping which could result in bathwater inhalation and should be distinguished from FBM. As a result, fetal wellbeing should be adequately monitored during provision of IPI, and the practice should be restricted to healthy parturients and neonates during uncomplicated childbirth.

*Fetal freshwater and respiratory drowning.* Differentiation between types of fluid intake has not always been demonstrated in the few reports of drowning and neardrowning incidents related to WB (Alderice et al., 1995b; Barry, 1995; Gilbert, 2002; Gilbert & Tookey, 1999; Nguyen, Kuschel, Teele, & Spooner, 2002; Robinson, 1993; Rosser, 1994). These case reports must be viewed cautiously in light of large descriptive studies of IPI and WB, in which no aggregate increased risk to neonates was observed in comparison to those born into air (Burke & Kilfoyle, 1995; Chinze M. Otigbah Research Registrar et al., 2000; Fehervary et al., 2004; Geissbühler & Eberhard, 2000; Geissbühler et al., 2004; Gilbert & Tookey, 1999; Hawkins, 1995; Nightingale, 1994; Ponette, 1995; Thoeni, Zech, Moroder, & Ploner, 2005; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006; Zanetti-Dällenbach, Tschudin et al., 2007). However, case reports should be carefully considered given the significant weaknesses in most prior study designs. This discussion will cover the physiology underpinning case reports, and chapter three will provide a critical discussion of the literature.

When the intake of large quantities of non-saline water occurs, significant electrolyte alterations can result and the diagnosis of "freshwater drowning" will be made, even when no death occurs (Barry, 1995). Water intake can occur through either swallowing or inhalation; although in the case of inhalation, "respiratory drowning" is a more likely diagnosis. There are reports of two infants with "fresh water drowning" diagnoses following WB (Barry, 1995; Gilbert, 2002; Gilbert & Tookey, 1999). In the first

case, a general practitioner described an infant with "some difficulty breathing" who was admitted to the nursery where he convulsed, was found to be hyponatremic, and subsequently made a full recovery (Barry, 1995, p.310). This letter to the editor failed to provide sufficient information for complete analysis but indicated that the neonate experienced enough intake of bathwater to cause hemodilution and reduction of serum sodium beyond normal limits. The case prompted the reporting practitioner to propose adding salt to the bathwater in attempt to create an isotonic solution in which neonates could be born underwater with less risk (Barry, 1995). The journal that published the case report requested evaluation of this suggestion by a British professor of child health who recommended against the addition of salt to bathwater until animal models demonstrate safety (Pearn, 1995). In general, salinated water is not recommended in IPI protocols. In 1999 there was an additional report of an infant diagnosed with freshwater drowning after findings of hyponatremia and hypoxic ischemic encephalopathy (HIE) following WB (Gilbert, 2002; Gilbert & Tookey, 1999). There has not been subsequent mention of freshwater drowning or use of isotonic bathwater in the IPI literature.

Respiratory drowning is a separate matter that is theoretically possible during WB if the fetus experiences severe acute hypoxic gasping. Failure to adequately monitor fetal well-being and assess for hypoxia may explain several reported cases of neonatal bathwater inhalation and drowning (Alderice et al., 1995b; Gilbert & Tookey, 1999; Nguyen et al., 2002; Robinson, 1993; Rosser, 1994; Zimmermann et al., 1993).

In one extreme example, an oft cited case of water aspiration resulted in severe neonatal brain damage. The incident occurred in Sweden after a concealed pregnancy when a newborn emerged into a public pool without a health care provider in attendance (Pinette et al., 2004; Robinson, 1993; Rosser, 1994). In this instance, undiagnosed intrapartum fetal hypoxia may have played a role in the drowning as might other factors, including excessively prolonged submersion. Aside from bathwater inhalation through

hypoxic inspiration, drowning may occur if a newborn attempts to take its first breath while submerged after delivery underwater. The question posed by many is "Why doesn't drowning occur after WB on a routine basis?" This query will be explored further.

The dive reflex. Inhalation of bathwater after WB is partially inhibited by the dive reflex. The reflex is present in humans at birth and involves obstructive expiratory apnea and closure of the larynx (Eldering & Selke, 1996). The laryngeal obstruction resulting from the dive reflex is similar to the mechanisms by which ingress of amniotic fluid is prevented during FBM, and to conditions required for pulmonary development in utero. The dive reflex is distinguished from these mechanisms primarily by virtue of extrauterine rather than intrauterine observation. Additionally, the dive reflex should be differentiated from what adults experience while swimming. When adults prepare to dive they consciously achieve obstructive respiratory apnea by holding their breath during inspiration. This voluntary physiologic mechanism is distinct from the involuntary expiratory apnea of the neonatal dive reflex.

The chemosensitive caudal surface of the epiglottis adjacent to the larynx is instrumental in the dive reflex (Johnson, 1996). Chemoreceptors are capable of triggering airway closure in response to foreign substances including food and water (Eldering & Selke, 1996; Johnson, 1996). This mechanism is responsible for the reflex observed when infants regurgitate food, at which time the larynx obstructs the airway as a protective mechanism against aspiration (Eldering & Selke, 1996). Similarly, the dive reflex protects against water inhalation in response to water near the vocal cords, as well as facial skin contact with water. Receptors in the facial skin transmit to the central nervous system (CNS) via afferent trigeminal nerve pathways resulting in the reflexive response.

The dive reflex was clearly demonstrated in Harned and colleagues' (1970) study involving newborn lambs. Lambs completely submersed in either cool or warm water

experienced the obstructive apnea characteristic of the dive reflex, as did lambs when just their heads were submersed. In contrast, when just the lambs' bodies or snouts were submersed, respiratory effort decreased but no apnea was observed (Harned, Herrington, & Ferreiro, 1970). These findings are consistent with the theoretical human physiologic dive reflex in which facial stimulus is the primary initiating factor.

Theoretically, the dive reflex posits that prolonged reflexive action will divert blood flow to essential organs from the periphery, resulting in bradycardia and oxygen conservation (Eldering & Selke, 1996). As with suppression of FBM in utero, the dive reflex can be overridden with prolonged facial stimuli and the presence of severe asphyxia. This understanding of the proportional-differential control mechanisms involved in the dive reflex reiterates the importance of adequately monitoring for fetal well being during WL and WB. Undiagnosed perinatal asphyxia could override the normal dive reflex and result in bathwater inhalation during WB. Similarly, physiologic theory informs clinicians that after WB an infant's face should be brought to the surface quickly and should not be re-submersed so as to avoid excessive risk.

Although physiologic theory posits that the dive reflex is present in newborns, and persists through four to six months of age, it cannot explain why this is so. Limitations of physiologic theory give rise to questions including: 1) What purpose is served by the dive reflex once an infant has emerged from the watery environment of the womb? 2) Why does a two month old infant need the dive reflex given that it cannot independently propel itself into water? 3) Why does the newborn dive reflex persist beyond four to six months of age only among infants who are "trained" in water prior to that time? 4) What does the dive reflex indicate about human evolutionary origins?

*Phylogenetic theory.* Among proponents of IPI are a select and fervent few who assert that human beings have a genetic "memory" or phylogenetic propensity for labor and birth in water because *Homo sapiens* were originally adapted to coastal living and

land-sea interface, not the savannah as conventional evolutionary theory suggests (Harper, 1995; Odent, 1996; Richmond, 2003a). This theory of aquatic origins was independently proposed by German Westenhöfer in 1942 and British Hardy in 1960, and expanded over the last 15 years in publications by marine biologists, physiologists, nutritionists, physicians and anthropologists who cite the large human brain, salt glands, thermal regulatory mechanisms, sexual anatomy and behavior, the low larynx, large sinuses, and fetal diving reflex among human characteristics more similar to observations of oceanic rather than land mammals (Harper, 1995; Odent, 1996).

Phylogenetic theory proponents also assert that WL and WB have occurred for thousands of years. Ancient Egyptians and Minoans on Crete are known to have considered WB a sacred practice (Mackey, 2001). WL and WB have also been practiced by Maoris, Aboriginal Australians, some Pacific Islanders, Panamanian Indians, the Chumash tribe of central California, and traditional cultures in Japan, Guyana, Mongolia, Scotland and Germany (Mackey, 2001). Although less common in the Northern Hemisphere, European settlers in America continued to utilize "water cures" to prevent painful labors in the 1830's and 1840's (Mackey, 2001; Wertz & Wertz, 1979). The first published account of WB did not occur until 1805 when a French medical society offered a case report to its members (Embry, 1805). Although phylogenetic theory could never independently support IPI provision, continued exploration and application to IPI might complement a physiologic theoretical framework and research on IPI safety and efficacy in contemporary populations. At minimum, it is an interesting perspective from which counter the common assertion that human labor and delivery in water is "unnatural" (Edwards, 1994; Odent, 1996).

*The first breath.* The precise mechanisms by which the first extrauterine breath is initiated are poorly understood. In the IPI literature it is commonly asserted that combinations of factors are responsible including (a) release of mechanical thoracic

compression as the newborn exits the birth canal, (b) a change in temperature as the newborn leaves its mother's body and encounters cooler ambient temperatures, and (c) constriction of cord vessels resulting from uterine contraction or cord manipulation at delivery (Eldering & Selke, 1996; Pinette et al., 2004). A hierarchal model of importance among determinants of respiration following WB has not been published, likely due to inadequacies of both data and physiologic theory. However, careful review of the physiologic literature on initiation of neonatal respiration may significantly advance the theoretical framework.

Contrary to conventional belief, it does not appear that thoracic compression in the birth canal is involved in the initiation of neonatal respiration (Eldering & Selke, 1996; Johnson, 1996; Karlberg, Adams, Geubelle, & Wallgren, 1962; Karlberg & Koch, 1962). It was previously theorized that this compression removed pulmonary fluid and that higher rates of respiratory distress following cesarean birth resulted from the absence of compression (Eldering & Selke, 1996; Pinette et al., 2004). However, data indicate that hormonal mechanisms are responsible for pulmonary fluid production and absorption, while ambient temperature is the primary determinant of respiratory initiation as well as inhibition (Johnson, 1996). In utero, warm body temperatures witness intermittent FBM and occlusive apnea as previously described. Intermittent FBM and apnea continued in studies of fetal lambs that remained in warm environments after umbilical cords were occluded (Harned et al., 1970; Johnson, 1996). In these studies, severe asphyxia and gasping eventually occurred because fetal lambs did not initiate respiratory effort even in the presence of tracheotomies or snorkels which provided access to air. It was only after the ambient temperature of the normal fetal environment was reduced by one to two degrees Celsius (C) that respiratory effort was undertaken. At this time muscles involved in diaphragmatic inspiratory activity became synchronized and physiologic airway obstruction was resolved. In separate studies, reduction of ambient temperature initiated

inspiration in the absence of umbilical cord occlusion, demonstrating simultaneous oxygenation through fetal circulation and pulmonary respiration (Harned et al., 1970; Johnson, 1996).

This theoretical understanding informs IPI protocols in that most literature recommends avoiding cord manipulation and maintaining water temperature close to that which would have been experienced in utero in order to prevent premature stimulus to breathe during WB. In light of animal models previously discussed, clinicians should take care not to grasp or otherwise occlude the umbilical cord during and immediately following WB. Further, bathwater temperature at the time of underwater delivery should be no less than 35°C, but ideally 37°C or higher to prevent bathwater inhalation.

Fetal hyperthermia. Some authors have advised that tub water temperature during labor may reflect the mother's preference and needs regulation only when delivery is imminent. However, animal models and case reports of fetal hyperthermia suggest it is prudent to monitor bathwater temperature during labor as well as birth. IPI recommendations should reflect understanding of the maternal-fetal temperature gradient in which fetal temperature is normally expected to be at least 0.5°C higher than maternal temperature (Cefalo & Hellegers, 1978; Rosevear, Fox, Marlow, & Stirrat, 1993). This gradient changes as maternal temperature increases beyond normal levels (Cefalo & Hellegers, 1978). Cefalo and colleagues (1978) demonstrated in pregnant ewes that as maternal temperature increased by  $1^{\circ}$ , the maternal-fetal temperature difference decreased from 0.61°±0.05℃ to 0.19°±0.0 3℃ (p<.01). However, when maternal temperatures were increased by 2.0° ± 2.5° C above normal, the temperature difference increased significantly (p<.01) to 1.27°±.08°C (Cefalo & Hellegers, 1978). If these findings are applied to humans, maternal temperatures as low as 37.5°C could translate into fetal temperatures as high as 38.9℃. Given the hydrothermal properties of water, elevations of maternal temperature are likely to occur with IPI, particularly during

prolonged immersion in water at temperatures significantly higher than normal body temperature.

Although women may reduce core temperatures through oral hydration with cooler fluids as well as sweating and heat loss, fetuses have inadequate thermoregulatory mechanisms in both excessively warm and cool ambient environments (Brown, 1982; Cefalo & Hellegers, 1978; Rosevear et al., 1993). Animal models demonstrate that fetal heat dissipation primarily occurs through the umbilical-placental circulatory exchange, although some heat loss may also occur through the amniotic fluid (Cefalo & Hellegers, 1978). When both fetal and maternal temperatures are elevated, heat does not effectively disburse and fetal hyperthermia may result. This hyperthermia may cause dilated cerebral vasculature and increased oxygen consumption, with potential for hypoxia, particularly in a fetus already compromised for other reasons (Rosevear et al., 1993).

This mechanism was proposed by Rosevear and colleagues (1993) as the etiology involved in grade three HIE diagnosed in two infants after IPI. Insufficient information about maternal temperature was provided; authors note just that temperatures were recorded as 37.5°C or less throug hout the intrapartum and postpartum periods. In the first case, the infant was born conventionally after maternal immersion for two and a half hours during the first stage of labor, without water temperature noted in the record. The infant was born in poor condition with a severely acidotic cord-blood pH of 6.82, despite reassuring fetal heart tones intermittently auscultated throughout labor and delivery (Helwig, Parer, Kilpatrick, & Laros, 1996). After a straightforward resuscitation, the infant developed HIE and bilateral thalamic hemorrhages and died 15 hours after birth. Autopsy revealed no alternative hypothesis so death was attributed to IPI-related hyperthermic asphyxia, although authors concede that no causal relationship could be established. The second case involved a woman

who labored in water for four and a half hours. Upon tub entry, water was noted to be quite warm at 39.7°C (103.4°F) although the woman r emained technically afebrile throughout immersion. Fetal heart rate was noted to be 160 beats per minute or less on intermittent auscultation. As in the first case, the infant was born in poor condition but was resuscitated without difficulty. It is unclear whether the infant was born in water or not. Cord-blood pH was noted to be 7.16, which indicates mild physiologic acidemia clearly within the range of normal values (Helwig et al., 1996). Grade three HIE was diagnosed but the infant's subsequent clinical course was not described.

Rosevear and colleagues (1993) were the first to describe hyperthermic HIE attributed to IPI. From a theoretical perspective, their physiologic hypothesis is logical, although application to specific women and their compromised infants may not be conclusively demonstrable. Given Cefalo and colleagues' (1978) study of maternal-fetal temperature differences in ewes, the infants described by Rosevear et al. (1993) could have had intrapartum temperatures of up to 38.9°C a s well as an unmet increased oxygen demand due to hyperthermia. Although the infants described by Rosevear et al (1993) were born to low risk women, it is possible that there was underlying pathology exacerbating hyperthermic compromise. In light of this possibility, IPI protocols should continue to contain appropriate exclusion criteria and emphasize assessments of fetal well being as well as cautious temperature regulation.

Geissbühler and colleagues (2002) observed excellent outcomes of IPI when women were permitted to self-select bath water temperature. However, limitations of the analytic methods employed in the study prevent certainty that extremes of temperature were not associated with increased perinatal risk. Accordingly, women should be advised that they may safely regulate bathwater temperature during labor according to comfort, provided it does not exceed 37.7°C. Durin g second stage labor it should be recommended that bath water temperature remain between 36.1°C and 37.7°C to avoid
both fetal hyperthermia and premature respiratory stimulus upon birth in water. Close monitoring and regulation of bathwater temperature may seem onerous to clinicians interested in providing the option of IPI to their clientele. However, automated temperature regulation mechanisms often accompany pools designed and marketed for use during the intrapartum period (AquaDoula, 2005). Further, these pools are designed to minimize the risks of contamination and infection which will be discussed in the next section.

## Immersion and Infection

Theoretical mechanisms of infection transmission during IPI are (a) from mother to child, including group B streptococcus or other pathogenic organisms found in the vagina or rectum; (b) from a support person, if someone with lesions or infection joins the mother in the tub, (c) from mother to health care provider via bathwater, if universal precautions are not followed; (d) from one mother to another mother, if tub cleaning protocols or adherence are insufficient; and (e) mother or child may become infected by organisms found in contaminated water sources used to provide IPI.

Both neonatal and maternal infections are commonly examined obstetric outcome variables and are usually measured in the intrapartum and postpartum periods. Maternal infection has been operationalized in IPI research as 1) intrapartum fever; 2) documented incidence of chorioamnionitis; and 3) endometritis diagnosed after birth. Some operational definitions have proved problematic. For example, the use of intrapartum fever as a proxy for maternal infection is likely to overestimate the actual incidence since febrile states may have non-infectious etiologies. Some researchers have also captured neonatal infection indirectly, using rate of admission to neonatal intensive care units as a proxy for all adverse neonatal outcomes including infection. Others have operationalized infection as any incident of work-up for sepsis, whether pathogenic organisms were eventually identified or not. Both methods are problematic in

IPI research where vigilance may be heightened due to the controversial nature of the practice. The incidence of work-ups for sepsis should be differentiated from the diagnosis of infection. However, it is an important additional variable to examine since it can involve invasive testing such as veinipuncture or spinal tap, antibiotics later realized to be unnecessary if the work-up is negative, and separation of mother and baby if nursery admission occurs during testing.

Regardless of how infection has been operationalized, no increased aggregate incidence has been observed in either mothers or babies following WL or WB (Chinze M. Otigbah Research Registrar et al., 2000; Church, 1989; Eriksson, Ladfors, Mattsson, & Fall, 1996; Fehervary et al., 2004; Geissbühler et al., 2004; Hawkins, 1995; Ohlsson et al., 2001; Robertson et al., 1998; Schorn et al., 1993; Zanetti-Dällenbach, Holzgreve, & Hosli, 2007; Zanetti-Dällenbach, Lapaire, Maertens, Frei et al., 2006; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006; Zanetti-Dällenbach, Tschudin et al., 2007). The physiologic explanations for these findings follow.

*Bathwater ingression.* Uterine infection following IPI has not been demonstrated in the research literature because there is rarely ingress of bathwater, the theoretical reservoir of pathogenic organisms. An early study demonstrated that water treated with potassium iodide could not be recovered from tampons used by women bathing at term gestation or in the immediate postpartum period (Siegel, 1960). Although not specifically studied in the intrapartum period, there is no theoretical explanation for bathwater ingression if not observed preceding labor or following delivery. Ingression of bathwater into the uterus is only possible if the mucus plug has been expelled, membranes are ruptured, and an internal examination or other introduction of potentially infectious material occurs during immersion. This principle is evidenced by research demonstrating greater bacterial growth on cultures of the cervix following digital exams compared to cultures taken previously (Imseis, Trout, & Gabbe, 1999). Nonetheless, internal exams

commonly take place during immersion. Given that is so, why is an increased rate of infection not observed in IPI research?

Dilutional effect of bathwater. Research demonstrates that the organisms commonly found on a woman's body are dispersed and diluted in bathwater, which may make migration to the uterus and transmission to infants or providers less likely than during conventional delivery (Zanetti-Dällenbach, Holzgreve et al., 2007; Zanetti-Dällenbach, Lapaire, Maertens, Frei et al., 2006; Zanetti-Dällenbach, Tschudin et al., 2007). For example, Colombo and colleagues (2000) examined the likelihood that human immunodeficiency virus (HIV) would be transmitted from an infected woman to her providers during or following IPI. They examined the hemoglobin concentrations found in bathwater after 14 WB with varied levels of documented postpartum blood loss. These data were used to create a computerized model in which hypothetical HIV viral loads could be studied. Researchers also examined the midwives in attendance. Data collection included adherence to infection precaution procedures, providers' immunization status, and documentation of providers' skin lesions. Investigators concluded that even with high viral loads, the dilutional effect of bathwater made it "unlikely" that HIV could be transmitted from childbearing woman to provider, but no further details were provided (p. 152). However, they noted that infections with more robust organisms, such as Hepatitis B or C, could occur because a number of midwives had skin lesions or failed to use universal precautions, including gauntlet gloves and protective eye wear. They also noted that one midwife was splashed and pool water contacted her face.

Arguably, providers would be at greater risk for infectious exposure through splashing during IPI compared to conventional delivery. This area requires further study, beginning with inquiry into whether increased splashing actually occurs. If so, researchers would need to evaluate whether increased splashing with organisms diluted

in bathwater confers greater risk to providers than fewer episodes of splashing with concentrated body fluids. In the meantime, microbiologists and clinicians have advocated restricting immersion during birth among women infected with blood-borne pathogens, or without documented negative screening for such organisms (Sutter Davis Hospital, 1995).

In addition to risk of provider infection, IPI researchers have examined bath water dilution of organisms with the potential to infect neonates. In particular, neonatal colonization with group B beta streptococcus (GBS) following conventional birth and WB has been assessed (Zanetti-Dällenbach, Holzgreve et al., 2007; Zanetti-Dällenbach, Lapaire, Maertens, Frei et al., 2006; Zanetti-Dällenbach, Tschudin et al., 2007). In a Swiss study, women who delivered conventionally were asked to bathe in the postpartum period so that bathwater samples could be assessed for both groups of subjects (Zanetti-Dällenbach, Lapaire, Maertens, Frei et al., 2006). GBS was more likely to be identified in bathwater used for intrapartum immersion than postpartum immersion (p<.001). However, infants born in water were 50% less likely to have GBS identified on nasal (p=.005) or pharyngeal cultures (p=.024) compared to those born outside of water, even in cases with preterm premature rupture of membranes (Zanetti-Dällenbach, Lapaire, Maertens, Frei et al., 2006). Researchers concluded that there may be a "wash-out" effect that is protective of neonates born in water (Zanetti-Dällenbach, Lapaire, Maertens, Frei et al., 2006, p.231). This dilutional effect could be protective against potentially pathogenic organisms but whether it is desirable in all cases remains questionable.

Bacteria normally found on and in the human "ecosystem" have innumerable and significant implications for health. Although some of these organisms are associated with infectious and adverse outcomes, human bacterial colonization is essential for optimal physiologic functioning and health. Emerging research is expanding and informing

physiologic theory regarding newborn exposure to maternal organisms during the birth process. This theoretical development has already resulted in altered clinical practice. For example, shaving and antiseptic cleansing of the vulva and perineum prior to childbirth were once considered necessary for protection against newborn infection, as was a routine enema (Davis-Floyd, 2003). Research subsequently demonstrated that these routines did not have a beneficial effect on newborn infectious outcomes, although the practices also declined because women found them to be uncomfortable and demeaning, and resisted their use (Davis-Floyd, 2003). Women also questioned why newborns had to be routinely "protected" from their mothers' vaginal flora if childbirth was a physiologic rather than pathologic condition (Davis-Floyd, 2003; Singleton, 2007). Viewed from this perspective, recent research indicating there may be benefits of such "vaginal inoculation" of newborns during childbirth is hardly surprising. It is now theorized that the newborn gut becomes colonized with essential microorganisms during the birth process, when in contact with organisms in the maternal ecosystem (Singleton, 2007). As Singleton (2007) remarked:

Birth is well designed to effectively colonize a sterile newborn with healthy bacteria. It's no mistake that we exit our mother's body so close to her rectum. We are meant to encounter her gut bacteria on our way into the world. After heavily exposing her baby to friendly gut bacteria, an undisturbed mother will naturally nuzzle her baby to her breast, so close to her armpit where the second largest number of bacteria in the human body reside. If birth were designed by nature to minimize the infant's contact with bacteria, we would exit our mother's body from the back of her neck and nurse off her forehead (p. 18-19).

Investigators have begun to examine the utility of probiotic administration in pediatric populations. Probiotics are micro-organisms normally found in the digestive tract which confer health benefits by optimizing the balance of intestinal flora essential to digestive process and immune system functioning (Cabana, Shane, Chao, & Oliva-Hemker, 2006). Pediatric probiotic administration is efficacious in treatment of gastrointestinal disorders ranging from infectious and antibiotic-induced diarrhea to necrotizing

enterocolitis and inflammatory bowel disease (Cabana et al., 2006). They have also been used in the treatment of urogenital infections and atopic disease such as eczema, asthma and allergy to cow's milk (Cabana et al., 2006). Probiotics include *Lactobacilli* which are abundant in healthy female genitalia, after migration from the gut via the rectum (Singleton, 2007). Since newborns benefit from contact and colonization with some of the organisms comprising maternal recto-vaginal flora, could the dilution observed during WB be detrimental? The wash-out effect of bath water should be reevaluated given this developing theoretical perspective. This aspect of physiologic theory has not been articulated or explored in IPI research to date.

*Contaminated water sources.* Discussion of theoretical risks and benefits of the dilutional effect of bathwater are underpinned by an assumption that uncontaminated water is available for use during IPI. Five case reports of neonatal infection attributed to a contaminated water supply demonstrate the danger of this assumption (Franzin, Scolfaro, Cabodi, Valera, & Tovo, 2001; Nagai et al., 2003; Parker & Boles, 1997; Rawal, Shah, Stirk, & Mehtar, 1994; Vochem, Vogt, & Doring, 2001).

Nagai and colleagues (2003) were the first to describe a newborn diagnosed with *Legionella pneumophila* pneumonia following birth into contaminated water. They discussed the case at a conference in 1999, although an account of the incident was not published until 2003 (Franzin et al., 2001; Nagai et al., 2003). The case involved a Japanese infant born at 42 weeks gestation into the bathtub of her family's home. Midwives did not arrive until approximately 15 minutes after the birth. The infant remained healthy until the fourth day of life when she became jaundiced and febrile. She was admitted for inpatient treatment for 24 hours and all symptoms resolved. On the seventh day of life, she became febrile and began vomiting. Her parents brought her back to the hospital with apnea on the eighth day of life, at which time she could not be revived. An autopsy three hours after death demonstrated infection with *L. pneumophila* 

which was subsequently isolated from tap water in the family's bathtub. The bathtub had a circulating system which filtered and recycled water that remained in the tub at all times.

Franzin and colleagues (2001) contributed the other published case of neonatal *Legionella* infection following WB. Their case took place at an Italian hospital where the organism was eventually cultured from hot water tanks and water outlets in both the pool room and patient's room. Although pneumonia symptoms presented at seven days of life, the diagnosis of *Legionella* was not made until the infant was one month old. Intensive antibiotic therapy resolved chest x-ray findings by 3 months of age, and the infant was healthy when examined six months later.

In addition to the two cases of infection with *Legionella*, *Pseudomonas aeruginosa* was implicated in complications of WB in three case reports. Rawal and colleagues (1994) were the first to identify WB as a possible mode of *P. aeruginosa* transmission. They published a case report which described suspected septicemia in a term infant who became cyanotic 11 hours after birth into water at an English facility. *P. aeruginosa* was cultured from the neonatal umbilicus and pinna, as well as from bathwater samples. The infection was attributed to a contaminated water supply. The infant received a seven day course of antibiotics and recovered without long-term sequelae. The case was reviewed by a microbiologist who questioned the diagnosis of septicemia given that neonatal serum, urine and cerebrospinal fluid cultures were sterile (Sanderson, 1994). Furthermore, Sanderson (1994) asserted that *P. aeruginosa* has been cultured from superficial sites on infants without sepsis, and suggested that maternal feces were the source of the organism rather than the water supply.

Parker and Boles (1997) described the second case of *Pseudomonas* infection related to WB. Their case report involved an infant who was born in water at 37 weeks gestation, attended by nurse-midwives in southern California. The infant was diagnosed

with a perforated tympanic membrane, otitis media and bacteremia at 19 days of life. The infant had experienced purulent ear drainage for one week prior to medical evaluation. Cultures of ear drainage were positive for *P. aeruginosa* and *Escherichia coli*. Blood cultures identified *P. aeruginosa* without antibiotic resistance. The infant received antibiotic therapy for two weeks and was healthy when examined one month later. The infection was attributed to contaminated water when cultures of the bathtub filling hose were positive for *P. aeruginosa*.

Vochem and colleagues (2001) described one other case in which IPI was identified as the etiology for neonatal infection with *P. aeruginosa*. The case they published involved a woman who bathed for 30 minutes during early labor at a German hospital. The woman gave birth to a vigorous boy later that day, without additional immersion. The infant was healthy at discharge home on the third day of life. Eleven days after birth he became lethargic and seized. Meningitis and bacteremia were diagnosed when serum, cerebrospinal and conjunctival cultures identified Pseudomonas. The organism was also present in cultures taken from multiple sites in the hospital including the bathtub, shower and sink drain in the patient's room. Additionally, P. aeruginosa was isolated from samples of infant skin creme used in the patient's home. The inpatient shower was determined to be the source of infection when genotyping revealed identical bacterial strains in the neonate's blood cultures and samples taken from the skin creme and shower tubing. Despite immediate and aggressive antibiotic therapy, the infant developed acute hydrocephalus requiring ventriculostomy with external drainage and a ventriculoperitoneal shunt. Symptoms resolved at six months of life and the infant appeared to have normal psychomotor development three months later.

*P. aeruginosa* is one of several pathogenic organisms identified in infection control audit activities, unrelated to adverse patient outcomes (George, 1990; Loomes &

Finch, 1990; Robb, Spiby, Stewart, & Norman, 1991). For example, *P. aeruginosa* was isolated from a water pipe used to fill birthing tubs at an English hospital during routine quality control inspections (Robb et al., 1991). The pipes were autoclaved and subsequent cultures were negative. This type of infection control activity is essential, as evidenced by the case reports described. Although research has not revealed an increased aggregate rate of infection among neonates born to women who bathed during labor or birth, case reports reveal that infection from contaminated water is possible. This may be why Taiwanese midwives use sterile water for IPI provision (Wu & Chung, 2003). This precaution has not been described elsewhere in the IPI literature, which uniformly recommends municipal tap water in developed nations. These case studies should compel continued efforts to ensure hygienic bathing conditions as well as research on the safety of IPI with regard to infection. Furthermore, the case studies indicate that pediatric providers should consider infection with unusual etiologies, like *Legionella* or *Pseudomonas*, when presented with symptomatic babies born in water. *Physiologic Responses to Immersion* 

This discussion will now focus on the physiologic responses to immersion relevant to the childbearing process. Most neonatal effects of immersion are secondary to maternal hemodynamic changes which result from the hydrostatic pressure experienced during IPI.

*Hydrostatic pressure.* Upon entering water we are immediately subject to hydrostatic pressure maintained throughout immersion and directly proportional to the depth and volume of water being used, as well as the percentage of total body area immersed (Katz, McMurray, Berry, Cefalo, & Bowman, 1990; Katz, Rozas, Ryder, & Cefalo, 1992; Katz, Ryder, Cefalo, Carmichael, & Goolsby, 1990). Maximal hydrostatic pressure is experienced when the body is in vertical sitting or standing positions (Kwee et al., 2000). Hydrostatic pressure forces abdominal organs upward toward the

diaphragm and thorax, theoretically decreasing ease of respirations (Zimmermann et al., 1993). However, respiratory discomfort or difficulty has not been mentioned in IPI research. Hydrostatic pressure is also thought to ease forces on the fetal presenting part and has been credited with creating a gentle mode of entry for the newborn (Zimmermann et al., 1993). However, the pressure differential experienced by babies born into water compared to air would be minimal (Zimmermann et al., 1993). Hydrostatic pressure does rapidly force extravascular fluid into the vasculature (Katz, McMurray, Berry et al., 1990; Katz et al., 1992; Katz, Ryder et al., 1990). In non-pregnant women, mobilization of 700 milliliters of fluid has been observed within seconds of becoming immersed (Kwee et al., 2000).

Intravascular volume expansion. When extravascular fluid returns to the vasculature it results in central volume expansion and becomes available for renal elimination (Katz, McMurray, Berry et al., 1990; Katz et al., 1992; Katz, Ryder et al., 1990). Immersion also increases renal blood flow by inducing renal vasodilatation, but does not effect the glomerular filtration rate (Coruzzi, Biggi, Musiari, Ravanetti, & Novarini, 1986; Van Tilborg, Rabelink, Koomans, & 1995). Central hypervolemia and increased renal blood flow result in significant diuresis as well as natriuresis (Coruzzi et al., 1986; Katz, McMurray, Berry et al., 1990). The natriuresis of immersion occurs in both the diluting and proximal sections of the nephron and appears to occur due to a combination of factors including renin-aldosterone suppression, changes in intrarenal blood flow, mechanisms of tubular sodium reabsorption, atrial natriuretic peptide and renal prostaglandin release; as well as decreased sympathetic nervous system activity (Coruzzi et al., 1986; Epstein, 1978, 1992).

This general understanding of the physiologic responses to immersion is consistent with the findings of several investigators who have examined the hemodynamics of immersed pregnant women, although intrapartal changes have not

been specifically studied. Findings have included temporary reductions in blood pressure, increased urine production and output, natriuresis, and resultant decreases in edema (Goodlin, Hoffmann, Williams, & Buchan, 1984; Katz, McMurray, Goodwin, & Cefalo, 1990; Kwee et al., 2000).

These are significant findings given that pregnant women normally experience an increase in total body water content of 6 to 8 liters, 4 to 6 of which is extravascular and contributes to clinically evident edema in eighty percent of pregnancies (DiPasquale & Lynett, 2003). In addition to causing discomfort, edema may reduce tissue elasticity with implications for the occurrence of perineal lacerations during delivery. The relationship between decreased edema and perineal integrity has not been specifically discussed in the IPI literature although Nightingale (1996) empirically noted that "the tissues of the vulva and perineum are softened by the warm water and appear to stretch more easily," adding that "most women experience less perineal pain in water, therefore the delivery is more controlled" (p. 66). Further, improved perineal outcomes have been observed in some studies of IPI (Chinze M. Otigbah Research Registrar et al., 2000; Geissbühler & Eberhard, 2000; Nightingale, 1996).

Placental perfusion. Maternal intravascular volume expansion, as seen with immersion, increases cardiac output and decreases systemic vascular resistance (Strong, 1993). Epstein (1978) and others have suggested that these effects of immersion are equivalent to those following a two liter bolus of fluid delivered via intravenous (IV) catheter (Epstein, 1978, 1992; Khosla & DuBois, 1981; Strong, 1993). IV fluid administration has been observed to result in recurrence of end-diastolic umbilical arterial blood flow as a result of maternal cardiovascular changes and intravascular volume expansion (Strong, 1993). These changes may increase placental perfusion thereby increasing blood flow to the fetus (Strong, 1993). This physiologic mechanism may explain findings that suggest fetal oxygenation is improved during IPI compared to conventional labor and delivery (Chinze M. Otigbah Research Registrar et al., 2000; Geissbühler et al., 2004; Laudanski, 2002; Zanetti-Dällenbach, Tschudin et al., 2007).

In studies of IPI, fetal oxygenation status during labor has primarily been evaluated with intermittent or continuous external electronic fetal heart rate monitoring (EFM), although at least one researcher used continuous EFM via fetal scalp electrode (Eldering & Selke, 1996). Improved fetal oxygenation was associated with IPI as measured with external EFM (Mesrogli, Goeschen, Siefert, Pohl, & Schneider, 1987; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006), as well as fetal scalp sampling and hemoglobin oxygen saturation (Laudanski, 2002).

At birth, Apgar scores are routinely used to assess oxygenation during fetal transition to extrauterine life and have been examined in all studies of WB. Differences were observed only by Geissbuhler and Eberhard (2000) who found that babies delivered underwater had significantly (p<.0001) higher Apgar scores at five and ten minutes compared to those born outside of the water. An alternative Apgar scoring system has been proposed for use among infants born in water, but the complete description with rationale has not yet been obtained by the author for critical analysis (Enning, 2004).

It should be noted that interpretation of Apgar scores is complicated by lack of sensitivity and predictive ability, particularly in term infants and when scores are more than 3 but less than 7 and therefore considered abnormal (American Academy of Pediatrics, 2006; Gradert et al., 1987; Sykes et al., 1982). Middle range scores are not indicative or predictive of neurologic dysfunction and do not have clinical implications unless accompanied by other abnormal findings (American Academy of Pediatrics, 2006). The five minute Apgar score is generally considered more predictive of long term outcomes than the score at one minute, but recent studies confirm that wide variations in

interobserver scoring is possible even at the five minute mark (O'Donnell, Kamlin, Davis, Carlin, & Morley, 2006).

A more precise measurement of fetal oxygenation status following birth is umbilical cord gas assessment, an expensive analysis generally reserved for cases in which neonatal compromise is suspected. However, routine cord gas analyses have been used by several IPI researchers. Statistically significant differences have been observed in umbilical arterial pH (Geissbühler et al., 2004; Schrocksnadel et al., 2003) and carbon dioxide levels (Woodward & Kelly, 2004), as well as umbilical venous pH values (Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006). Findings indicate that babies born in water experience less acidemia than babies born to women who were either immersed during labor but not at the moment of birth, or who were never immersed during parturition. This suggests that physiologic theory accurately represents the effect of immersion-induced central volume expansion on uterine and placental perfusion. Accordingly, fetal parameters other than oxygenation could also be affected by immersion and measurable in research. For example, fetal urine output measured on ultrasound as amniotic fluid indices could be altered (Strong, 1993).

*Amniotic fluid indices.* Amniotic fluid indices (AFI) are assessed as a proxy for uteroplacental sufficiency since decreased placental blood flow to the fetus will result in decreased fetal urine production and output (Cunningham et al., 2005). After the fourth month of gestation, most amniotic fluid is comprised of fetal lung fluid that is swallowed by thoracic movements and subsequently urinated (Cunningham et al., 2005; Johnson, 1996). Oligohydramnios, generally defined as an AFI measurement of 5 centimeters (cm) or less, is a controversial predictor of poor perinatal outcomes since both uteroplacental insufficiency and maternal dehydration may be implicated (Strong, 1993). Other conditions that can result in oligohydramnios include fetal renal pathology and maternal diabetes (Cunningham et al., 2005). Underlying etiology may be more

predictive of poor prognosis than oligohydramnios per se, but lack of amniotic fluid does pose a unique risk to the fetus by several mechanisms. Inadequate AFI can result in pulmonary hypoplasia and growth-restriction among other serious sequelae (Cunningham et al., 2005). Amniotic fluid provides protection against cord compression and trauma, allows for freedom of fetal movement and physical space to accommodate unrestricted growth, and maintains intrauterine temperature regardless of external conditions (Cunningham et al., 2005).

Conventional treatment of oligohydramnios involves increasing placental perfusion by expanding maternal intravascular volume with either oral or IV hydration (Strong, 1993). Since immersion appears to have the same effects on intravascular volume as IV fluid administration, Strong (1993) hypothesized that immersion could be used to increase AFI. He described five women at 27-34 weeks gestation with decreased AFI and significant comorbidities including intrauterine growth retardation, diabetes, hypertension and preterm labor. Immersion therapy was initiated in conjunction with conventional therapies including aspirin, magnesium sulfate, bed rest and oxygen. Significant temporary reversal of oligohydramnios was observed after two days of immersion therapy consisting of 30 minutes in water to the level of the shoulders twice daily. Subjects' average AFI prior to immersion was 4.9 +/- 3 cm, with an average increase of 6 +/- 2.2 cm. When immersion treatment was discontinued for three of the subjects, they experienced a reduced AFI by an average of 4.7 cm, but measurements normalized when immersion therapy was reinitiated. Immersion was credited with prolonging gestation by improving subjects' AFIs and avoiding complications of oligohydramnios that might have necessitated hastened and premature deliveries. As a result of his findings, Strong concluded that immersion may help reverse oligohydramnios resulting from uteroplacental insufficiency but his hypothesis has not

been tested in other studies. Strong's findings support descriptive studies that observed an association between improved fetal oxygenation and IPI.

The effects of water immersion are not limited to hemodynamic changes resulting from hydrostatic pressure. Immersion also directly affects alterations in maternal and fetal physiology due the hydrothermal properties of warm water and the buoyancy experienced during IPI. These alterations in physiology include pain relief and relaxation. *Pain Relieving Qualities of Hydrotherapy* 

*Hydrothermal properties of water.* Water absorbs and maintains heat more effectively than most substances due to its hydrogen component (Brown, 1982). When the human body enters water with higher temperatures, it receives heat through conduction. Prolonged immersion in warm water will result in increased core temperature eventually, but warmth is first distributed to the skin and subcutaneous tissues where sweat glands and superficial capillaries are found in abundance and can disperse excessive heat (Brown, 1982). These glands and vessels are controlled by the sympathetic nervous system which contributes to physiological maintenance and is responsive to psychological input (Brown, 1982). Warm water immersion results in peripheral vessel dilatation and decreased resistance to blood flow, while cutaneous nerve endings experience increased conduction velocity, local tissue metabolism increases and skeletal muscles relax (Brown, 1982). This psychologic and muscular relaxation likely contributes to the pain relieving qualities attributed to hydrotherapy.

*Maternal movement during hydrotherapy.* It is widely believed that maternal position changes in labor minimize pain and facilitate progress by encouraging optimal fetal presentation, lie, descent and cardinal movements through the pelvis and birth canal (Milner, 1988). Women laboring in water without pharmacologic pain relief can freely adopt a variety of postures and positions of comfort (Aderhold & Perry, 1991; Stark et al., 2008). Without analgesic sedation or confusion, anesthetic immobility, uncomfortable

gravitational constraints, or tethering to continuous electronic fetal monitors, women utilizing IPI are generally quite mobile and transition through a variety of positions during labor and delivery (Milner, 1988; Stark et al., 2008). Some the purported advantages of IPI including decreased length of labor, decreased assisted vaginal or operative deliveries, improved perineal outcomes, and decreased severity of labor pain are thought to result from this increased mobility. For example, the hands-and-knees position commonly adopted by women during WL is credited with facilitating optimal fetal rotation from the occiput posterior to occiput anterior position reducing associated back pain, augmentation of labor and assisted vaginal or operative delivery (Aderhold & Perry, 1991; Milner, 1988; Ponkey, Cohen, Heffner, & Lieberman, 2003).

## Intrapartum Pain and Stress

This section will primarily discuss intrapartum stress and review maternal and fetal stress responses. Since pain and stress are inexorably intertwined, particularly in childbirth, pain will be discussed as a physiologic stressor. The physiology of intrapartum pain and its perception will be discussed in a subsequent section on theories of pain.

Stress is defined as a physiologic or psychologic stimulus that provokes a stress response, either acutely or over time (Simkin, 1986). Pain is one of innumerable potential stressors, which can be as benign as an unexpected loud noise or take the form of a serious physical injury (Simkin, 1986). Stressors can be an event which occurs, or an anticipated experience (Simkin, 1986). An individual's response to stressors is dependent on their adaptability and the degree to which they stimulate a stress response (Simkin, 1986). Responses to stress will promote either homeostasis or disease, damage and injury (Simkin, 1986).

In labor, women experience multiple acute stressors including pain, worry, and dramatic physiologic processes (Benfield et al., 2001; Simkin, 1986). The baby indirectly experiences maternal stress while coping with changes in the intrauterine environment

and intermittent hypoxic conditions during uterine contractions (Simkin, 1986). The stresses of labor result in maternal and fetal adaptations that are physiologically beneficial (Lagercrantz & Slotkin, 1986). It is only when excessive stress is experienced that physiologic adaptations become distress (Lagercrantz & Slotkin, 1986; Simkin, 1986). Physiologic theory is currently unable to conclusively demonstrate the point at which labor stress becomes distress, or explain how to maintain a physiologic rather than pathologic condition in labor. However, theory does offer a framework for understanding the continuum of stress and distress during childbirth, and the physiologic mechanisms underlying research findings that maternal pain and anxiety are associated with fetal distress and prolonged or difficult labors (Benfield, 2002; Benfield et al., 2001). Given that conventional treatments for intrapartum pain and anxiety and their sequelae involve pharmacologic, medical and surgical intervention, non-invasive alternatives are desirable. IPI appears to be one efficacious alternative, the study of which requires theoretical grounding in the physiologic experience of pain and anxiety

Proponents of IPI believe that immersion induces relaxation and decreases stress thereby reducing pain and facilitating the normal intrapartum hormonal milieu (Aderhold & Perry, 1991; Church, 1989; Milner, 1988; Rosenthal, 1991). Clinicians have described observing women give audible sighs of relief and relaxation as soon as they entered the bath (Odent, 1997). Quantitative research has documented reductions in reported pain severity and decreased use of pharmacologic pain relief methods among women who utilized IPI (Cluett & Burns, 2009; Declerq et al., 2006). Emerging qualitative research has confirmed these findings but also points to psychosocial factors involved in pain relief provided by IPI including retention of autonomy and control in decision-making and utilization of IPI (Hall & Holloway, 1998; Richmond, 2003b; Wu & Chung, 2003). The psychosocial aspects of pain perception will be discussed in a

subsequent section on theories of pain. The physiologic mechanisms by which IPI confers pain relief and stress reduction will be reviewed as follows.

When humans experience acute stress the sympathetic nervous system is activated and catecholamines are released (Benfield et al., 2001; Simkin, 1986). These stress hormones include adrenaline (epinephrine) and noradrenalin (norepinephrine) which can either stimulate sympathetic nerve endings or directly affect end organs (Simkin, 1986). Catecholamine production is the physiologic adaptive response to acute stress commonly known as the "fight or flight" response. Catecholamines effect physiologic processes in order to facilitate coping and survival during periods of stress (Simkin, 1986).

Fetal stress response. During labor, fetal and maternal catecholamine production differs as is required for optimal physiologic adaptations to intrapartum stress (Gunnar & Quevedo, 2006; Lagercrantz & Slotkin, 1986; Lederman, Lederman, Work, & McCann, 1978, 1985; Simkin, 1986). Adult stress response prepares for action (fight or flight) while fetal stress response creates conditions in which hypoxia can be tolerated. Fetal catecholamine production results in higher levels of noradrenalin and lower levels of adrenalin than would be observed following an adult's response to stress (Gunnar & Quevedo, 2006; Lagercrantz & Slotkin, 1986; Simkin, 1986). Noradrenalin does not increase fetal heart rate or divert blood flow to skeletal muscles the way that adrenaline would. Instead, a vagal response occurs and results in physiologic bradycardia and conservation of oxygen (Lagercrantz & Slotkin, 1986; Simkin, 1986). In addition to conservation of oxygen, fetal stress response prepares a fetus for the work of labor and transition to extrauterine life by increasing the efficiency of oxygen uptake, shunting blood to vital organs, and by mobilizing energy stores to prevent hypoglycemia even when maternal blood sugar levels are low. After birth, fetal catecholamines result in dilated pupils and initial alertness, likely adaptive mechanisms to facilitate breastfeeding

and bonding. Additionally, the stress hormones facilitate thermoregulation through heat production, and increase absorption of lung fluid as previously discussed.

IPI enthusiasts believe immersion optimizes fetal tolerance of labor and transition to extrauterine life, but few differences have been observed in studies of neonatal outcomes following WB compared to conventional birth. Nonetheless, IPI is promoted as facilitating a gentle birth and clinicians report that babies appear unusually calm and relaxed (Burns & Greenish, 1993; Sinquefield, 1989). Anderson (1992) remarked that appearances can be deceiving, noting that "babies in this situation [submerged] *seem* peaceful enough, but that is no guarantee that they are not experiencing discomfort. Extreme passivity is a common response to severe stress in the newborn; some babies appear to 'sleep through' circumcision" (p. 110).

Objectively measuring fetal stress following emergence in water is difficult, in part because fetal stress response during pregnancy, labor and conventional delivery is not well understood (Anderson, 1992). Objective measures require serum samples for hormonal assay. Such samples have been obtained from umbilical cord blood but require clamping and cutting the cord immediately after birth, before the physiologic benefits of delayed clamping are conferred (Hutton & Hassan, 2008). Otherwise, veinipuncture becomes necessary, which could induce an acute stress response and alter findings. In studies of adults, indwelling catheters are used to collect serum specimens after the stress associated with needles has diminished. This is not possible in newborn subjects.

Two investigators have used umbilical cord blood to examine neonatal stress hormones following WL and WB (Forrister, 2007; Gradert et al., 1987). In an unpublished New Hampshire study, umbilical cortisol levels were examined in 40 babies born in water compared to 40 born in air; no significant differences were found (Forrister, 2007). Cortisol, a glucocorticoid, may not be the best biochemical marker of an acute

stress response, as occurs with intrapartum events like WB. For this reason, most research on neonatal cortisol has been informed by theories of chronic stress, including psychoneuroimmunology and allostasis.

Research findings suggest that baseline fetal cortisol levels rise and fall at predictable intervals during normal pregnancy and are consistently and sharply increased during the last month of gestation (Murphy, 1982). At term, cortisol and androgen are secreted from the fetal hypothalamus and adrenal glands, and result in prostaglandin synthesis and increased placental estrogen which contribute to labor onset (Simkin, 1986). The circadian rhythm of cortisol secretion observed in adults is not established until 3 months of life (Gunnar & Quevedo, 2006). Prior to three months of age, infants have cortisol peaks every 12 hours regardless of time of day or sleep patterns, but when this begins is not well established (Gunnar & Quevedo, 2006). Mean serum cortisol measurement in term fetuses is 45.1 ng/mL, an amount that doubles during normal labor (Murphy, 1982). A reference range for cortisol levels in infants from birth to 2 years old was developed recently, with normal values of <28-966 mmol/liter (Soldin, Hoffman, Waring, & Soldin, 2005). This large reference interval speaks to gaps in physiologic understanding of optimal cortisol levels during early infant development.

Interpreting specific cortisol measurements in individual infants proves difficult because values at both ends of the reference range may be problematic. Since stress response is adaptive, both diminished and excessive stress responses may be detrimental. It appears that exposure to stress during gestation and birth may alter the hypothalamic-pituitary adrenal (HPA) axis during fetal programming, thereby affecting subsequent HPA axis function and reactivity to stress (Kajantie, 2006; Mears, McAuliffe, Grimes, & Morrison, 2004; Miller, Fisk, Modi, & Glover, 2005; Rothenberg et al., 1996; Vogl et al., 2006; Wust, Entringer, Federenko, Schlotz, & Hellhammer, 2005).

During gestation, fetal stress is mediated by maternal physiology and biochemistry. Maternal stress hormone levels during pregnancy predict excessive HPA axis activity in offspring (Kajantie, 2006). This finding has implications for life-long health given that increased HPA axis activity is associated with disorders including depression, post-traumatic stress syndrome, chronic pain and fatigue, and will likely be implicated in a host of other diseases as this area of inquiry evolves (Kajantie, 2006).

Stress response has also been examined at the end of gestation in relationship to intrapartum events and mode of delivery. In neonatal studies, umbilical cortisol levels are highest after forceps and vacuum assisted births, followed by spontaneous vaginal births (Gitau et al., 2004; Mears et al., 2004; Miller et al., 2005; Vogl et al., 2006). Elective cesarean birth is associated with the least response. Medically necessary cesareans have generally been excluded from analyses. Interpretation of these findings is limited by weaknesses in study design and methodology. For example, high levels of umbilical stress hormones observed after an instrumental vaginal birth would likely reflect both the stressful indication for expedited delivery as well as the fetal experience of extraction. Measurement of neonatal stress hormone concentrations in the immediate postpartum period cannot adequately explicate the dynamic hormonal milieu of parturition, and has precluded adequate differentiation between the effects of stressful events during labor and those related to the mode of delivery.

Data derived from research in the immediate postpartum period have been complemented by examinations of stress in early infancy. Researchers have examined infant stress responses related to pain from circumcision and vaccination. This has significantly advanced the understanding of perinatal stress and sequelae. For example, investigators have observed increased pain behaviors during vaccination at four to six months of life among circumcised infants compared to uncircumcised infants (Taylor, Fisk, & Glover, 2000). This finding, and data from animal models, has suggested that

early experiences of pain are associated with development of stress reactivity. Since birth is likely to be an infant's most significant experience, and the one with greatest potential for stress or pain, researchers have sought to explore the relationship between neonatal stress hormone levels at birth and subsequent pain behaviors. Taylor, Fisk and Glover (2000) found that the duration of crying after vaccination injections at eight weeks of life is related to mode of delivery. Greater distress during inoculation was observed among infants after assisted vaginal birth (n=20) compared to spontaneous birth (n=46). Crying times were shortest among babies born by elective cesarean (n=10). Pain behaviors were closely correlated with neonatal salivary cortisol measurements, but not maternal Edinburgh postnatal depression scale scores which were similar among study groups. These finding support the theory that early experiences of stress and pain contribute to HPA axis programming and alter subsequent stress reactivity (Rothenberg et al., 1996; Taylor et al., 2000; Wust et al., 2005).

It is difficult to interpret findings from perinatal stress research since little is known about optimal hormone levels in newborns, particularly at term. The preponderance of research on neonatal cortisol levels has taken place with premature infants in studies of mechanisms by which chronic stress contributes to premature birth. Although there is no published research on newborn cortisol concentrations following WB, unpublished data previously mentioned would be useful to have for with future investigations. Minimally, collecting umbilical cord blood for cortisol measurement in term newborns following WB would add to theory development and become increasingly useful as our understanding of fetal stress response evolves.

There are few alternatives to cortisol for the evaluation of fetal stress response and optimal neonatal transition to extrauterine life. Other stress hormones are possibilities for further exploration but they are as poorly understood and may be more difficult or expensive to obtain and analyze. Gradert (1987) prospectively measured and

analyzed umbilical arterial blood concentrations of noradrenalin and adrenalin, as well as the corticosteroid Beta-endorphin, for 13 babies born to women who used hydrotherapy during the first stage of labor and 9 babies born to women who did not; no differences were observed in this small sample. Replication of this study in a larger sample following WB could be interesting given that noradrenalin and adrenalin are released during acute stress. Fetal catecholamine levels, particularly noradrenalin, normally increase ten-fold during the stress of labor (Eldering & Selke, 1996; Johnson, 1996; Simkin, 1986). They may be more reflective of intrapartum events than cortisol, which is implicated in response to both acute and chronic stress. Future examinations of fetal catecholamine concentrations following WB would reflect the theoretical understanding of labor and birth as acute rather than chronic events, and could also contribute to explication of protective versus maladaptive intrapartum stress response (Melzack, 1993).

*Maternal stress response.* In early labor, when a woman is calm and not experiencing severe pain, catecholamine concentrations are similar to those observed during late pregnancy (Simkin, 1986). As labor progresses, catecholamine levels rise in relationship to pain and anxiety (Lederman, Lederman, Work, & McCann, 1985; Simkin, 1986). Anxiety is a psychological stressor involving fear, apprehension and tension resulting from an expectation of discomfort, distress or danger (Benfield, Herman, Katz, Wilson, & Davis, 2001). Pain is a physical sensation that involves suffering and can contribute to anxiety, but will be explored in the subsequent discussion of pain theory.

When intrapartum anxiety and pain result in an excessive stress response, negative effects on labor progress and fetal condition are observed (Lederman et al., 1985). Adrenalin, noradrenalin and cortisol levels are correlated with progress of labor, or lack thereof (Lederman et al., 1985). Although adrenalin and noradrenalin both increase with pain, anxiety and physical exertion, adrenalin is more strongly associated

with anxiety while noradrenalin levels are primarily predicted by physical exertion (Lederman et al., 1985). Both hormones have vasoconstrictive properties with implications for fetal oxygenation via placental circulation (Lederman et al., 1985). For example, high levels of maternal adrenalin are significantly correlated with nonreassuring fetal heart rate observations and abnormal umbilical cord blood pH, as well as maternal subjective reports of anxiety (Lederman, Lederman, Work, & McCann, 1978; Simkin, 1986). Elevated adrenalin levels are also predictive of poor uterine contractility and prolonged labor via beta-adrenergic receptor stimulation (Lederman et al., 1978). In contrast, noradrenalin has the opposite relationship to progress in labor, which is consistent with the physiologic understanding that noradrenalin does not increase heart rate or divert blood flow to skeletal muscles the way that adrenalin does. Noradrenalin may actually increase central blood flow and improve uterine contractility (Lederman et al., 1978). In summary, increased maternal adrenalin and cortisol concentrations are antagonistic to normal progress and fetal tolerance of labor while noradrenalin appears to facilitate normal parturition (Lederman et al., 1978). However, the theoretical understanding of stress hormones' effects on parturition may not apply to all phases of labor or specific clinical scenarios. For example, it has been hypothesized that the effects of adrenalin differ in advanced labor compared to early labor. Adrenalin is thought to be responsible for adaptive "physiologic fear" that results in the final phase of the fetal ejection reflex first described by Newton and colleagues in 1966 (Newton, 1987; Odent, 1987).

The theoretical understanding of the effects of stress hormones on intrapartum physiologic processes is further advanced by studies of the relationship between mode of delivery and maternal stress response. As was observed in neonatal examinations, maternal cortisol concentrations are lowest after elective cesarean and highest after assisted vaginal birth (Vogl et al., 2006). Middle range neonatal and maternal cortisol

values observed subsequent to spontaneous vaginal birth suggest that moderate stress hormone concentrations reflect the adaptive, physiologic mechanisms of uncomplicated parturition. However, interpretation of the correlations between neonatal and maternal cortisol levels and mode of birth become more complex when epidural analgesia is controlled for in analyses. Among women who experience spontaneous vaginal birth, epidural analgesia is associated with significantly lower cortisol levels than are observed after unmedicated labor. In contrast, concentrations of fetal stress hormones are significantly higher after labor and birth with epidural analgesia compared to unmedicated childbirth. Inadequacies of data and physiologic theory make evaluation and interpretation of these findings difficult. The optimal multifactorial balance of stress hormones within the maternal-fetal dyad has not yet been established.

Physiologic understanding of the maternal-fetal hormonal milieu could be advanced with measurements of maternal stress response following IPI (Benfield, 2002; Benfield et al., 2001). Data are currently limited to a small RCT performed by Benfield and colleagues (2001) who measured urinary catecholamines among women who were either assigned to conventional care or one hour of immersion hydrotherapy during active labor. No significant differences in hormone concentrations were observed although bathers (n=9) had significant decreases in self-reported anxiety (p=.03) and pain (p=.03) compared to non-bathers (n=9), when assessed 15 minutes into the study. Bathers reported an average decrease in pain of 24.5 mm using a visual analog scale. In contrast, non-bathers reported a 8 mm mean increase in pain scores during the study period. Although this study is unique in its focus on maternal stress response to IPI, several others have examined catecholamine concentrations during immersion outside of parturition. Reductions in norepinephrine and epinephrine have been observed during immersion with and without exercise (Grossman, Goldstein, Hoffman, Wacks, & Epstein, 1992; Norsk, Bonde-Petersen, & Christensen, 1990).

Continued measurement of maternal stress hormones before, during and after intrapartum immersion would contribute to the physiologic understanding of parturition. This could advance efforts to prevent maladaptive stress response in both women and children, since maternal hormone concentrations are correlated with neonatal findings. Furthermore, postnatal maternal cortisol levels are positively correlated with fearful behavior in breastfed neonates suggesting a continued interplay between maternal and neonatal biochemistry even after delivery (Glynn et al., 2007).

Any discussion of maternal stress and pain in labor must include endorphins and enkephalins, neuropeptides that alter pain perception during particularly stressful situations (Marieb, 1991). Enkephalin activity is particularly pronounced during labor, although both neuropeptides increase during exercise and can result in a "runner's high" (Marieb, 1991). Endorphins and enkephalins are natural opiates that diminish the experience of pain and have amnesiac properties (Marieb, 1991). Neuropeptide secretion in labor is enhanced in women who are unmedicated and physically fit (Trout, 2004). Effective pain medication decreases pain and concomitant endorphin levels. Pain medications may also be sedating and diminish endorphin production related to the "exercise" of labor. In light of this, women who utilize IPI may have higher endorphin levels than women who utilize pharmacologic pain relief methods. High endorphin concentrations may be optimal, especially if effects persist in the postpartum period when women experience pain and fatigue, and sedation from pain medications can interfere with bonding, breastfeeding, ambulation and recovery from childbirth (J. Johnson & Odent, 1994).

Summary of hydrotherapy effects on pain and stress. The pain relieving qualities of immersion have been conclusively demonstrated in numerous RCTs during labor, and clinicians have empirically noted that laboring women are more relaxed in water (Cluett, Nikodem, McCandlish, & Burns, 2004; Odent, 1983). However, biophysical research on

specific mechanisms of IPI pain relief and stress reduction has been limited and inconclusive. Neither maternal nor fetal stress hormones have been observed to differ following WB compared to conventional birth (Benfield et al., 2001; Forrister, 2007; Gradert et al., 1987). Theoretical mechanisms of anxiolytic and pain relieving effects of immersion include the hydrothermal properties of water, the buoyancy and ease of movement experienced during submersion, maternal relaxation and reduction of muscular tension. A subsequent review of pain theory will discuss additional mechanisms including hydrotherapy as a distracting and competing nerve stimulus. Pain relief and relaxation experienced during immersion is likely involved but not exclusively responsible for other IPI research findings, including decreased labor lengths and reduced rates of medical intervention. With pain relief comes relaxation and facilitation of physiologic parturition since some stress hormones are antagonistic to labor progression and can result in fetal compromise. The physiology and biochemistry of labor will be discussed further.

## Physiology and Biochemistry of Labor

Obstetric theorists have not yet come to consensus about the physiologic processes responsible for initiation of labor. Major hypotheses include a) maternal cessation of pregnancy maintenance, b) maternal uterotonin induction of labor, and c) fetal initiation of parturition (Cunningham et al., 2005). Although these distinct hypotheses have been articulated, it is likely that a combination of factors is involved in the onset of labor. Several factors have already been discussed, including elevation in fetal androgen and cortisol concentrations at term. Another factor is the Ferguson reflex which is involved in both the clinical onset of labor and progression of established labor. The reflex involves fetal pressure on the cervix which results in manual cervical dilation and uterine contractions. It has been theorized that cervical pressure results in uterine contraction by stimulating maternal oxytocin (OT) release but this physiologic

mechanism has not been demonstrated in research. Instead, digital manipulation of the cervix and fetal membranes has been observed to induce increased serum prostaglandin  $F_{2\alpha}$  metabolite which may contribute to uterine contractility. Complete explication of the physiology involved in labor onset will require much additional data, including inquiry into the effects of immersion on cervical pressure exerted by the fetus, which has not been conducted to date. Physiologic theory is better developed with regard to the physiologic mechanisms of established labor and will be reviewed briefly.

When fetal cortisol and androgen stimulate placental estrogen, maternal progesterone levels plateau or decrease and the uterus begins to contract. With increased estrogen levels, prostaglandins are released and exert a direct effect on the smooth muscle of the uterus. Once the uterus is prepared by prostaglandins, OT is produced and then bound to uterine receptors markedly increasing uterine contractility. Progressive labor involves uterine contraction and cervical dilation. At the cellular level, uterine contraction depends on nervous and hormonal excitation of the organ's smooth muscle cells (Wray, Kupittayanant, Shmygol, Smith, & Burdyga, 2001). Physiologic theory has not yet integrated a complete framework for understanding uterine contractility at the cellular level (Wray et al., 2001). For example, pacemaker activity in the myometrium remains unclear; that is, whether some or all of the myometrial cells have pacemaker function (Wray et al., 2001). However, research in this area is ongoing and promises to advance physiologic theory. The electrophysiologic differences among types of uterine muscle fibers at varied gestational ages have recently been demonstrated, and uterine electrical activity can be observed and recorded using electromyography (Wray et al., 2001). This technology is being used in an ongoing study of the ways in which immersion effects uterine contractility, results of which will significantly inform the physiologic theoretical underpinnings of IPI (Benfield, Newton, & Hortobagyi, 2007).

To date, discussion of the physiologic theory involved in labor progression in water centers around OT, the primary hormonal determinant of uterine contractility (Brown & Grattan, 2007). OT is produced in the hypothalamus and released from the posterior pituitary. In addition to uterine contraction, OT is responsible for female orgasm and male ejaculation as well as breast milk let-down. Johnson and Odent (1994) have described OT as the "love hormone" given research indicating it facilitates bonding, social interaction, communication and cultural participation (Block, 2007). Normal OT production, release and uptake contribute to the emotional connection between friends, the intoxication experienced by lovers, and the intimate bonding between a mother and her child (Block, 2007; Brown & Grattan, 2007). Disregulation of OT can disrupt the normal processes of social connection in intimacy or community, and may be implicated in conditions ranging from impaired maternal-child bonding to autistic spectrum disorders (Block, 2007).

Maternal-child bonding is evidenced by specific maternal behaviors in the postpartum period across mammalian species, including close proximity and touch (Feldman, Weller, Zagoory-Sharon, & Levine, 2007). In humans, maternal bonding behaviors associated with attachment include gazing, "baby talk" vocalizations, smiles and positive expression as well as adaptation to infant expressions (Feldman et al., 2007). In both animal and human models, postpartum maternal bonding behavior has significant long-term effects on the neurobehavioral, cognitive and social-emotional growth of infants, including the capacity to form meaningful relationships throughout life (Feldman et al., 2007). In animal models, deficits in maternal bonding behavior were correlated with decreased maternal OT levels (Feldman et al., 2007). Additionally, individual variations in OT receptors observed in female voles were associated with the maternal behaviors experienced as pups as well as the bonding behaviors provided to

their own young (Feldman et al., 2007). This points to a cross-generational effect of OT on maternal-infant bonding (Feldman et al., 2007).

Research on human OT and bonding is limited but demonstrates that early parental neglect reduces peripheral OT levels (Feldman et al., 2007). Intranasal OT administration among humans increases trusting behavior (Feldman et al., 2007). Peripherally measured OT is associated with empathy and trust and is released with human maternal-infant closeness and touch following birth (Feldman et al., 2007). Postpartum maternal bonding behaviors are predicted by OT levels during pregnancy and the postpartum period. Maternal bonding behavior is positively associated with OT and negatively associated with cortisol levels given the inverse relationship between these hormones (Feldman et al., 2007). In light of this human research, OT is implicated in the initiation of maternal-infant bonding, probably through mechanisms of reduced stress, increased trust and the integration of physiologic and psychologic states that facilitate calmness and closeness (Feldman et al., 2007).

The emerging understanding of the relationship between OT and stress hormones stimulates questions about modern maternity care in which a significant number of women experience obstetric interventions associated with increased stress response (Declerq et al., 2006; Martin et al., 2008). Similarly, a re-evaluation of the widespread use of synthetic OT is compelled by research revealing the hormone's profound and wide-ranging effects. The majority of women who give birth in the US received exogenous OT for induction or augmentation of labor, and/or as prophylaxis against postpartum hemorrhage (Declerq et al., 2006; Martin et al., 2008). For example, in a study of women who gave birth in the US in 2005, 27% were induced with Pitocin and 55% received Pitocin to augment the progress of spontaneous labor (Declerq et al., 2006). National birth certificate data indicate that at least one-quarter of inductions that occurred in the US in 2004 had no discernable medical indication and that inductions of

labor have doubled in the US since 1990 (Martin et al., 2006). Inductions of labor are associated with increased rates of cesarean delivery, particularly among nulliparous women, regardless of cervical ripening prior to induction (Martin et al., 2007; Vahratian, Zhang, Troendle, Sciscione, & Hoffman, 2005; Vrouenraets et al., 2005). Of note, the US cesarean rate is at an all-time high; 31.1% of childbearing women experienced abdominal delivery in 2006 which represents a 50% increase since 1996 (Martin et al., 2008). In addition to increased operative deliveries, synthetic OT administration may increase the subjective experience of labor pain and use of pharmacologic pain relief methods as well as other medical interventions including intrauterine pressure catheters, external or internal continuous electronic fetal monitoring, and oxygen administration (Cunningham et al., 2005; Enkin et al., 2000). Furthermore, researchers are beginning to explore the direct effects of synthetic OT administration on endogenous OT levels, as well as the theoretical maternal and neonatal sequelae of these altered levels.

If IPI enthusiasts are correct and IPI effectively facilitates physiologic birth, OT administration would be reduced with immersion. The primary theoretical mechanism by which this could occur is reduction of stress hormones and resultant labor dystocia. This is evidenced by several studies in which the length of labor was reduced with immersion, particularly for first time mothers (Aderhold & Perry, 1991; Aird, Luckas, Buckett, & Bousfield, 1997; Burke & Kilfoyle, 1995; Chinze M. Otigbah Research Registrar et al., 2000; Coe, 1997; Geissbühler & Eberhard, 2000; Helwig et al., 1996; Thoeni et al., 2005; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006). Similarly, research has revealed that labor augmentation with Pitocin and/or amniotomy is more commonly required among women who do not use IPI compared to women who are immersed during the intrapartum period (Burke & Kilfoyle, 1995; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006). Additionally, several investigators observed less postpartum blood loss following birth underwater, indicating that circulating OT levels

were sufficient to stem blood flow via uterine contraction around arterioles at the placental site (Bodner et al., 2002; Geissbühler & Eberhard, 2000). This finding indicates that uterine contractility in response to endogenous OT present after WB supersedes the theoretical risk of increased blood loss following IPI due to dilated vasculature and uterine atony in warm water (Zimmermann et al., 1993).

Furthermore, emerging research has compared the effect of IPI with that of Pitocin administration for labor dystocia (Cluett, Pickering, & Brooking, 2001; Cluett, Pickering, Getliffe, & St George- Saunders, 2004). Cluett and colleagues (2004) examined 99 primiparous women experiencing protracted labor, 49 of whom were randomized to WL instead of conventional treatment with amniotomy and Pitocin administration. Women randomized to WL were significantly less likely to require Pitocin or amniotomy to achieve delivery, and were less likely to receive any medical intervention (Pitocin, amniotomy, epidural or operative delivery). Length of labor and operative delivery rates did not differ among groups indicating that Pitocin and immersion were essentially equally efficacious in resolution of labor dystocia. However, women randomized to IPI reported significantly less pain and were more satisfied with the freedom of movement and privacy afforded by their treatment compared to those who received standard care. This study reinforces the physiologic theoretical basis for associations between IPI, pain reduction and optimal physiologic childbirth.

There are at least two alternative or additive physiologic explanations for hypothesized increased endogenous OT related to IPI. First, tubs are often filled to the level of the nipple where stimulation may occur as water moves in response to maternal position changes or in jetted tubs (Aderhold & Perry, 1991; Balaskas & Gordon, 1990). Nipple stimulation increases endogenous OT levels and uterine contractility, as observed with nipple stimulation induced contraction-stress tests of fetal well-being or during the milk let-down reflex (Cunningham et al., 2005). Secondly, after WB babies are

generally kept in their mother's arms with their heads above the water's surface while their bodies remain submersed for purposes of thermoregulation. This skin-to-skin contact increases endogenous OT production and facilitates bonding (Feldman et al., 2007).

In summary, OT is the primary determinant of labor progress and is implicated in the neuroendocrinological foundation of human affiliation (Cunningham et al., 2005; Feldman et al., 2007). Administration of exogenous OT has demonstrable and theoretical risks, including intrapartal fetal distress, increased obstetric intervention, suboptimal postpartum maternal-fetal bonding, and the potential for disruption of social learning and behavioral development in children (Wahl, 2004). If IPI could safely reduce the need for intrapartal OT administration, associated risks could be avoided. Physiologic theory provides explanations for how this could occur, and should be tested in future IPI examinations. Specifically, IPI researchers could consider measuring serum OT concentrations in women and children during and after WL and WB, for comparison to non-immersed control groups who did and did not receive synthetic OT. Long-term follow-up would be informed by, and contribute to, relevant developments in physiologic theory.

## Summary of Physiologic Theory Related to Intrapartum Hydrotherapy

The numerous maternal and neonatal physiologic processes involved in parturition are complex, inter-related and poorly understood. Alterations in several of these physiologic processes have been observed during IPI research, while additional effects of IPI remain theoretical. The most profound physiologic effects of immersion are related to alterations in the maternal circulatory system. The hemodynamic changes primarily result from the hydrothermal properties of water and hydrostatic pressure experienced during immersion. These physiologic processes and effects are summarized in Table 2-1 and Table 2-2.

The effects and outcome measures found in both tables illustrate the complex and multifactorial physiologic processes involved in parturition and immersion. As indicated, improved placental perfusion and resultant increases in uterine contractility and fetal oxygenation are attributed to central volume expansion caused by hydrostatic pressure, as well as sympathetic nervous system control of superficial glands and vessels exposed to the hydrothermal effect of warm water immersion. These types of inter-related and dynamic biochemical and biophysical processes are involved in every aspect of IPI, although the degree to which physiologic theory and data have explicated these processes varies.

Gaps in physiologic understanding include the mechanism(s) by which blood pressure is reduced during immersion. This effect, which may be involved in the relaxation typically experienced during hydrotherapy, is theorized to result from central nervous system suppression but is poorly understood due to limitations of existing data. Similarly, data indicate that the reduction in adrenalin concentration during immersion is involved in the optimal progress of labor observed during immersion. However, physiologic theory posits that endogenous OT concentrations and maternal postures may also be involved and should be examined in future research. Additional theoretical hormonal effects of IPI include higher endorphin and enkephalin concentrations than are associated with pharmacologic pain relief methods. The demonstrable and theoretical physiologic benefits of IPI must be weighed against several maternal and neonatal risks associated with the practice.

Ellology	Hydrostatic pressure		
Physiologic	Maternal intravascular volume	expansion.	
processes	Increased maternal cardiac ou	utput.	
	Decreased maternal systemic	vascular resistance.	
	Vasodilatation with improved n	naternal renal and uterine blood fl	OW.
Effects	Maternal diuresis.	Improved uterine contractility.	Improved placental perfusion
Outcome	Reduced edema.	Shorter labors.	Reassuring EFM.
rneasures	Maternal comfort.	Reduced augmentation.	Higher Apgar scores.
	Improved perineal outcomes.	Resolution of labor dystocia.	Improved umbilical gasses.

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Outcome Reduced labor measures augmentation.		· Shorter labors.	Improved uterine contractility.	Increased blood	Pain relief and de	Effects Skeletal muscle	processes <sup>1</sup> Sympathetic nen	· Warmth is distrib	Etiology Hydrothermal pro	
SCOTES.	Higher newborn APGAR	· Reassuring EFM.	Improved placental perfusion.	flow to the uterus.	ecreased stress response.	relaxation.	/ous system involvement.	uted to the skin and subcutaneous tiss	perties of water	
	Reduced adrenalin and noradrenalin.	•	Comfort and relaxation.					Ues.		

Table 2-2. Effects of intrapartum immersion related to the hydrothermal properties of water.
The primary risks of IPI include maternal and neonatal infection, and neonatal bathwater aspiration and drowning. Review of related physiology has offered a framework for understanding why these potential harms do not pose increased aggregate maternal or neonatal risks during WB compared to conventional birth, provided that IPI utilization is restricted to healthy parturients who are closely monitored. The dilutional effect of bath water may prevent maternal and neonatal infection assuming that an uncontaminated water supply is available for use. Further research is required to address gaps in physiologic understanding related to bath water dilution of organisms implicated in patient-provider transmission of infection and optimal colonization of the newborn gut with maternal recto-vaginal flora. Physiologic theory is better specified regarding immersion and neonatal drowning. Although both fresh water and respiratory drowning are possible, adequate monitoring of fetal well being and water temperature regulation lessen these risks. In the absence of fetal hypoxia, bath water inhalation is suppressed by a variety of physiologic mechanisms, particularly when water temperature is consistent with normal maternal body temperature.

In summary there are a variety of areas ripe for physiologic inquiry regarding immersion during parturition. Existing data suggest that IPI, when used appropriately and in healthy populations, facilitates optimal physiologic processes during labor and birth. Future examinations are required to strengthen theoretical support for the practice. Examinations will likely be aided by grounding in pain theory in addition to the physiologic framework provided. Since pain relief is a primary effect of IPI, pain theory will be explored in detail.

# Gate Control and Neuromatrix Theories of Pain

Most expectant women plan to manage and reduce childbearing pain with coping strategies and either medications or non-pharmacologic pain relief methods including IPI. Multiple RCTs have observed reductions in use of pharmacologic pain relief

methods among women who labor in water (Benfield et al., 2001; Cluett, Pickering et al., 2004; Iker, 1993; Rush et al., 1996; Waldenström & Nilsson, 1992). Limited qualitative data also suggest that IPI alters the maternal experience of labor (Hall & Holloway, 1998; Wu & Chung, 2003). The most recent Cochrane Collaboration review of RCTs involving IPI asserts that pain relief is the only effect conclusively demonstrated in the literature (Cluett, Nikodem, McCandlish, & Burns, 2004). Although one can argue that this position is difficult to defend given the larger body of descriptive literature, pain relief is a primary and important effect of IPI worthy of further discussion. As such, pain theory will be reviewed.

Labor pain primarily originates in the cervix and uterus where dilation and contraction result in transmissions to the thalamus where pain is interpreted (Cunningham et al., 2005; Marieb, 1991). The cervix is innervated with small A delta fibers which conduct pain sensations that are sharp in quality. The uterus contains larger C fibers that primarily transmit dull and aching sensations of pain. Additional painful stimuli originate in distension of the birth canal and perineum where visceral C fibers and cutaneous tissue A delta fibers are located.

Although pain in childbirth is the norm, not every woman experiences childbearing as painful. Some women describe pleasant, positive or even sexual sensations (Davis-Floyd, 2003; Gaskin, 1990; Trout, 2004). One explanation for this finding is the relationship between pain and anxiety previously discussed. Pain is typically accompanied by anxiety related to cognitive understanding of pathologic etiology (Benfield et al., 2001; Trout, 2004). However, the pain associated with childbearing is unique in that it does not indicate a disease process is occurring (Trout, 2004). Recognition of this, and prenatal preparation aimed to reduce pain in labor by diminishing anxiety, has been found to be only marginally efficacious (Melzack, 1993). Clearly anxiety and stress are not the only determinants of childbearing pain. Despite

physiologic processes shared by childbearing women there are perplexing variations in the intrapartum sensations reported, as well as the choices made about intrapartum pain relief methods and responses to such methods (Melzack, 1993; Trout, 2004).

The physiologic frameworks reviewed thus far fail to provide a satisfactory theoretical understanding of these findings (Melzack, 1993). Accordingly, this section will explore and critique Melzack's Neuromatrix Theory of Pain which arose from the seminal Gate Control Theory of Pain (GCTP). These theoretical frameworks will be examined for utility in research on the effects of IPI for use in addition to the physiologic foundation previously established. The discussion of these pain theories will be informed by the method of theory critique described by Meleis (2007). Areas of exploration will include theory origins, utility, significance, circle of contagiousness, congruence with personal and professional values, and relationships between theoretical structure and function (Meleis, 2007).

# Gate Control Theory of Pain

*Origin, description and usefulness.* The GCTP was first described in a 1965 issue of the journal Science (Melzack, 1999a, 1999b; Melzack & Wall, 1965). Prior to this publication the conceptualization of pain was limited by simple neurophysiologic theoretical underpinnings described in specificity theory (Melzack, 1999b; Trout, 2004). Physical pain was believed to originate from the activation of nociceptors which are specific pain receptors in the periphery of the body (Trout, 2004). A simple sensory stimulus-response model represented the conceptualization of pain at that time (Trout, 2004). Within the conceptual model, neural signals of pain were thought to travel from nociceptors to the brain along spinal neural pathways, and the brain's role was limited to responding to the ascending afferent sensory inputs from the periphery (Trout, 2004). The GCTP radically altered this conceptualization by demonstrating that during pain transmission from peripheral nerves through the spinal cord, signals were modulated at

both the level of the neuron and brain (Dickenson, 2002). The factors affecting modulation were viewed as "gates" which could be "closed" to effectively disrupt or alter the transmission and experience of painful stimuli. After the GCTP was described, medical and biological sciences began to view the nature and perception of pain as more complex than simple neural transmissions along a nerve pathway (Trout, 2004). Understanding of brain function was also informed and a new view of the brain was developed in which inputs were actively filtered, selected, modulated and interpreted (Melzack, 1999b; Trout, 2004). Understanding of the dorsal horn also shifted from that of "passive transmission stations" to one of dynamic activity involved in the perception of pain (Melzack, 1999a). As a result, scientists could no longer view pain as an exclusive phenomenon of the body's periphery (Melzack, 1999a).

Although Melzack and Wall's conceptualization of the GCTP included specific regions and activity in the spinal cord and brain, the diagram accompanying the written description did not adequately represent this (Melzack & Wall, 1965). In their simple but effective diagram the brain and spinal column are represented as central control although the large and small nerve fibers of the substantia gelatinosa are represented, as are their inhibition and excitation of neural transmissions (Melzack & Wall, 1965). Although not comprehensive or sufficiently detailed, the diagram supported explanations of the theory in the text and reinforced the clearly defined and consistent relationships between components and concepts within the theoretical model (Meleis, 2007; Melzack & Wall, 1965).

The theory had implications for clinical practice in addition to research. Clinicians incorporated the model's recognition of psychological influences on pain perception and began exploring new pain control methods (Melzack, 1999a). The practice of surgically cutting neural pathways to interrupt pain signal transmissions declined as other methods of sensory modulation were employed (Melzack, 1999a). For example, physical

therapists and other providers including midwives, began using transcutaneous electrical nerve stimulation for both acute and chronic pain with the newfound recognition that electricity was one of multiple interventions that could modulate the transmission, reception and recognition of pain and its intensity (Melzack, 1999a).

Furthermore, the GCTP made profound contributions to the state of the science in pain research and management through the work of clinician and researcher John Bonica (Melzack, 1999a). Bonica was inspired to articulate the GCTP as rationale for researching pain as a unique syndrome warranting specialized inquiry and funding (Melzack, 1999a). Bonica's work resulted in his establishment of the International Association for the Study of Pain and the peer-reviewed journal *Pain* (Melzack, 1999a). By the mid-1970's almost every major medical and biological textbook presented the GCTP indicating that its circle of influence was large, as was its significance and utility in research, clinical and educational realms (Melzack, 1999a). This widespread use satisfies Meleis' (2007) final test of theories that requires adoption and use by scientists other than the author(s).

*External components.* The GCTP arose from collaboration between professional colleagues and friends. Although not interdisciplinary, Melzack and Wall's collaboration demonstrates an essential component of sound theory building and research, as well as congruence with nursing's professional values, this author's personal values and socially valued cooperation (Meleis, 2007). The profound impact of the GCTP on understanding pain perception in research, clinical care and education demonstrates its social significance (Meleis, 2007).

#### Neuromatrix Theory of Pain

*Origin, description and usefulness.* The Neuromatrix Theory of Pain (NTP) was conceptualized by Ronald Melzack as an extension and expansion of the GCTP that he and Wall articulated in 1965 (Melzack, 1999b; Trout, 2004). Although key concepts and

relationships from the GCTP have endured and are retained, the NTP incorporates more recent research and offers a more comprehensive framework for understanding the subjectivity and interpersonal variation of the experience of pain (Dickenson, 2002; Trout, 2004). The NTP identifies inputs or modulators not recognized by the GCTP (Trout, 2004). Additionally, the NTP places emphasis on the significance of both ascending and descending input pathways unlike the GCTP, which mainly described ascending routes of neuronal message transmission (Melzack, 1999a).

Melzack and Loeser first extended the GCTP in 1978 when they published a complimentary conceptual model focused on synaptic areas along pain signal transmission routes from the dorsal horns, thalamus and cortex which was informed by their observations of pain in paraplegics (Melzack, 1979, 1999b). This expanded the theoretical understanding of stimuli processing sites beyond that encompassed by the original GCTP. Furthermore, Melzack and Loeser's (1978) work indicated that the synaptic areas examined may become capable of generating patterned neural responses and projecting rapid, patterned nerve impulses to communicate with areas that subserve the experience and localization of pain (Melzack, 1999a).

This observation informed Melzack's subsequent work describing the "phantom limb" phenomenon, in which he observed rapid nerve impulses and abnormal impulse patterns originating in tissue near injured or amputated areas of the body (Melzack, 1999a, 1999b). As a result of these observations, Melzack proposed that our peripheral bodies are subserved by neural processes taking place in the brain (Melzack, 1999a). These brain processes are usually activated and moderated by signals from the body but they can also occur in the absence of peripheral inputs, e.g. in the case of pain experienced as originating in a missing limb (Melzack, 1999a). Additionally, Melzack asserted that any sensory experience of the body, including but not limited to pain, can occur without peripheral origination (Melzack, 1999a). The explanation for this lies in the brain's neural networks where stimuli can induce patterned responses but do not necessarily produce the patterns themselves. Melzack (1999a) interprets this as indicative of a body that is perceived as a unified whole and is identified as a "self" differentiated from others and from the environment. As such, Melzack (1999a) theorized that the integration and unification of the diversity of sensations and feelings experienced within and by the body, including the "self" as the point of reference in the environment, must be a result of central neural processes and cannot originate in the periphery or at the level of the spinal cord. Furthermore, Melzack (1999a) asserted that the neural processes of the brain which inform the "body-self" must be, to some degree, inherent genetic specification which is then moderated by lived experience. These conclusions and assumptions are the foundation for the NTP.

The NTP posits that neural transmission of sensory input and genetic inheritance are joined by neural-hormonal stress mechanisms in an explanatory model of pain and its perception (Melzack, 1999a). The NTP describes a "neurosignature" or pattern of neurological responses underlying an individual's experience of pain determined and characterized by genetic and sensory influences on synaptic architecture (Melzack, 1999a). The neurosignature pattern is also influenced by "cognitive events" that include emotional and physical stress (Melzack, 1999a). The Neuromatrix is a result of the body's attempts at homeostasis and stress regulation through activation of the neurosignature (Melzack, 1999a).

Melzack (1999a) provided an elegant but complex diagram of the NTP and the many concepts involved in pain perception within the model. The concepts include somatic input, visual and other sensory information involved in cognitive situational interpretation, intermittent and sustained cognitive and emotional inputs, neural modulation inherent in brain function, and stress regulation including activity within the endocrine, immune, autonomic and endogenous opioid systems. The diagram

strengthened the theory presentation by synthesizing but not replacing explanation of the theory within the text (Meleis, 2007). Relationships between concepts and their impact on the phenomenon of pain perception within the NTP are clear and consistent despite the model's complexity. Such complexity is appropriate given data that identified a multitude of factors involved in modulation of pain perception (Melzack, 1999a, 1999b, 2001). Although conceptual factors are located within the model due to their modulation of pain perception, their properties and mechanisms of action are described, thus avoiding a teleological theory in which only the consequences of concepts are considered (Meleis, 2007).

The NTP was first described just eight years ago. As such its significance largely remains to be seen. Melzack recommended that the model be used to inform the creation of interdisciplinary pain clinics involving endocrinologists and immunologists, indicating that the theory has great potential for usefulness in practice (Melzack, 1999a). This theory is likely to become utilized in research and educational arenas as well, particularly as our understanding of stress responses and genetics progresses.

*External components.* The NTP is consistent with this author's personal values and professional values as a nurse-midwife. Midwifery philosophy dictates that pain can be purposeful and is a multidimensional experience with many determinants. The NTP incorporates this philosophy and rejects Cartesian concepts of pain in which pathology and injury are deemed wholly responsible. This is consistent with clinical observations of a wide range of experiences and responses to pain in childbearing patients, as well as research demonstrating such variations (Melzack, 1993). Rather than blaming a woman for her response to pain, the NTP helps us to recognize the many factors contributing to the experience of pain, some of which are genetic or learned responses beyond immediate control (Trout, 2004).

#### Childbirth, Hydrotherapy and Pain Theories

The effect of IPI on intrapartum pain is explained by both the GCTP and its extension, the NTP. Within both models IPI can be seen to inhibit the awareness of pain by providing alternative and competing stimuli in peripheral sensory receptors and by distracting a woman's cognitive attention away from painful sensations (Simkin & Bolding, 2004). Specifically, water's hydrothermal effect may "close the gate" by altering or disrupting transmission along pain pathways ascending from the uterus, cervix and birth canal to the thalamus where pain is interpreted. Furthermore, the relaxation and distraction experienced during immersion may alter or interrupt transmission of pain perception along descending pathways as well. This understanding is perhaps the most useful application of the theories to the study of IPI, although both models also have significant general implications for nurse-midwifery care of childbearing women, particularly in the area of prenatal preparation for childbirth and other pain relief methods during labor.

Additionally, the NTP and GCTP that it encompasses, offer sound explanations for individual variations in intrapartum sensations, as well as choices to utilize specific pain relief methods and responses to such methods (Melzack, 1993; Trout, 2004). The NTP recognizes that the experience of pain in childbirth is impacted by differences in synaptic architecture within women's neurosignatures, as a result of past experience, memory, genetics, stress and immune responses (Melzack, 1999a; Trout, 2004). This theoretical understanding explains why women with a history of significant pain (e.g. a prior injury), report experiencing less labor pain than women without this history (Melzack, 1993). Women experienced with pain have developed coping strategies as well as synaptic differences, which decrease their pain experience. This is also evidenced by research in which multiparae report less pain in childbirth than primiparae (Melzack, 1993). However, the NTP reminds us that experience of pain and possession of coping strategies are just some of the factors influencing pain perception.

A history of pain associated with trauma may not reduce a woman's subsequent experience of pain and may actually increase it, particularly if the trauma was both physical and emotional in nature. For example, women with a history of sexual abuse often report significantly more pain during labor and have greater need for pharmacologic pain control methods than women without a history of sexual trauma (Simkin, 2000). For these women, being touched in labor (massaged) or undressing to enter the bathtub for IPI, may provoke extreme discomfort and necessitate alternative pain control strategies.

The NTP reminds obstetric providers that individual women will need individualized plans of care for coping with the anxiety and pain that may accompany labor and birth. This is consistent with holistic nursing and midwifery philosophies in which women are encouraged to participate in decision-making about pain relief methods because no single method is appropriate for all women, particularly given their varied circumstances and neurosignatures. In addition to the clinical realm, individual variation should be considered in IPI research, particularly when randomization does not occur and women self-select to utilize or avoid IPI. Individualized holistic care is also supported by feminist theory, which will be discussed briefly.

#### Feminist Theory

The evolution of feminism and feminist theory during the last century gave rise to a variety of theoretical subsets and the application of feminist tenets to a range of disciplines. This discussion will be centered on application of general feminist theory to the practice and study of nursing and midwifery.

#### Feminist Nursing and Midwifery

Woman-centered care and the appropriate use of technology are hallmarks of midwifery philosophy and practice (Kennedy & Shannon, 2004). Within the midwifery model of care women are encouraged to actively participate in health care management decisions (Davis-Floyd, 2001, 2003; Rooks, 1997). This facilitated self-empowerment extends to provision and use of IPI, a non-pharmacologic pain relief method thought to facilitate physiologic childbirth and reduce medical intervention (Burns & Greenish, 1993; Daniels, 1989). Theoretical analysis of midwifery philosophy and practice is ongoing but not organized or unified by consensus to date (Cragin, 2004). Emerging midwifery theoretical scholarship is informed by feminist nursing theory, which is farther along in development and recognizes the importance of women as subjective actors as well as the importance of sociocultural context to women's health and health care (Cragin, 2004; Craven, 2007; McCool & McCool, 1989). This contextualization is beyond the frameworks provided by physiologic and pain theories. As such, feminist theory is an essential additional theoretical perspective with which to view midwifery provision of IPI.

Feminist theory was applied to women's health care since its original articulation (Andrist & MacPherson, 2001; Taylor & Woods, 2001). Early feminist nursing scholars developed a theoretical framework for women's health with assertions that included a) women should be included as subjects in research, particularly given the lack of supportive data for treatment that women routinely receive; b) sociocultural factors that influence health and illness should be recognized; c) women's negotiation of the health care system includes inadequate participation in medical decision-making and unnecessary surgery; and d) transitions in women's lives, such as childbearing or menopause, should be viewed as physiologically normative rather than disease states (Andrist & MacPherson, 2001; McBride & McBride, 1981). Early feminist scholars

pregnancy, rather than their experiences with childbearing (Andrist & MacPherson, 2001; Block, 2007; Taylor & Woods, 2001). Although feminist theory has described the biomedicalization of female physiology including pregnancy and childbirth, and was involved in the natural childbirth movement of the 1970's, contemporary obstetric care has largely escaped feminist analysis (Andrist & MacPherson, 2001; Block, 2007; Taylor & Woods, 2001). This may be due to a conscious movement within feminism to view women's health as more than reproductive health, and to incorporate research on the many roles assumed by women in addition to mothering (Andrist & MacPherson, 2001; Taylor & Woods, 2001).

Physiologic and pain theories are well suited to structure inquiries about the safety and efficacy of IPI, but women remain the objects of such inquiries. From a feminist perspective, one can transform women into the subjects of IPI research. Both childbearing women and their healthcare providers are participants with potential to inform investigations of the phenomenon. Feminist theory has rarely been specifically applied to the philosophy and practice of midwifery by American scholars, and has not yet been a lens through which IPI has been viewed (McCool & McCool, 1989).

Feminist theory could provide a framework for inquiry into why women utilize IPI and how they experience it, in addition to types of providers likely to provide the practice. Research questions could be broadened to include "What is involved in women's decision-making around IPI utilization?" and "How do women describe their experiences with IPI?" These questions have only begun to be explored using qualitative data arising from the voices of women.

### Motivation for Hydrotherapy

As suggested by physiologic and pain theories, women have reported deciding to use IPI for its pain relieving qualities as well as other factors (Hall & Holloway, 1998; Richmond, 2003b; Wu & Chung, 2003). A commonly cited motivation is desire for

"natural childbirth," usually defined as spontaneous vaginal birth without pharmacologic pain relief (Hall & Holloway, 1998; Richmond, 2003b; Wu & Chung, 2003). Women have also described desiring and enjoying IPI because the tub or pool created a physical distance from the outside world and/or provider. This physical separation was described as "protective" and affording privacy, as well as likened to an obstacle which would reduce the likelihood of medial intervention (Hall & Holloway, 1998; Wu & Chung, 2003). The decision to use IPI has been reported to be an explicit rejection of the biomedical model of childbirth (Wu & Chung, 2003) as well as a tool for retaining control during the childbearing process (Hall & Holloway, 1998; Richmond, 2003b; Wu & Chung, 2003). Future examinations of IPI should expand on this data and seek information about what motivates women to choose the practice. From a feminist perspective, IPI is not merely a non-pharmacologic pain relief method with physiologic mechanisms of action, but a phenomenon that illuminates a woman's critique and rejection of contemporary biomedical obstetric care.

# Hydrotherapy in Context

Despite historic origins, IPI was only recently re-introduced into modern maternity care. It was done at the insistence of childbearing women and their attendants, not after academic scrutiny and peer reviewed examinations (Rosenthal, 1991). Institutions report introducing the option of WL and WB in response to childbearing women's requests, and have marketed IPI as a means of attracting female consumers of healthcare (Burns & Greenish, 1993; Forrister, 2007). Women's requests for IPI are better documented in European studies than in the US, although just three qualitative analyses of women's narratives have been published (Hall & Holloway, 1998; Richmond, 2003b; Wu & Chung, 2003). US literature is more likely to conceptualize women's choices in childbearing as "consumer demand" rather than a fundamental human right. US feminists and supporters of midwives have encouraged this "consumer rights" rhetoric which has

proved efficacious in expanding access to midwifery care (Craven, 2007). Feminist anthropological scholarship first encouraged women to challenge the biomedical model of childbirth by exercising their power as consumers of health care, and now reveals that the concept of consumption has disenfranchised low-income women (Craven, 2007). Feminist theory reminds us that choices in childbirth take place within a stratified system of reproduction where power differentials result in varied abilities to consume and limited access to reproductive choices (Craven, 2007). This perspective has implications for obstetric research, including examinations of IPI.

Examinations of IPI incidence and assessments of women's demands for the practice are influenced by histories of health care consumption and familiarity with IPI. In other words, what women want in childbirth is related to what they have witnessed and know of childbirth (Newburn, 2006). When the pervasive biomedical model of childbirth restricts access to IPI and dictates that women require and benefit from high levels of technologic intervention, the average woman may not report a strong desire for WB to researchers. However, a feminist perspective would value women's stories of WB, even if atypical or unusual. Feminist research would find parallels in women's motivations for WB and other extreme choices in childbirth, from unassisted childbirth to elective cesarean births. From a woman-centered perspective, these choices could be collectively viewed as reaction to the biomedical model of childbirth, and parallels would lend more to examinations of obstetric context and less to analyses of the safety and efficacy of specific practices.

Theoretical models of childbirth. Opponents of IPI caution against acquiescence to women's requests for IPI, citing concerns for neonatal safety in an ethical dilemma involving the balance of autonomy, beneficence and non-maleficence (Grunebaum & Chervenak, 2004). Feminist theory does not dictate that providers must comply with a woman's every wish, but simply that they engage in shared decision-making after joint

review of options and supportive evidence. Ethical decision-making by obstetric providers is complicated when the maternal-fetal dyad is viewed as two patients rather than a single, unified entity (Grunebaum & Chervenak, 2004; Mattingly, 1992). From this perspective, a woman's desire for IPI utilization can be trumped by provider concern for fetal and neonatal well-being. However, the grass-roots origin of IPI may have ignited controversy that is not fueled simply by concerns for maternal and fetal well-being.

In addition to explicit questions about safety and benefits or lack thereof, controversy over IPI speaks to larger issues about empowerment and control in the childbirth process (Harper, 1995). It may remain controversial longer than other obstetric innovations or interventions, in part because it is beyond the immediate control of medical institutions (Harper, 1995). Some scholars assert that distortions of risk (Lyerly et al., 2007) and misrepresentations of IPI research represent an explicit attempt to retain control of childbirth by providers operating within a biomedical framework (Hall & Holloway, 1998; Redwood, 1999). Accordingly, the IPI debate can be viewed as conflict between the medical and social models of childbirth (Harper, 1995). These contrasting theoretical models have also been described as biomedical, technocratic or obstetric frameworks compared to feminist, midwifery, holistic, biopsychosocial or humanistic perspectives (Davis-Floyd, 1998, 2001, 2003). Although IPI is generally believed to be a phenomenon occurring within the purview of the midwifery model of care, it is not exclusively so. Woman-centered approaches to care have resulted in access to IPI for women attended by both midwives and physicians (Geissbühler et al., 2004).

*Feminist provision of hydrotherapy.* WL and WB are typically among many elements of a feminist approach to maternity services (Johnson, 1996). Midwife and physician authors who have described integrating IPI into maternity services often mention doing so because it was consistent with, or an extension of, their general

philosophy of care (Balaskas & Gordon, 1990; Burns & Greenish, 1993; Forrister, 2007; Geissbühler & Eberhard, 2000; Lichy & Herzberg, 1993; Odent, 1983). This philosophy includes eliciting active participation from the childbearing woman and facilitating physiologic childbirth whenever possible. This philosophical context generally lends itself to IPI provision within a thoughtfully developed, woman-centered environment for childbearing which might include dim lighting, privacy, music or aromatherapy, and facilitated emotional support from friends and family in addition to providers (Balaskas, 1996; Daniels, 1989; Leboyer, 1975; Milner, 1988; Odent, 1997).

The "hormone enhancing" (Balaskas, 1996) environment in which IPI is usually provided has not been adequately controlled in most examinations of IPI. The resultant question is: Does IPI facilitate physiologic childbirth and offer benefits independent of the feminist model of childbirth in which it is usually provided? Feminist perspectives on IPI would inform examinations of concomitant practices, several of which offer theoretical benefits that have little to do with the effects of immersion per se. Examples include a delay in clamping and cutting the umbilical cord and immediate skin-to-skin contact between mother and child, as well as increased maternal perception of control over the process of childbearing and resultant increased satisfaction with the experience (Downe, 2004; Green & Baston, 2003; Green et al., 1990; Hunter, Hofmeyr, & Kulier, 2007; Hutton & Hassan, 2008; Moore, Anderson, & Bergman, 2007). Further, the context of IPI provision lends itself to application of additional theoretical frameworks. For example, the social and emotional support provided in conjunction with IPI within the feminist midwifery model of care suggests that social support theory or related environmental psychology might have utility in future IPI research.

# Conclusions

Midwives are uniquely situated to apply feminist theory to the discussion of women's health care and address *how* women give birth in addition to considering *if* they

will and what their biophysical outcomes may be. IPI provides an ideal entry into this discussion given that childbearing women have already begun to articulate the ways in which water is symbolic and literal resistance to biomedical control of reproductive practices. In addition to providing a general context, feminism can also inform the specifics of IPI research that include identification and control of potentially confounding variables inherent to the model of care in which IPI is offered. Feminism also informs the optimality principle and other concepts inherent in the OI-US instrument used in this research, particularly assertions that childbearing is a normal, physiologic process and that childbearing women are subjected to unnecessary technologic intervention during contemporary maternity care.

Summary of Theoretical Approaches to Intrapartum Hydrotherapy Theories of physiology, pain and feminism all have utility in the practice and examination of intrapartum hydrotherapy and immersion. Although there is some overlap among these theories, each provides important and unique contributions to structure the phenomenon of interest. Figure 2-1 provides a conceptual model of the theories and their relationship to each other as well as to IPI.





Physiologic theory is able to describe mechanisms by which WL and WB occur, provide explanations for maternal and fetal outcomes of IPI research, and inform clinical recommendations for IPI provision. The framework includes physical characteristics and physiologic processes that allow for safe fetal emergence underwater, however counterintuitive the practice may seem. The theory also demonstrates physiologic factors by which IPI could improve maternal outcomes by decreasing perineal lacerations, length of labor, use of pharmacologic pain relief methods and the maternal experiences of pain and anxiety. The GCTP and NTP elaborate on the precise mechanisms by which pain perception is altered during hydrotherapy, and offer explanations for individual variations in the experience of pain and immersion. Physiologic and pain theories focus on the effects of IPI and are limited to questions such as "What occurs during IPI?" and "How does it occur?" Feminist theory is the only framework to address the question "Why?" (i.e. "Why do women choose to utilize IPI and in what context?"). This contextualization is important for any examination of the phenomenon, even when research questions are biophysiologic in nature. In such instances, application of feminist theory reminds researchers that the phenomenon under examination arose from the desires and organizing of women as an antidote or alternative to the biomedical model of childbearing. Accordingly, examinations of hydrotherapy have potential to inform general contemporary obstetrics in addition to provision of the specific practice.

#### CHAPTER 3

#### Review of the Literature

# Introduction

A comprehensive critical review of IPI literature was conducted to inform this dissertation research and contribute to the ongoing debate in the lay and scientific childbirth literature about the risks and benefits of WL and WB. In particular, clinical opinions are divergent regarding the appropriateness of immersion at the moment of birth, the primary focus of this chapter. Conflict about WB largely stems from the paucity of methodologically rigorous research and from passionate editorializing by both opponents and proponents of the practice. Enthusiasts discuss benefits of WB ranging from pain relief to improved perineal outcomes and reduced operative delivery rates, although the quality of the evidence in support of most claims is poor. Skeptics express concerns ranging from infection to drowning, citing isolated case reports of adverse events attributed to IPI, while dismissing existing reassuring descriptive research as unconvincing in the absence of RCTs.

#### Background and Purpose

Despite controversy within clinical and research communities, the provision of IPI and occurrence of WB is increasing internationally (Alderice et al., 1995b; Cohen, 1996; Forrister, 2007; Mackey, 2001; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006). This increased utilization compels further examination.

Several prior publications have offered reviews of IPI research limited to the most rigorous of study designs (Alfirevic & Gould, 2006; Cluett & Burns, 2009; National Collaborating Centre for Women's and Children's Health, 2007). Although arguably appropriate for clinical decision-making, stringent exclusion criteria have resulted in underrepresentation of relevant knowledge, particularly regarding WB. For example, the most recent Cochrane Collaboration review of IPI included just two studies of WB. One study was presented at a conference and proceedings are no longer available, while the other study included just 16 WB.

Lack of access and knowledge of WB data proves problematic for interested parturients and health care providers. Accordingly, a comprehensive review of health sciences research literature was performed. The review was indicated given the number of recent editorials and position statements which failed to accurately describe the range and nature of published IPI data (Batton et al., 2005; Schroeter, 2004; Schuman, 2006). Polarized opinions about IPI may leave childbearing women confused recipients of contradictory health counseling. This review aims to describe the state of the science to enable informed decision-making by clinicians and patients alike.

## Methods

# Search Strategy

Locating IPI research was difficult due to inconsistent terminology used to describe the phenomenon. Key words were numerous and included *immersion*, *hydrotherapy*, *tub*, *bath*, *bathwater*, *pool*, *whirlpool*, *water*, *birth*, *waterbirth*, *Leboyer*, *alternative birth method*, and *natural childbirth*. Databases included PubMed, CINAHL, PsychINFO, and the Cochrane library. Queries were not initially limited by study design, language of publication or other parameters, given the global nature and relatively recent emergence of scientific inguiry into the phenomenon.

#### Results

A significant body of literature was located including 19 examinations of WL, 39 studies of WB, and 13 case reports involving IPI. An additional 12 articles involving WL or WB were located but excluded because English language versions could not be obtained (Table 3-1). In total, 70 articles were reviewed. After excluding cases described in multiple publications, 46,289 unique subjects were identified including 15,641 women who were immersed during labor and 25,790 who gave birth in water. A synthesis of IPI

research findings will be provided after a description of evolution in IPI study design and methodology over time.

# Overview of Research Designs

# Labor in Water

The Cochrane Collaboration review of IPI published by Cluett and colleagues(2009) discusses 11 RCT of WL and concludes that the pain relieving effect of hydrotherapy is well established, without apparent risks or disadvantages. Given the experimental and conclusive nature of identified studies, a detailed review of literature on WL will not be provided. Identified studies of WL are described in Table 3-2.

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ts analyzi	1992	2008	1993	1996	1998	2001	1987	2002	1997	1987	2004	1997	1996	2001	2007	2004	2001	1994	2001		Year	S OT IADO
ed in prior publica	Sweden	SO	SO	Canada	SO	Sweden	Denmark	Poland	Sweden	Denmark	England	Sweden	Sweden	Australia	Brazil	England	England	Belgium	SN		Setting	r in water publish
ations.	Retrospective case-controlled	Observational pilot	RCT	RCT	Retrospective case-controlled	RCT	Prospective cohort	RCT	RCT pilot	Prospective cohort	Retrospective case-controlled	RCT pilot	Comparative observational	RCT	RCT	RCT	Pilot RCT	RCT	First author		Design	ied in English (n=19).
	89	7	45	393	77	612	88	25	200	13	27	200	538	137	54	49	4	54	9	Immersion	Number o	
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#### Birth in Water

#### Quantitative WB Data

In contrast to the experimental research on WL, the study of immersion during birth has primarily been limited to observational designs.

*Clinical audits and descriptive studies.* Clinicians and childbearing women began utilizing IPI prior to investigation or publication of related outcomes. Accordingly, most of the early published IPI data involved simple descriptive statistics offered by clinicians who examined outcomes within their own practices. These publications are rife with limitations including poor record keeping and data collection, failure to differentiate between WL and WB, and minimal description of clinical guidelines and immersion equipment. However, these reports indicate that IPI was primarily utilized by healthy women, who rarely required obstetric intervention and experienced excellent outcomes expected of low risk populations.

IPI research eventually began to evolve from descriptive reports to comparative or cohort designs. The groundwork laid by early publications informed and altered clinical policies thereby changing and increasing data available to researchers. Investigators began to include descriptions of study samples and protocols, and incorporated an increased number of variables. The previous use of descriptive statistics gave way to more sophisticated analyses, but bivariate approaches were the norm. Nonetheless, these contributions to the literature did much to expand the understanding of IPI utilization and associated outcomes. Table 3-3 outlines the 29 clinical audits, descriptive and comparative observational studies identified.

Year	Setting	N	lumber of subjects	
		WL	ШW	No IPI
1996	Austria	Unknown	200	Unknown
2006	England	102	229	0
1998	England	198	343	541
1993	England	131	171	0
1989	SU	349	483	503
1994	England	81	41	0
1995	England	61	51	0
2005	Switzerland	Unknown	3327	3812
2004	Germany	26	134	136
2000	Switzerland	Unknown	2014	3470
2002	Switzerland	Unknown	3192	5289
2004	Switzerland	647	3617	5254
1996	England	245	116	118
2005	SN	Unknown	102	0
1996	Italy	0	1000	0
2007	Italy	0	25	27
1996	Malta	0	1000	0
1996	England	0	370	0
1983	France	0	100	0
1995	Belgium	Unknown	1853	2908
2003	England	œ	181	0
1991	SN	721	679	779
1996	SO	839	923	1208
2005	Italy	Unknown	2462	549
1996	Denmark	592	183	140
1996	Australia	0	888	
2006	Switzerland	133	68	291
2007	Switzerland	133	89	146
2007	Switzerland	213	261	0
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	Year 1996 1998 1998 1998 1998 1998 1998 2006 2006 1996 1996 1996 1996 1996 1996 1996 1	Year Setting 1996 Austria 2006 England 1998 England 1993 England 1993 England 1994 England 2004 Germany 2004 Switzerland 2005 US 1996 England 1996 England 1996 England 1996 England 1996 England 1996 England 1996 England 1996 Switzerland 2007 Italy 2005 Italy 1996 Australia 2007 Switzerland 2007 Switzerland 2007 Switzerland	Year Setting WL N   1996 Austria Unknown 102   1996 England 110 110   1993 England 131 131   1993 England 131 131   1993 England 131 131   1994 England 131 131   1995 England 131 131   2004 Germany 26 200 Switzerland Unknown   2004 Switzerland Unknown 26 200 131   2005 US Switzerland Unknown 26   2007 Italy 0 0 0   1996 England 0 0 0 0   1996 Us 0 0	Year Setting WL WB   1996 Austria Unknown 200   2006 England 102 229   1998 England 138 343   1993 England 131 131   1994 England 61 51   2005 Switzerland Unknown 3027   2004 Germany 104 61   2005 Switzerland Unknown 313   2004 Switzerland Unknown 3192   2005 Switzerland Unknown 3192   2006 England 647 3617   1996 England 0 100   1996 Italy 0 2014   2007 Italy 0 100   1996 Haly 0 370   1996 Natraliand 0 370   1996 Justraliand 100 226   1996 Justraliand 13

First author	Year	Setting	Numb	)er of sub	ijects
			Control	Ň	WB
Aird	1997	England	100	<u>ш</u>	67
Bodner	2002	Austria	140	0	140
Burke	1995	England	100	0	100
Chinze M. Otigbah Registrar	2000	England	301	0	301
Garland	2002	United Kingdom	080	0	089
Hawkins	1995	England	16	0	16
Schroksnadel	2003	Austria	265	0	265

First autho	Table 3-5.
r Year	Epidemiol
Setting	ogic, natio
	nal survey
Design	and randomized
	data involving
	birth
	in water i
	(n=3)

First author	Year	Setting	Design	Number	r of subjects	
				No Immersion	WL	WB
Alderice	1995	England and Wales	Survey	0	9853	4693
Gilbert	1999	England and Wales	Longitudinal survey	Unknown	Unknown	4032
Woodward	2004	England	Pilot RCT with preference arm	42	15 5	16

*Quasi-experimental and epidemiologic research.* The rigor of WB research and quality of existing data was improved with 6 quasi-experimental case-controlled analyses and two epidemiologic examinations contained in Table 3-4 and Table 3-5. Alderice and colleagues (1995) undertook a retrospective survey of English and Welsh obstetric facilities and midwifery services in order to identify the prevalence of IPI and identify adverse outcomes of the practice. Findings were significantly limited by the quality of data provided by respondents. Just 54% of units with birthing pools provided data based on audits or written records; other units provided "good" or "rough" estimates. Analyses were performed only for WB given the presumed significant underestimation of WL. Similarly, Gilbert and Tookey (1999) surveyed pediatricians in the British Isles on a monthly basis over a two year period to identify adverse effects of WL and WB. They identified a perinatal mortality rate of 1.2/1000 live births for WB but could not calculate rates for WL given inadequate data.

*Experimental WB research.* Many authors have lamented the observational nature of existing WB research and called for examination within RCTs, the gold standard of scientific inquiry (Alderice et al., 1995a; Atalla & Weaver, 1995). Others have wondered whether randomizing women to WB is ethical or feasible (Cluett & Burns, 2009; Coe, 1997; Geissbühler & Eberhard, 2000; Richmond, 2003b; Woodward & Kelly, 2004). However, most believe that RCTs are both possible and necessary. RCTs could establish causality thereby validating or refuting both optimal and non-optimal outcomes associated with the practice in existing literature.

Woodward and Kelly (2004) conducted the only study published in English to address these issues to date. They performed a feasibility study in England involving a pilot RCT of WB (n=40) compared to standard maternity care (n=20), with an additional preference study arm comprised of women who had chosen either WB (n=10) or conventional care (n=10) at antenatal study enrollment. The study was designed to

determine how a RCT involving WB could best be conducted and how it would be perceived by childbearing women. Investigators experienced difficulties with recruitment, allocation and treatment administration, and crossover among groups was significant. Nonetheless, their findings indicate that a large RCT of WB could be performed.

#### Qualitative Data

Quantitative data dominates the IPI literature although rich description of the subjective experience of WB was provided by three publications described in Table 3-6 (Hall & Holloway, 1998; Richmond, 2003b; Wu & Chung, 2003).

First	Year	Setting	Method	Numbe	er of part	icipants
author		-		No	ŴL	WB
				Immersion		
Hall	1998	England	Grounded theory	0	9	Unknown
Richmond	2003	England	Questionnaire and interviews	0	164	181
Wu	2003	Taiwan	Phenomenolo gy	0	0	9

Table 3-6. Qualitative studies of birth in water published in English (n=3).

Hall and Holloway (1998) were the first to provide women's descriptions of IPI, and they used data collected in 1996 on an English midwifery-led maternity unit. Semistructured interviews were conducted with women who labored or birthed in water, using grounded theory methodology to explore the experience of IPI. Investigators Wu and Chung (2003) conducted a complementary qualitative study in Hsinchuang, Taiwan and reported consistent findings despite slightly different research questions and methodology. They performed phenomenological interviews with women who had given birth in water within the preceding twelve months at a free-standing clinic run by midwives. Although the interviews took place in the postpartum period, they focused on the prenatal experience of decision-making about IPI utilization rather than reflections on the experience of such use. Richmond (2003) utilized a different approach to assessing women's perspectives on WB. She administered questionnaires to 189 English women who gave birth in water, 9 of whom were also interviewed. Study participants were asked about decision-making for WB, including information sources utilized. Further, they were asked to describe the sensations of immersion, duration of use, concomitant pain relief methods, and satisfaction with WB. Multiparae were also asked to compare water born babies with prior children. Findings were similar to prior qualitative studies, although more comprehensive.

Findings from these qualitative inquiries will be discussed subsequently and should be confirmed with further inquiry among diverse populations in international settings. In particular, the voices of childbearing women in the US are notably absent from existing qualitative research, despite almost 30 years of documented utilization (Brown, 1982; Church, 1989; Dansby, 1988; Rosenthal, 1991).

# Limitations

Existing WB research has significant limitations related to study design and methodology that warrant discussion prior to description of findings. As previously noted, several authors failed to adequately differentiate between WL and WB, or compared WB to non-WB groups without accounting for WL (Adam, 1996; Eberhard et al., 2005; Geissbühler et al., 2002; Geissbühler et al., 2004; Hall & Holloway, 1998; Mack et al., 2005; Ponette, 1995; Thoeni et al., 2005). This represents inadequate explication of constructs and limits the ability to interpret findings. For example, in descriptive research conducted in Basel, Switzerland, women who initially labored in water but gave birth by cesarean were excluded from analyses, while those who experienced instrumental deliveries were analyzed with women who did not utilize IPI prior to assisted vaginal birth (Geissbühler & Eberhard, 2000). This failure to analyze WB outcomes by intention to treat risked masking complications related to IPI. Data from RCTs of WL are reassuring

that this limitation did not obscure significant negative effects of WL. However, there is the possibility that this design flaw resulted in diminished ability to observe significant effects of WB.

Analysis of negative or positive treatment effect(s) of immersion were further limited by failures to describe, much less control for, the timing and duration of immersion, water temperature and salinity, and percentage of body surface area covered during immersion related to tub size and volume of water contained (Barry, 1995; Datta & Tipton, 2006; Deans & Steer, 1995; M Epstein, 1992; Geissbühler et al., 2002; Goodlin et al., 1984; Katz et al., 1988; Katz, Ryder et al., 1990; Richmond, 2003a; Zimmermann et al., 1993).

The most significant limitation of research reviewed was the inability to control for multiple confounding factors inherent to the model of care in which IPI is provided. The option of IPI, particularly WB, is generally offered as one aspect of a holistic approach to maternity care. Other elements of care with potential to impact maternal and neonatal outcomes were not controlled in analyses, including a therapeutic environment, continuous physical and emotional labor support, and skin to skin contact or delayed cord clamping in the immediate postpartum period (Enkin et al., 2000; Hodnett, Gates, Hofmeyr, & Sakala, 2007; Moore et al., 2007). The synthesis of research findings that follows should be reviewed with these limitations in mind.

Synthesis of Research Findings

## Maternal Considerations

# Demographics and Clinical Characteristics

Women self-select to give birth in water and are more likely to be well-educated, middle-class Caucasians without language barriers, compared to women who give birth conventionally (Geissbühler & Eberhard, 2000; Richmond, 2003b). Although specific IPI inclusion criteria differ among clinical settings, use is generally restricted to healthy, lowrisk parturients. Some research has involved women desirous of WB with variant clinical characteristics including induction of labor (Church, 1989; Eldering & Selke, 1996; Garland, 2002; Garland & Crook, 2004; Muscat, 1996; Rosenthal, 1991, 1996). Women with prior cesareans have also been observed to labor or birth in water (Church, 1989; Garland & Crook, 2004; Muscat, 1996; Ponette, 1995). In other facilities, women with twins and breech presentations were permitted WL or WB if vaginal birth was anticipated (Muscat, 1996; Ponette, 1995).

#### Choosing Water Birth

Wu and Chung (2003) are the only investigators whose primary aim was to explore factors involved in women's decision-making around WB. Their Taiwanese participants' descriptions of motivations for WB were highly consistent and included dissatisfaction with conventional obstetric practices and desire for autonomy.

Dissatisfaction with conventional obstetric practices largely stemmed from prior experiences with childbirth, or from prenatal care and hospital tours during the index pregnancy. Specifically, women described feeling that doctors control childbirth and often choose to perform Cesareans or assisted vaginal deliveries, which are "fast and brutal" (p. 264) but not necessarily medically indicated. In addition to provider prerogative, women described feeling that instrumental deliveries occur frequently in Taiwan because routine fasting, IV medications and other interventions make women too weak to independently give birth. Additional contributing factors were mentioned including an inhospitable hospital environment with cold ambient temperatures, uncomfortable delivery tables, and inadequate staff support. Participants also described feeling that the hospital and staff did not recognize them as individuals or try to meet their specific needs

Dissatisfaction with obstetric practices led participants to strive for autonomy in childbearing. The search for autonomy began during the index pregnancies with

examinations of alternative childbirth practices in comparison to mainstream methods. This examination led to utilization of midwifery care despite beliefs that midwifery facilities were "less advanced than those at hospitals" (p. 265), and that midwifery care is gradually becoming obsolete. Researchers concluded that participants felt their midwives were instrumental in facilitating their autonomy, but the mechanisms involved were not fully explicated. Autonomy was operationalized as an ability to make decisions that differed from the mainstream, rather than independent decision-making. The theme "trusting the midwife" (p. 265) was emphasized in discussion of autonomy by participants' who may have transferred control of childbearing from doctor to midwife. Participants discussed relying on the midwives' experience and techniques, trusting them and taking their advice, and defending them when questioned by relatives. Autonomy and dissatisfaction with conventional obstetric care may be cross-cultural themes given similar earlier findings reported by Hall and Holloway (1998) for British women.

# Experience of Water Birth

Hall and Holloway (1998) identified four major themes related to the experience of IPI and WB among English women: 1) exercising choice, 2) letting go of inhibitions, 3) coping with pain, and 4) experiencing fulfillment. Underlying these themes was the central concept of control. Control was involved in the participants' perceptions of their experiences with childbirth and affected their ability to cope with pain, become uninhibited, and confidently participate in decision-making by exercising choice. Factors involved in control were identified by investigators as attaining mastery during labor, decision-making, and negotiating support. Most participants did not articulate the precise ways in which immersion helped them achieve control but mentioned believing that it did. Comments included "I try to be the sort of person who is in control and I believe the water helped me to control the situation" (p. 33). One woman remarked, "I sank my ears

under the water so even if I had wanted to hear the midwife telling me what to do I couldn't. I was able to feel I was in control of my labour" (p. 33). This comment demonstrates one strategy for attaining mastery and indicates an internal locus of control, while others identified an external locus and relied on others, particularly their midwife.

Study findings are limited by the small and homogeneous sample which lacked socioeconomic or ethnic variation. As the researchers noted, the emphasis on personal control in childbirth may be more likely to emerge in discussions with wealthier women. These women may enjoy and expect greater autonomy in all areas of life, and may have more educational or experiential opportunities that result in recognition of power dynamics between patients and providers and increased awareness of alternative choices in childbirth. As such, this study's findings should not be generalized to all populations of childbearing women but should inspire examinations in divergent settings. *Satisfaction* 

Research has demonstrated an association between IPI use and high levels of maternal satisfaction with childbirth, although study designs and selection bias preclude determination of causality. Satisfaction with WB has been measured during the inpatient postpartum stay using questionnaires, visual analog scales and Likert scales (Cluett, Pickering, Getliffe, & St George- Saunders, 2004), and following discharge home via postal surveys and face-to-face interviews (Richmond, 2003b; Woodward & Kelly, 2004). *Relaxation and Pain Relief* 

The most recent Cochrane Collaboration review concluded that pain relief is the only effect of hydrotherapy conclusively demonstrated in the literature, based on evidence from 11 RCTs of WL published prior to 2009 (Cluett & Burns, 2009). Researchers have used a variety of techniques to assess pain relief and relaxation during IPI. Most studies have used self-reported measures of pain intensity and indirect

measurement of pain through examination of analgesia use. Regardless of measurement, each study found decreased pain with IPI utilization (Benfield et al., 2001; Bodner et al., 2002; Chinze M. Otigbah Research Registrar et al., 2000; Cluett & Burns, 2009; Geissbühler & Eberhard, 2000; Geissbühler et al., 2004) with four exceptions (Cammu, Clasen, Van Wettere, & Derde, 1994; Eckert, Turnbull, & MacLennan, 2001; Lenstrup et al., 1987; Ohlsson et al., 2001). One RCT examined the effect of WL on selfreported pain and anxiety, and both were decreased among immersed women compared to those receiving conventional maternity care (Benfield et al., 2001). Two studies examined maternal and neonatal stress hormones but results were not significant, possibly due to very small sample sizes (Benfield et al., 2001; Gradert et al., 1987).

#### First Stage of Labor

Many clinicians and investigators believe that IPI is associated with decreased length of labor despite the recent Cochrane Collaboration conclusion to the contrary (Cluett & Burns, 2009). The review did not include observational data in which an association between IPI and progress of labor was observed in either primiparae alone (Chinze M. Otigbah Research Registrar et al., 2000), or regardless of parity (Aird et al., 1997; Burke & Kilfoyle, 1995; Lenstrup et al., 1987). Two RCTs also support an association between WL and improved uterine contractility or decreased labor length (Cluett, Pickering et al., 2004; da Silva, de Olivera, & Nobre, 2007). Notably, a trial by Cluett and colleagues (2004) included 99 women randomized to hydrotherapy or conventional care upon diagnosis of labor dystocia. When compared to women receiving standard augmentation with oxytocin and amniotomy, labor length among immersed women was equivalent. Similarly, investigators have reported increased need for labor augmentation in descriptive studies of women who did not use IPI compared to those who did (Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006). Ongoing

research is continuing to explicate the relationship between immersion, contractility and progress of labor with measurement of uterine electromyographic activity (Benfield et al., 2007).

# Second Stage of Labor

Spontaneous and assisted births. The relationship between IPI and mode of delivery has been examined in most studies of the phenomenon. Findings from descriptive studies have been inconsistent, and no differences in assisted vaginal delivery or cesarean have been observed in RCTs of WL, thus it is unlikely that mode of delivery is affected by IPI (Cluett & Burns, 2009).

*Perineal outcomes.* Perineal outcomes are commonly examined in IPI research. Findings have suggested that IPI is associated with equivocal or decreased laceration. Most investigators have reported significantly fewer episiotomies among women who had WL or WB (Bodner et al., 2002; Chinze M. Otigbah Research Registrar et al., 2000; Geissbühler & Eberhard, 2000; Geissbühler et al., 2004; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006; Zanetti-Dällenbach, Tschudin et al., 2007). Multiple descriptive studies have also observed an association between IPI and a reduced incidence and degree of perineal laceration, although episiotomy has not been consistently controlled (Bodner et al., 2002; Chinze M. Otigbah Research Registrar et al., 2000; Geissbühler & Eberhard, 2000; Geissbühler et al., 2004; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006; Zanetti-Dällenbach, Tschudin et al., 2007). *Third Stage of Labor* 

Few studies have examined third stage considerations beyond subjective estimated maternal blood loss. However, some studies have also examined postpartum hemorrhage using objective measures such as manual placental removal rates and serum hemoglobin or hematocrit, with either actual or calculated change values. Specific measurements and findings are inconsistent among studies, but research generally
supports either equivalent (Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006) or decreased postpartum blood loss following WB when compared to conventional birth (Bodner et al., 2002; Geissbühler & Eberhard, 2000; Geissbühler et al., 2004). Evaluation of findings is complicated by treatment inconsistency and failure to control for confounders such as physiologic versus active management of third stage labor or placental delivery while immersed (Woodward & Kelly, 2004).

## Maternal Infection

Investigators have not reported increased incidence of intrapartum or postpartum uterine infections following hydrotherapy during labor or birth (Bodner et al., 2002; Chinze M. Otigbah Research Registrar et al., 2000; Cluett & Burns, 2009; Eriksson et al., 1996; Fehervary et al., 2004; Geissbühler & Eberhard, 2000; Ohlsson et al., 2001; Robertson et al., 1998; Schorn et al., 1993; Zanetti-Dällenbach, Tschudin et al., 2007). Bodner and colleagues (2002) found a significantly (p=.03) decreased rate of uterine infection among women who had WB (1.4%) compared to those who birthed conventionally (5.7%) in their case-controlled examination.

### Hemodynamic Implications

Hydrostatic pressure experienced during immersion results in intravascular volume expansion with accompanying increased maternal urine production and decreased edema (Goodlin et al., 1984; Katz, McMurray, Berry et al., 1990; Katz et al., 1992; Katz, Ryder et al., 1990; Kwee et al., 2000). Edema may reduce tissue elasticity with implications for the occurrence and severity of perineal laceration during delivery. Central volume expansion may also improve uterine perfusion and placental circulation with implications for the fetus including alterations in amniotic fluid quantity and oxygenation (Eldering & Selke, 1996; Khosla & DuBois, 1981; Laudanski, 2002; Mesrogli, Goeschen, Siefert, Pohl, & Schneider, 1987; Strong, 1993).

### Neonatal Considerations

# Fetal Oxygenation

Maternal intravascular volume expansion, as seen with immersion, increases cardiac output and decreases systemic vascular resistance (Strong, 1993). These changes may increase placental perfusion thereby increasing fetal oxygenation (Laudanski, 2002; Strong, 1993). Research findings suggest improved fetal oxygenation during IPI as measured with external electronic fetal monitoring (Mesrogli et al., 1987; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006), as well as fetal scalp sampling and examinations of hemoglobin oxygen saturation (Laudanski, 2002). Data also indicates that fetal oxygenation may be improved after WB compared to conventional birth as measured with Apgar scores and umbilical cord gas analyses (Geissbühler & Eberhard, 2000; Geissbühler et al., 2004; Schrocksnadel et al., 2003; Woodward & Kelly, 2004; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006).

### Neonatal Outcomes

Eleven RCTs of WL followed by standard delivery have demonstrated equivalent neonatal outcomes among experimental and control groups (Cluett & Burns, 2009). Epidemiologic research has also failed to demonstrate increased morbidity or mortality WB (Gilbert & Tookey, 1999). This is consistent with findings from descriptive and quasiexperimental studies in which no clinically significant differences in outcomes were associated with newborns born in water versus air (Bodner et al., 2002; Chinze M. Otigbah Research Registrar et al., 2000; Geissbühler & Eberhard, 2000; Geissbühler et al., 2004; Zanetti-Dällenbach, Tschudin et al., 2007).

Specific neonatal concerns. Despite the grade I evidence supporting the safety of WL, and grade II evidence in support of WB, isolated case reports have suggested

associations between IPI and neonatal complications including infection, polycythemia, cord avulsion requiring neonatal transfusion, hyperthermia, asphyxia, bathwater aspiration and freshwater drowning (Austin, Bridges, Markiewicz, & Abrahamson, 1997; de Graaf, Heringa, & Zweens, 2000; Franzin et al., 2001; Hagadorn et al., 1997; Kassim, Sellars, & Greenough, 2005; Mammas & Thiagarajan, 2009; Nagai et al., 2003; Parker & Boles, 1997; Pearn, 1995; Rawal et al., 1994; Rosevear et al., 1993; Vochem et al., 2001). Table 3-7 describes case reports in detail. Although case reports do not "constitute reliable evidence," (p. 1447) they make further research on IPI imperative and should be discussed with childbearing families who are considering IPI (Cluett, McCandlish, Burns, & Nikodem, 2005).

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First Author	Year	Timing of Immersion	Setting	Outcome
Austin	1997	Birth	Home	After delayed cord clamping and retained placenta for 40 minutes after WB, neonatal polycythemia was observed at 24 hours of life Exchange
				neonatal polycythemia was observed at 24 hours of life. Exchange transfusion was performed with normal follow-up at one month.
de Graaf	2000	Birth	Home	Neonate required hospital admission and red blood cell transfusion after hypovolemia resulted from avulsed umbilical cord during WB.
Franzin	2001	Birth	Hospital	Infant re-admitted seven days after birth with fever and dyspnea; Legionella pneumophila pneumonia diagnosed 26 days later. Chest $\kappa$ -ray normalized at three months of age with normal follow-up at nine months.
Hagadorn	1997	Birth	Home	Infant with aspiration pneumonitis due to surfactant deficiency, and incidental colonization with Berkholderia pickettii. No long-term sequelae noted.
Kassim	2005	Birth	Hospital	Began grunting one hour after WB with chest x-ray consistent with water aspiration. Normal chest x-ray on third day of life. Cultures negative for infection. Normal follow-up three months later.
Mammas	2009	Birth	Unknown	<ol> <li>Chest x-ray consistent with water aspiration after symptoms of respiratory distress at two hours of life. Discharged home eight days after birth.</li> <li>Chest x-ray consistent with water aspiration after poor feeding and tachypnea at 12 hours of life. Discharged home on sixth day after birth.</li> </ol>
Nagai	2003	Birth	Home	Sudden neonatal death at seven days of life attributed to Legionella pneumophila identified in the water source. Infant had previously been admitted on the fourth day of life for fever and jaundice, and was discharged after phototherapy the following day.
Nguyen	2006	Birth	Unknown	<ol> <li>Accidental WB with respiratory distress noted 5 hours later. Infant was ventilated for three days when weaned to room air. Chest x-ray demonstrated pleural effusions and interstitial and alveolar edema. Mild hypoxic ischemic encephalopathy diagnosed. Blood cultures negative. Readmitted with seizure on ninth day with normal exams. Normal development and follow-up for one year.</li> </ol>

Table 3-7. Case reports of adverse outcomes attributed to labor or birth in water (n=13).

Table 3-7 cc First	ontinued. Ca	ase reports of Timing of	adverse out	comes attributed to labor or birth in water (n=13).
				<ol> <li>Infant tachypnea noted six hours after planned WB, on oxygen &lt;24 hours. Chest x-ray findings as above. Blood cultures negative.</li> <li>Infant with respiratory distress five minutes after WB, following initial Apgar score of seven. Chest x-ray with alveolar edema. Oxygen administered &lt;24 hours. Negative blood cultures.</li> <li>Infant with respiratory distress 10 minutes after WB, following Apgar scores of 8 at one and five minutes of life. Chest x-ray with interstitial and alveolar edema. Required oxygen for &lt;24 hours. Blood cultures negative. Discharged home on third day of life.</li> </ol>
Parker	1997	Birth	Birth center	Infant presented at 19 days of life with seven day history of purulent ear drainage. Diagnosed with otitis media and sub-clinical bacteremia; cultures positive for Pseudomonas aeruginosa. Normal follow-up at one month.
Pearn	1995	Birth	Unknown	Seizure prompted evaluation of neonate found to have hyponatremia attributed to bathwater ingestion/inhalation. Sequelae were not described.
Rawal	1994	Birth	Hospital	Poor feeding and cyanosis were observed in infant 11 hours after WB. Ear and umbilical cultures grew Pseudomonas aeruginosa. Other cultures were negative. Discharged home after seven days of antibiotics.
Rosevear	1993	Labor	Hospital	<ol> <li>Neonate died 15 hours after conventional birth in poor condition following 2.5 hours of maternal immersion during labor. Death attributed to grade three hypoxic ischemic encephalopathy and thalamic hemorrhages.</li> <li>Neonate with grade three hypoxic ischemic encephalopathy after conventional birth in poor condition following maternal immersion for 4.5 hours during labor. Long term sequelae were not described.</li> </ol>
Vochem	2001	Labor	Hospital	Meningitis and bacteremia were diagnosed when Pseudomonas aeruginosa was isolated from cultures of neonate born conventionally after maternal immersion for 30 minutes in early labor. Ventriculoperitoneal shunt was required with 10 revisions in six months. Infant was developmentally appropriate at nine months.

### **Discussion and Conclusions**

This review of the literature revealed a significant body of WB data, although study designs, methodological rigor, and outcomes of interest varied greatly. Most quantitative research on IPI has been observational in nature, in part because utilization preceded study. The body of literature first evolved from descriptive studies to comparative observational approaches. Multiple quasi-experimental case-controlled studies were then published, followed by a recent pilot RCT. This evolution represents maturation of both the practice and related research.

Future investigations should incorporate both the successes and failures of prior researchers. Qualitative researchers, and investigators who administered questionnaires as part of observational studies, have successfully described the decision-making and experiences of IPI. However, these narrative data have been limited to British and Taiwanese samples and need replication in diverse settings and populations.

Quantitative outcomes research has not been as consistently successful, but has significantly advanced and should continue to do so. In future IPI research, physiologic theory and prior studies should inform the selection of salient variables and collection of data. Critical baseline variables must include demographic and confounding clinical characteristics as basic as parity, obstetric risk factors, care processes and interventions. Specifics of immersion provision should also be included, namely dilation at tub entry and exit, water temperature and duration of immersion. WL must be differentiated from WB, and management of the third stage should be described. Given the state of the science, any number of maternal and neonatal outcomes would be significantly advanced with research utilizing objective measurements in addition to subjective assessments to improve the validity of findings, and multivariate analyses to control for confounding variables.

Self-selection bias was inherent in all studies reviewed. Although minimized in Woodward & Kelly's (2004) pilot RCT, women still self selected study participation, could enter a preference arm, and represented an extremely small percentage of women who gave birth at the facility during the study period. This bias is problematic in terms of methodological rigor. However, convenience sampling was appropriate for exploratory IPI research, as it is for any study of phenomena that cannot be reliably examined using probability sampling. It has been argued that this is true of WB. Although Woodward and Kelly (2004) disagreed, their feasibility study demonstrated the difficulty of recruiting women to randomization of interventions, and witnessed high levels of cross-over among study arms. Regardless, descriptions of realistic IPI use in convenience samples are useful and relevant to clinicians caring for women who articulate preferences and exercise choice in childbearing.

Despite the significant limitations to IPI research, several general conclusions can be made regarding findings. First, factors involved in decision-making about IPI involve both preferences for immersion and the relaxation it affords, as well as a rejection of conventional obstetric management independent of IPI. In this way, IPI research can be viewed not just as an evaluation of an alternative obstetric intervention but as a critique of the contemporary maternity care. Qualitative inquiry and other studies designed to explore these themes have the potential to inform not just clinicians providing IPI, but also those whose conventional practices have inspired women to seek alternatives elsewhere.

Investigators have also demonstrated that women who choose to use IPI are healthy and experience outcomes anticipated in low risk populations. Additionally, such women describe significant pain relief and are satisfied with both the intervention and related experience of childbirth. Research is less conclusive regarding any additional effects of IPI, including those related to duration of labor or perineal outcomes. One

promising area of ongoing research is the effect of hydrotherapy on uterine contractility and labor dystocia. There is no evidence to suggest that method of delivery is effected by WL or WB.

Although epidemiologic and descriptive research indicates that WB is relatively safe for the fetus, data remain limited and concerns expressed in case reports of adverse outcomes attributed to IPI have not been conclusively addressed. Accordingly, many have called for continued investigation of WB within institutions and experimental protocols after informed consent (Eckert et al., 2001; Gilbert, 2002; Nguyen et al., 2002; Zimmermann et al., 1993). To date, Apgar scores less than 7 and intensive care admission rates have been the primary outcomes measures used to evaluate neonatal sequelae of IPI, and have precluded assessment of long term neonatal morbidity and mortality. Although Apgar scores at 5 minutes are more predictive of long term sequelae than scores at one minute of life, there are wide interobserver variations and middle range findings are not predictive of neurologic dysfunction unless other abnormal findings are present (American Academy of Pediatrics, 2006; O'Donnell et al., 2006). Similarly, over-reliance on intensive care admission rates in neonatal outcomes evaluation is problematic. Although the incidence of admission may be similar for babies born underwater or conventionally, one wonders whether treatment or outcomes following admission may differ. Future IPI research should consider these questions as well as longitudinal and experimental approaches to research.

Previous descriptive and quasi-experimental WB research methodologies have precluded the establishment of causal relationships, although pilot work has suggested this may be possible in the future. In addition to experimental trials, future qualitative IPI research is indicated since both the psychological and physiological effects of IPI remain largely unexplored. Since existing data are almost exclusively from European samples, descriptions of women utilizing IPI on other continents are needed. This would test the

assumption that the provision of hydrotherapy and related outcomes are similar among divergent populations and settings. In particular, research involving contemporary IPI in the context of inpatient US obstetric care would be a significant contribution to the body of IPI knowledge. Obstetric providers in the US and elsewhere will remain reluctant to increase the availability and provision of IPI without such data, thereby inappropriately restricting the choices available to childbearing women.

Prior reviews of the IPI literature have excluded large portions of the overall body of research, systematically or otherwise. Although more comprehensive than others, this review still failed to include all IPI data by virtue of excluding unpublished trials and literature exclusively published in languages other than English. Although systematic exclusion of specific research methodologies or outcomes measures is appropriate in certain circumstances, it contributes to underestimation of available IPI data on the part of providers and parturients grappling with decisions about utilization. Given the emerging nature of scientific inquiry into the phenomenon, it is critical that existing data are understood and disseminated, as was intended for the comprehensive review presented in this chapter. Publication will satisfy these aims.

The final purpose of this review, that of informing this author's WB research, was also fulfilled. Since existing published data has failed to incorporate inpatient US WB, a community hospital in California was selected as the study site. The relative dearth of US WB research also informed the decision to use a retrospective observational design rather than a randomized approach to prospective study. This comprehensive review also identified critical confounding variables for consideration, and compelled the use of multivariate approaches to analysis. Research methodology and findings will be described in Chapters 4-6.

### **CHAPTER 4**

#### Study Design and Methods

## Introduction

The purpose of this retrospective cohort study was to examine intrapartum IPI and outcomes in a US community hospital with a midwifery service, during the first decade that IPI was available to childbearing women at the facility. The study was designed to overcome some limitations of prior research, thereby increasing the quality of data with which to evaluate WL and WB. The study was also intended to significantly contribute to the state of IPI science presented in Chapter 3. Additional study aims included increased knowledge of safe and efficacious non-pharmacologic intrapartum pain relief and comfort measures, in order to increase evidence-based care practices available to childbearing women.

In addition to a comprehensive review of the IPI literature, an examination of general perinatal outcomes evaluation strategies informed the study design and will be described briefly. The major study instrument, the Optimality Index-United Sates (OI-US), will be discussed in detail. Finally, the study design and methods will be reviewed. *Research Questions* 

This descriptive study was intended to answer three general research questions:

- What proportion of childbearing women at the study site labored or birthed in water over time, and who attended them?
- 2. What are the demographic and clinical characteristics of women who labored or birthed in water, and how do they compare to other parturients at the site?
- 3. Does perinatal optimality differ by hydrotherapy utilization, as measured with the OI-US? If so, what care processes or maternal and neonatal outcomes contributed to differences?

# Hypotheses

Multiple hypotheses related to the research questions were tested including:

- The proportion of births involving hydrotherapy at the study facility will increase over time as providers and childbearing members of the community become more familiar with the practice.
- 2. Women who received midwifery care will be more likely to utilize hydrotherapy than women cared for by obstetricians or family practice physicians.
- Women's use of hydrotherapy will be significantly associated with the specific midwives and individual nurses who attend them.
- 4. Demographic characteristics of women who labor or birth in water will differ from other parturients at the study site with regard to age, parity, race/ethnicity, primary language, education, type of payment for obstetric services and significant social stressors reported.
- 5. Women who utilize intrapartum hydrotherapy will received less analgesia and anesthesia compared to those who receive conventional maternity care, after controlling for demographic and clinical factors.
- Women who utilize hydrotherapy during labor or birth will have less severe perineal lacerations than women who receive standard midwifery care, after controlling for demographic and clinical factors.
- 7. Within the midwifery clientele, OI-US will be highest for women who use intrapartum hydrotherapy, after controlling for baseline demographic and clinical factors.

# Perinatal Research

A review of perinatal outcomes research methods informed this study design and will be discussed, including the primary study instrument, the OI-US.

#### Conventional Approaches to Perinatal Outcomes Evaluation

Historically, perinatal research has focused on risk factors for disease, as well as the identification and incidence of pathology. In both epidemiologic and clinical research parameters of interest have primarily been biophysiologic in nature, with an emphasis on major morbidity and mortality (Murphy & Fullerton, 2001; Vause & Maresh, 1999). Maternal variables often include mode of birth, hemorrhage, infection, perineal trauma, and death. Neonatal morbidity and mortality is generally measured in terms of premature birth rates, birth weight, Apgar scores, and admissions to neonatal intensive care units (NICU). However, several limitations to the exclusive use of major morbidity and mortality measures were considered, including sample size and the complexity of determinants of perinatal outcomes.

Sample size. In the US most childbearing women are relatively healthy and give birth with few, if any obstetric complications (Berg, Mackay, Qin, & Callaghan, 2009; Murphy & Fullerton, 2006). For example, maternal mortality is calculated and reported per 100,000 women and is rarely observed in studies of childbearing women in developed nations (Berg, Mackay, Qin, & Callaghan, 2009; Cragin & Kennedy, 2006). Significant adverse events are rare in any childbearing population, but particularly in healthy women cared for by midwives like those at the study site. For this reason, performing research with a focus on risk and occurrence of adverse events is difficult and requires large samples as well as complex and expensive study designs (Flood & Small, In press; Kennedy, 2006; Murphy & Fullerton, 2006; Sorensen, Sabroe, & Olsen, 1996). These factors influenced the decision to retrospectively use data from more than a decade of maternity care at the study facility, and to incorporate examination of common care processes in addition to uncommon adverse outcomes.

*Minimal psychosocial data.* Perinatal research has been criticized for its biomedical orientation and exclusion of the psychosocial aspects health and healthcare

(Andrist & MacPherson, 2001; Taylor & Woods, 2001). This is particularly pertinent in maternal health care, which primarily involves normal physiologic processes rather than disease states (Andrist & MacPherson, 2001; Taylor & Woods, 2001). To some degree, the omission of psychosocial information in perinatal research has resulted from the limitations of public datasets as well as clinical documentation used for data abstraction. These factors have often precluded retrospective examinations of the subjective experience of childbirth and required expensive and challenging prospective collection of psychosocial data (Main, Bloomfield, & Hunt, 2004; Murphy & Fullerton, 2001; Sandin Bojo, Hall-Lord, Axelsson, Uden, & Wilde Larsson, 2004).

Demands for increased attention to women's subjective experiences of childbirth and other intersections with health care have been clearly articulated for more than a generation (Andrist & MacPherson, 2001; Taylor & Woods, 2001). Despite this feminist call to action, perinatal research has been slow to incorporate much emphasis on the psychosocial aspects of women's health and health care. Recent increased inclusion of women's perspectives has occurred with the advent of "report cards" issued for obstetric providers and organizations by insurers, governmental agencies, consumer advocacy groups and the media (Pillsbury, 2006). This increased oversight and focus on favorable obstetric outcomes has necessarily included measures of patient satisfaction with care (Main et al., 2004; Pillsbury, 2006). Burgeoning evaluation-based pay-for-performance schemes in obstetrics will likely result in a continuation of this trend (Pillsbury, 2006). Regardless of motivating factors, this larger perspective is a positive development within perinatal research. Previously, the exclusive focus on biophysical outcomes prevented observation and recognition of the potentially profound emotional, social and/or spiritual experiences of childbearing (Downe, 2004; Kennedy, 2006). Without attention to these parameters, evaluations of perinatal interventions and outcomes are incomplete.

Unfortunately, the retrospective nature of this study design precluded the evaluation of maternal satisfaction with maternity care practices, including hydrotherapy. However, maternal preferences and choices were reflected in this research given that women, who were clinically eligible, self-selected both midwifery care and hydrotherapy at the study facility. Although self-selection bias is a criticism of non-randomized research, in this instance it represents the inclusion of women's perspectives. Further, multiple psychosocial parameters were examined in order to approximate the lived experiences of women who gave birth at the study site. These parameters are frequently correlated with socioeconomic status and included maternal age; marital status; racial/ethnic origin; primary spoken language; educational attainment; health insurance status; enrollment in the Women, Infants and Children food and nutrition program; trimester of prenatal care initiation; housing/homelessness; incarceration; substance use; psychiatric diagnosis and treatment; involvement by Child Protective Services; adoption; lifetime history of abuse or assault; and domestic violence in the index pregnancy.

*Complexity.* In addition to a mix of biophysical and psychosocial variables, perinatal research must include considerations of both maternal and neonatal parameters. Research designs should reflect the complex nature of perinatal health in which maternal and neonatal conditions are inexorably interrelated but nonetheless independent. Exclusively focusing on one or more maternal variables could result in changes in clinical management detrimental to the neonate. Likewise, prioritizing neonatal parameters may be at the expense of maternal preferences or biophysical outcomes. For this reason, both maternal and neonatal care processes and outcomes were examined in this study

Confounding variables. Perinatal research demands careful evaluation and control of innumerable potentially confounding variables. Demographic parameters

including socioeconomic status and maternal age, clinical characteristics such as gestational age or parity, prior experiences with childbirth and pain relief methods, and pre-existing health conditions or those which evolve during the intrapartum period, are some of the multitude of variables requiring control in rigorous designs. These parameters may differ significantly in patient populations and research samples. This "case-mix" makes comparisons problematic whether performed within a single institution, across several maternity units, or among varied provider types (Cleary et al., 1996; Main et al., 2004).

The complexity of perinatal outcomes evaluations informed this study design which involved careful control of multiple parameters during the evaluation of primary outcomes, and analyses were performed in homogeneous sub-samples. Strategies used to reduce and control the case-mix will be described in detail in subsequent sections.

Additional limitations. Reliance on major morbidity and mortality measures frequently fails to provide valuable details about specific obstetric practices, particularly those of midwives working with moderate and low-risk women for whom traditional adverse outcomes are rare (Cragin & Kennedy, 2006; Murphy & Fullerton, 2001; Vause & Maresh, 1999). Aside from the psychosocial and spiritual dimensions of childbirth, the prevailing outcomes evaluation model also fails to sufficiently account for financial considerations in the evaluation of maternity care practices and obstetric interventions (Downe, 2004; Kennedy, 2006). This is particularly important since the high levels of technologic and medical intervention which typify contemporary childbirth experiences are associated with increased healthcare costs and increased rate of litigation, but not a corresponding improvement in traditional perinatal outcomes (Downe, 2004; Hamilton, Martin, & Ventura, 2009; Kennedy, 2006; Kornelsen, 2005; Martin et al., 2007; Martin et al., 2008; World Health Organization, 1996). Unfortunately, many interventions were introduced prior to systematic evaluation and without supportive data (Enkin et al., 2000; R McCandlish, 2004; World Health Organization, 1996). Simultaneously, the normal physiologic processes of childbirth were re-interpreted as potential or actual pathology (Kennedy, 2006; Taylor & Woods, 2001). For these reasons, among others, the World Health Organization and United States (US) Department of Health and Human Services (DHHS) have called for a re-evaluation of approaches to perinatal research (U.S. Department of Health and Human Services, 2002; World Health Organization, 1985, 1996).

The prevailing disease and risk management perspective, combined with the widespread use of unsupported obstetric interventions, gave rise to a re-evaluation of approaches to perinatal research and maternity care in the latter part of the 20<sup>th</sup> century. The recent evidence-based practice movement has inspired ongoing examinations of prevalent obstetric practices, many of which have been found to be either ineffective or more harmful than beneficial (McCourt, 2005; World Health Organization, 1996; World Health Organization technical working group, 1997). These practices, or processes of care, necessarily became part of the focus of rigorous contemporary perinatal research.

There has also been a movement within perinatal research away from the negative focus on adverse events with pathologic consequences, to a positive perspective inclusive of practices that facilitate optimal health in mothers and newborns. This philosophical and pragmatic shift has inspired the development of several instruments to assess the extent to which obstetric interventions are utilized relative to the baseline clinical characteristics and outcomes observed in a given childbearing population (Chalmers, Mangiaterra, & Porter, 2001; Chalmers & Porter, 2001; Murphy & Fullerton, 2001; Prechtl, 1980; Sandin Bojo et al., 2004; Touwen et al., 1980; Wiegers, Keirse, Berghs, & van der Zee, 1996; World Health Organization, 1996). Although each of these emerging approaches has potential value in examinations of healthy

populations for which historic approaches to outcomes evaluations have been inadequate, the OI-US was selected for use in this research.

# The Optimality Index-United States

The OI-US is a clinimetric instrument designed to assess the mix of care processes and maternal-fetal outcomes observed in a given population. The Index requires and understanding of the optimality concept which will be described.

*Optimality*. General English language dictionaries define optimality as the adverb form of the adjective "optimal," meaning "that which is most desirable or satisfactory" (Mish, 1993). Although optimality and related terms are not generally found in medical dictionaries, some define optimum as that which is most conducive to a particular function (Thomas, 1997). The characteristics of optimality can be extended beyond the robust functionality suggested by dictionaries to include the notion of efficiency and economy as necessary components (Kennedy, 2006). The idea that optimality is a balance between minimal output and maximal function is echoed throughout interdisciplinary literature (Kennedy, 2006). For example, optimality is described as ideal functioning with minimal energy expenditure in discussion of oxygen transport within vascular tissue (Kamiya, Wakayama, & Baba, 1993). When economists discuss optimality, the economization they describe is financial rather than biologic (Kennedy, 2006; Torti, Reed, & Schulman, 2006).

Perinatal optimality. Financial conservation is a key component of optimality as applied to the perinatal health arena as well. Kennedy (2006) defined perinatal optimality as "the maximal perinatal outcome with minimal intervention placed against the dynamic context of the woman's social, medical and obstetric history" (p. 766). Minimizing intervention in the physiologic processes of childbirth among healthy women could facilitate appropriate resource re-allocation in an era of unprecedented health care spending in the US. Research has demonstrated the ineffective or harmful nature of

common interventions indicating that minimization could occur without maternal or neonatal compromise (Enkin et al., 2000; World Health Organization, 1996). This is further supported by failure to observe improved perinatal outcomes despite increased technologic and obstetric management of parturition (J. A. Martin et al., 2006).

Instrument Origins. The OI-US represents a new framework for evaluating perinatal outcomes in which the focus is on the presence of optimum health rather than the occurrence or avoidance of adverse events and abnormal conditions. Murphy and Fullerton first described the OI-US in 2001 and have published several subsequent revisions in collaboration with the OI-US Working Group within the American College of Nurse-Midwives Division of Research, most recently in 2008 (Murphy & Fullerton, 2006, 2008).

The OI-US is an adaptation of the optimality concept and instrument which was first described in the 1960's by Prechtl, a Dutch pediatric neurologist (Murphy & Fullerton, 2001; Prechtl, 1967, 1980; Touwen et al., 1980). Prechtl coined the "optimality principle" theorizing that women in perfect health who experienced normal pregnancies and births, without complications or interventions, would give birth to infants in optimal health (Prechtl, 1980; Touwen et al., 1980). He noted that perinatal complications were poorly defined with relatively scarce normative data, making normal-abnormal dichotomies difficult to identify and utilize. However, he found high levels of consensus among colleagues and in the scientific literature regarding the definition of optimal states, and he began to focus on these instead of normal or abnormal conditions.

Prechtl developed the optimality concept into a related index to test the optimality principle and identify infants who had a "perfect" beginning in life (Murphy & Fullerton, 2001; Prechtl, 1967, 1980). In 1980, he further developed the optimality concept while others refined the index (Murphy & Fullerton, 2001; Murphy & Fullerton, 2006; Prechtl, 1967, 1980; Touwen et al., 1980). Initial testing by Touwen and colleagues (1980) found

that index scores were significantly correlated to neurologic and behavioral observations in the newborn. An additional version of the index was published and tested in the Netherlands in 1996 by Weigers and colleagues who applied the concept and its examination to the practice of midwifery in a study of birth at home (Wagner, 1998; Wiegers, Keirse, Berghs et al., 1996; Wiegers, Keirse, van der Zee, & Berghs, 1996).

The current OI-US represents at least seven revisions of the original Dutch instrument (MacDorman, Hoyert, Martin, Munson, & Hamilton, 2007; Murphy & Fullerton, 2006, 2008). The Index is based on early optimality indices, as well as studies that have examined the philosophy and processes of midwifery care. In particular, the instrument has been contextualized for use in research evaluating the outcomes of midwifery care in the US (MacDorman et al., 2007; Murphy & Fullerton, 2001; Murphy & Fullerton, 2006). Continued evaluation and revision of the instrument has been necessary due to the ongoing development of scientific knowledge to direct evidence-based obstetric practices, as well as the evolution and recognition of social and cultural factors that impact the receipt and provision of obstetric care (MacDorman et al., 2007; Murphy & Fullerton, 2001; Murphy & Fullerton, 2006).

Instrument Evaluation. The current OI-US is a two-part clinimetric instrument comprised of the Perinatal Background Index (PBI) and the Optimality Index (OI) which are contained in Appendix A (Murphy & Fullerton, 2008). The PBI contains 14 items used to describe a woman's sociodemographic characteristics prior to the onset of labor including marital status, ethnicity, alcohol and drug use, age, body mass index and preexisting health conditions. The PBI can be used to determine the case-mix of sample(s) under investigation and allows for assessment of the appropriate comparisons between groups.

The second part of the instrument, the OI, contains 40 items within four domains:(a) diagnostic and therapeutic measures during the current pregnancy, (b) events during

labor and delivery, (c) postpartum neonatal condition prior to discharge from care, and (d) postpartum maternal condition prior to discharge from care. These domains are not considered subscales and are not given individual sub-scores. As a clinimetric instrument, the OI-US simply documents the presence or absence of a clinical conditions and events. Each item is evidence-based with evaluation of the quality of supportive data provided and regularly updated by the authors (Murphy & Fullerton, 2008).

Measures of the subjective experience of maternity care and childbirth are noticeably absent. In the development of the OI-US, psychosocial aspects of care were limited by the nature of a clinimetric instrument. The tool was designed for exclusive examination of data culled from medical records, thus only data commonly noted in clinical documentation could be included (personal communication, J. Fullerton, November 27, 2008).

Scoring. Each item on the index is scored as either 0, when the optimal condition is not present, or 1 when the optimal condition is observed. Item scores are tallied and divided by the number of items to achieve a total optimality score. Higher scores indicate the observation of more optimal care processes and outcomes. Although each subject receives an individual optimality score, these scores are aggregated and reported as group means available for inter-unit comparisons. It should be stressed that the OI-US was not designed to evaluate individual women and the specific management or outcomes they experienced. Instead, the OI-US is used to capture a snapshot of how maternity care is provided and what outcomes are generated by that care, within a service, institution or region. In that sense it is an instrument for global rather than individual perinatal health research.

It is also important to distinguish *optimal* states from *normal* states in order to understand scoring of the OI-US. For example, since more than 50% of women in the US and Britain receive epidural analgesia during childbirth, it is considered a routine

intervention and normal occurrence (Enkin et al., 2000; Impey, MacQuillan, & Robson, 2000). However, optimality indices would not consider the use of analgesia optimal because of associated adverse maternal and neonatal effects (Anim-Somuah et al., 2005; Enkin et al., 2000; Impey et al., 2000; Webb & Kantor, 1992). In light of these data, the highest possible optimality score would require an unmedicated childbirth.

Self-weightedness. This example also lends itself to discussion of an important underlying assumption of the optimality concept and related indices, in the form of selfweightedness (MacDorman et al., 2007; Murphy & Fullerton, 2001; Murphy & Fullerton, 2006; Prechtl, 1980). Prechtl (1980) observed that the degree of neurological morbidity observed in newborns was clearly related to optimality scores on early indices, and that important index items were correlated with each other. Babies with severe neurological morbidity were likely to have clusters of non-optimal scores among correlated items. These clustered or correlated items are the basis of the instrument's self-weightedness.

This critical concept addresses criticism that each item on OI-US is weighted equally despite differences in perceived relative importance. For example, the use of an oral anti-anxiety agent during labor represents the loss of one potential point, since an unmedicated labor is biophysically optimal according to the evidence base. The use of epidural analgesia would also represent the loss of just one point, for the same reason. Critics of the Index argue that epidural analgesia poses greater risks than the one-time use of a mild sedative in early labor, and should be scored accordingly. However, the self-weighted nature of the OI-US ensures that the overall score for a woman who received an epidural would be significantly lower than for a woman who received an oral sedative but had an otherwise uncomplicated birth. This occurs due to the compounding or additive effects of multiple perinatal interventions and complications associated with epidural analgesia, which outweigh the sum of effects from a relatively benign individual intervention like an oral anxiolytic.

For example, women who receive epidurals generally also experience several other interventions, either prophylactically or as indicated by uncomfortable side effects or adverse effects of administration (Anim-Somuah et al., 2005; Lagercrantz & Slotkin, 1986; Leighton & Halpern, 2002a, 2002b; Nystedt, Edvardsson, & Willman, 2004; Sienko, Czajkowski, Swiatek-Zdzienicka, & Krawczynska-Wichrzycka, 2005). Women receiving epidurals are given intravenous hydration beforehand, in an attempt to prevent maternal hypotension which can result from analgesic administration. Maternal hypotension can result in poor placental perfusion and decreased fetal oxygenation evidenced by decelerations of the fetal heart rate observed on continuous electronic fetal monitoring. Supplemental oxygen is often given to women during and after epidural administration to prevent or minimize related fetal distress. Given data that continuous monitoring is associated with increased operative delivery rates but not significantly improved fetal outcomes among healthy parturients, its use would be scored as nonoptimal on the OI-US. Similarly, supplemental oxygen and the presence of fetal distress would result in the loss of potential points. Labor augmentation also commonly occurs in conjunction with epidural analgesia and would further diminish scores. Accordingly, due to the self-weighted nature of the instrument, a woman who received epidural analgesia and concomitant interventions would have a significantly lower Index score than one who received an oral sedative.

*Discriminatory ability.* The OI-US was designed for use in low-risk populations served by midwives. As such, it is important that the instrument be able to distinguish between groups of healthy women without relying on the presence of unusual health conditions or the occurrence of rare adverse events, as required in conventional perinatal outcomes evaluation strategies (Kennedy, 2006; Murphy & Fullerton, 2006). Pilot studies used in instrument development, as well as subsequent research performed with the Index indicate that it has this discriminatory ability (Cragin & Kennedy, 2006;

Kennedy, 2006; Low & Miller, 2006; Low, Seng, & Miller, 2008; Murphy & Fullerton, 2006). For example, Cragin and Kennedy (2006) used the Index to evaluate women with moderate pre-existing risk factors who gave birth at an urban, public teaching facility. Optimality scores among women who were attended by midwives were compared to those for women attended by physicians. Results demonstrated that midwifery care involved significantly more optimal care processes and less interventions than physician care, but achieved equivalent neonatal outcomes. This study demonstrated that the OI-US can facilitate perinatal outcomes evaluation with appropriate assessment of sample risk-status, as well as capture the style or practices inherent to the midwifery model of care. The ability to describe and evaluate midwifery processes of care is critical given the body of scientific literature which demonstrates excellent outcomes of midwifery care but has not fully described how or why these outcomes occur.

Administration. The OI-US is accompanied by a number of resource materials including a user manual, coding and scoring guidelines, a list of references for each item, and sample data abstraction forms (Murphy & Fullerton, 2008). These materials have helped to reduce ambiguity and ensure standardized use even in disparate practice settings by numerous researchers (Murphy & Fullerton, 2006).

Data required by the Index were readily accessible in written and electronic medical records at the study facility (Cragin & Kennedy, 2006; Murphy & Fullerton, 2006; Wiegers, Keirse, Berghs et al., 1996). This ease of data abstraction minimized missing data, contributed to complete explication of the concepts measured by the instrument, and improved its overall utility (Murphy & Fullerton, 2006). In instances where systematic missing data occur, the total number of items (the denominator) may be reduced in subject score calculations. The minimum number of items needed for instrument validity has not yet been determined but development and testing is ongoing in this area (personal communication, OI-US Working Group, November 28, 2007).

Five of 54 instrument items were excluded in this research due to systematically missing data, as outlined in Table 4-1. One such item, pre-pregnancy body mass index, is considered essential given the strong association with poor perinatal outcomes. However, the instrument was scored without these data by reducing the denominator as described previously. This parameter, and others, are well supported by the evidence base but are not commonly noted in routine clinical documentation. Prior users of the Index have experienced similar limitations (Cragin & Kennedy, 2006; Murphy & Fullerton, 2006).

Table 4-1. Optimality index-Onited States items Unavailable FOI Analys	Table 4-1. (	Optimality	Index-United	States Items	Unavailable	For Analy	ysis.
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Parameter
Pre-pregnancy body mass index
Presence of a support person during labor, other than care provider
Non-directed pushing
Non-supine position at birth
Skin-to-skin contact in the immediate postpartum period

*Reliability.* Evaluation of the reliability of a clinimetric instrument differs from that of a psychometric instrument (Murphy & Fullerton, 2006). Within a clinimetric instrument, tests of internal consistency and inter-item correlation are not appropriate given that items are generally discrete and are not intended to make combined contributions to the understanding of a concept (Murphy & Fullerton, 2006). Although clinical correlations between items may be present (e.g. an association between the prenatal diagnosis of a twin pregnancy, and the labor and delivery procedure code for a multiple birth), these associations are not theoretical or conceptual as they would be in psychometric instruments (Murphy & Fullerton, 2006). Given these distinctions, the reliability of clinimetric tools is generally assessed through examinations of reproducibility or intra and inter-rater reliability (Murphy & Fullerton, 2006). Assessment of OI-US inter-rater reliability, expressed as percent agreement, has ranged from 88.5% to 97.8%, with a mean of 92.7% (Seng, Mugisha, & Miller, 2008). These high levels of inter-rater reliability were observed when data abstraction was performed by both lay and clinician researchers, and when data were abstracted from both written and electronic medical records (Seng et al., 2008).

*Validity.* During OI-US instrument development, items were culled from prior optimality indices as well as review of the perinatal and midwifery research literature (Murphy & Fullerton, 2006). Expert panels were asked to evaluate the appropriateness of item inclusion based on the strength of the body of literature in support of optimal and non-optimal scores for each item (Murphy & Fullerton, 2006). Items were not included unless expert consensus on retention and scoring was achieved, which significantly strengthened the instrument's content validity (Murphy & Fullerton, 2006).

As previously described, the OI-US is a clinimetric rather than psychometric instrument, making evaluation of factor loading and subscales irrelevant (Murphy & Fullerton, 2006). Although the OI-US consists of the PBI and OI, each contributes to a total score and not an individual sub-scale (Murphy & Fullerton, 2006). Similarly, the theoretical domains within the OI portion of the Index are not scored separately. *Summary* 

The OI-US represents the most up-to-date scientific understanding of perinatal health and maternity care, was designed for use in the US, and is reflective of contemporary midwifery philosophy and practice (Murphy & Fullerton, 2008). Advantages of use were numerous and included ease, comprehensiveness, and prior rigorous testing. The primary disadvantage was its failure to address maternal experiences and satisfaction with childbirth, although it is recognized that this limitation was intentional given data are typically collected from medical record documentation. For this reason, multiple socioeconomic and demographic variables were included in this research, in addition to data involved in Index scoring. Despite disadvantages, the OI-US has significant potential for re-framing and influencing the future of perinatal health care

and related inquiry. Use in this research is expected to contribute towards this progression.

## Study Design

After ethical approvals were obtained, a retrospective cohort study of births at a California community hospital was conducted. The study period, January 1997 through June 2008, consisted of the first 10 and a half years that IPI was an option for childbearing women at the site. The sample was comprised of all birth events during the study period in which a pregnant woman was admitted to the facility and subsequently birthed at greater than 20 weeks gestation. Among 13,394 cases identified, 622 births occurred after immersion during labor (4.6%) and an additional 675 took place in water (5.0%).

In addition to review of approaches to perinatal research, review of IPI literature informed the research design to avoid pitfalls experienced by prior investigators. As previously described, limitations included violations of assumptions of analytic techniques (Geissbühler et al., 2004; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006), failure to control for multiple and complex determinants of perinatal outcomes (Aird et al., 1997; Bodner et al., 2002; L. Brown, 1998; Burke & Kilfoyle, 1995; Burns & Greenish, 1993; Church, 1989; Geissbühler et al., 2004; Haddad, 1996; Mistrangelo et al., 2007; Ponette, 1995; Rosenthal, 1991, 1996; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006), and poor explication of the construct(s) under study (Adam, 1996; Aird et al., 1997; Burns & Greenish, 1993; Church, 1989; Geissbühler et al., 2002; Haddad, 1996; Hall & Holloway, 1998; Hawkins, 1995; Thoeni et al., 2005; Woodward & Kelly, 2004). In contrast, hypothesis testing for this research was performed on sub-samples restricted to independent observations as required by analytic assumptions. Multivariate analyses were utilized and controlled for sociodemographic and biophysical parameters previously observed to predict poor

perinatal outcomes. Further, provider contributions to hydrotherapy use were examined and biophysical outcomes evaluations were restricted to births attended by midwives. This helped control for baseline demographic and clinical characteristics of subjects as well as the model of care in which hydrotherapy was provided. Importantly, subjects included women who both labored and birthed in water, and the timing of immersion was examined.

### Setting and Sample

The study facility was a suburban California community hospital located near two major metropolitan areas and expansive agricultural regions. The facility had relationships with several tertiary facilities for perinatology, neonatology and other specialty services. Whenever possible, women were transferred to tertiary affiliates for labor prior to 34 weeks gestation and other serious antepartum complications. This study did not include analysis of prenatal referrals to tertiary facilities. However, studies of the practice from 1990 to 1995 indicate that prenatal transfer rates ranged from 0.40% to 2.0% (Schimmel et al., 1992; Schimmel, Lee, Benner, & Schimmel, 1994; Schimmel, Schimmel, & DeJoseph, 1997).

The study site had a level I nursery used for neonatal stabilization and transitional care when required; otherwise babies roomed-in with their mothers or were transferred to intensive care units 30-90 miles away. Post-natal transfers to neonatal intensive care facilities were examined and will be described subsequently.

### Collaborative Practice

Although the study facility was the site of a family practice residency program, births were primarily attended by nurse-midwives, a physician assistant midwife, and obstetricians who comprise an inter-professional collaborative practice. The collaborative practice was founded in 1983 by an obstetrician who believed that nurses in advanced

practice are the most appropriate providers of maternity and gynecologic care for healthy women (Gaskin, 1996; Gaskin, 1996a; Gaskin, 1996b).

*Philosophy of care.* Members of the collaborative practice have asserted that nurses in advanced practice are not simply physician-extenders or substitutions for physicians, but offer a unique perspective and skill set that improves processes and outcomes of care in addition to practice finances (Gaskin, 1996; Gaskin, 1996a; Gaskin, 1996b). Reliance on nurses is believed to facilitate holistic and satisfying care that facilitates physiologic birth by being responsive to women's preferences; providing a greater degree of patient education, communication and labor support; and by reducing routine medical and surgical obstetric interventions as supported by research literature (Gaskin, 1996; Gaskin, 1996a; Gaskin, 1996b).

*Practice Organization.* Over more than two ensuing decades, the philosophy and model of collaborative care persisted and was validated with research while the practice structure evolved and grew significantly (Gaskin, 1996; Schimmel et al., 1997). During the study period the collaborative practice employed three nurse practitioners and four nurse-midwives. In addition to direct patient care for women enrolled in the private collaborative practice, the medical director supervised perinatal care provided by independent non-profit community clinics staffed by several additional midwives (2-6 midwives and 3-7 clinics depending on the period of time). These midwifery clinics served low-income women with satellite locations in most of the county's urban, suburban and rural communities. The clinics were founded in 1989, when women with health insurance through government programs were denied prenatal care by seven of the eight obstetricians in the county (Schimmel et al., 1992). In a unique arrangement, midwives from each of the non-profit clinics and the private collaborative practice comprised a shared on-call group and provided around the clock coverage for any woman seeking intrapartum midwifery care at the study facility.

### Protection of Subjects

Prior to data collection, approval for this research was obtained from the Committee of Human Research at the University of California, San Francisco (approval H12251-32894-01) as well as the institutional review board and chief of obstetrics and gynecology at the study site (Sutter Health Central Area Institutional Review Committee approval #0807065ex). Approvals did not require consent from subjects given the retrospective nature of inquiry and minimal associated risks. Accordingly, subjects were unaware that this research occurred.

*Privacy and confidentiality.* When eligible cases were identified, they were assigned a unique study identification number used during data entry and analysis. This de-identified data could only be matched with medical record numbers and other protected health information using a study roster maintained by the principal investigator under lock and key (hard copy) and password protection (electronic version). The roster was destroyed after study completion.

*Risks and benefits.* The retrospective nature of this research limited the risk of loss of privacy experienced by subjects. Risk was further minimized with the use of deidentified data and protection of the study roster. There were no direct benefits to subjects in this study although the local community could benefit from their participation, as could stakeholders in maternity care at the macro level. The research will contribute to the body of knowledge about comfort measures and pain relief methods for labor and birth, including IPI. This area of knowledge development will be useful to childbirth educators and maternity care providers as well as childbearing women and their families. Study findings have the potential to improve the ways in which they are assisted with comfort and pain relief methods during labor and delivery. The anticipated knowledge will ultimately result in improved patient care through evidence-based

practices. Additionally, findings have the potential to impact maternal satisfaction with childbearing with resultant implications for maternal and neonatal psychological wellbeing in the postpartum period.

### Power Analysis

Given the descriptive comparative study design involving retrospective review of medical records for data collection and analysis, the sample size was pre-determined. However, effect sizes were considered and sample adequacy was evaluated.

Prior research has indicated that the main effect of hydrotherapy is pain relief (Cluett & Burns, 2009). Women who give birth in water have an 8-40% reduction in use of pharmacologic pain relief methods compared to non-immersed women (Garland, 2000; Geissbühler & Eberhard, 2000; Geissbühler et al., 2004; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006). Thus, for testing of the fifth hypothesis, this study needed to be conservatively powered to detect a 20% reduction in pain medication use, which would be a clinically significant reduction. Prior data from the study facility indicated that 40-60% of women who give birth there use some form of pain medication (Schimmel et al., 1992; Schimmel et al., 1994; Schimmel et al., 1997). A 20% reduction would result in <48% of women using pain medication during parturition. This expected proportion was applied to sample size tables for descriptive studies with a dichotomous variable of interest (pharmacologic pain relief method used/not used). Tables indicated that 666 subjects would be required if pain medication use was expected in 50% of the sample, at the 99% confidence level, with a .10 confidence interval (CI) width (Hulley, Cummings, Browner, Grady, & Newman, 2007).

A significantly larger sample was required for examination of group means for OI-US scores related to the study's sixth hypothesis. The sample size required for a descriptive study with a continuous dependent variable is 2,665 at the 99% confidence level, with a .10 CI width (Hulley et al., 2007).

With a sample of 13,392 women, the study had ample power to detect differences in primary outcomes of interest (pharmacologic pain relief method use and perinatal optimality) as well as other important maternal and neonatal parameters. The large sample size permitted examination of rare adverse perinatal outcomes precluded in smaller studies, but risked the detection of statistically significant findings which were too small to be clinically meaningful. In light of this possibility, stringent criteria were set for statistical significance (p<.01) and a 99% CI was selected.

### Data Collection, Management and Validation

### Data Sources

Data were primarily obtained from electronic medical records (Site of Care data management software), with supplementation and validation with data from traditional paper medical charts and midwife log books.

*Electronic data.* Information in the Site of Care database was prospectively entered by clinicians and administrative staff during routine clinical charting, billing and interface with county and state birth certificate and newborn screening programs. Electronic data entry was phased in throughout the study period and documentation was initially duplicated in handwritten medical charts. Unit clerks and nurses were the first to use electronic documentation, followed by delivering providers (midwives, obstetricians and family practice physicians). Neither pediatricians nor anesthesiologists used computerized charting systems during the study period; thus, related data were few and primarily derived from nurses' notes. Due to the incremental introduction of electronic data management at the site, the number of data sources accessed for study depended on the period of time in which cases occurred. Whenever possible, data were triangulated using multiple sources.

Electronic data collection was complicated by idiosyncrasies of Site of Care software which does not facilitate retrieval of complex data for comparative purposes.

The system is organized into several primary domains including Admission, Mother, Baby, Events, and Demographics. Within each are sub-domains, e.g. Delivery (Mother) or Transports (Events). It was not possible to extract data associated with cases in which a specific event occurred (e.g. underwater birth) from more than one sub-domain at a time, particularly if desired data were located in more than one master domain. For example, a single query could not produce maternal outcomes data with associated care processes and neonatal outcomes. Instead, separate queries were required to be run within each of the domains and sub-domains, for each research question. Resultant data were then merged which required exacting management to ensure information was not altered or lost when multiple spreadsheets containing more than 13,000 cases and hundreds of variables were integrated. Syntax (Microsoft Excel) and manual verification of merges were performed.

After extensive integration and organization, significant transformation of electronic data was required. In addition, abstraction of both duplicate and additional data from traditional medical charts and midwife log books was performed. This was largely unexpected given that data in the Site of Care system initially appeared comprehensive. However, the study site used just a fraction of available field codes for electronic data entry. The most troubling practice was the use of a generic narrative data-entry field entitled *Medical Problems*, instead of condition-specific codes or worksheets designed to extract standard responses with checkboxes and scrolling menus. Entries for *Medical Problems* experienced by a particular subject could contain a variety of comments ranging from, "Reports bloody show" to "Prolapsed cord noted on admission," "Wants water birth," or "Gestational diabetic on oral hypoglycemics."

Most information in the *Medical Problems* field was entered in shorthand, phrases and terminology varied by data enterer, and spelling errors were common. Accordingly, for each parameter of interest, relevant data within the *Medical Problems* 

field were required to be manually identified in a process akin to content analysis. For example, medical problems in past and current pregnancies were examined including pyelonephritis in the index pregnancy and a history of chronic renal conditions. To obtain these data, the *Medical Problems* field was searched for multiple terms, phrases and variations including "renal," "pyelonephritis" "hx pyelo," and "kidney infection." Once commonly used terminology and phrases were located, remaining cases were manually individually searched to identify unusual variations and misspellings. Once all renal data were located, they were interpreted and entered elsewhere, either manually or with syntax, in condition-specific fields that enabled subsequent analyses.

Occasionally there was insufficient information in the *Medical Problems* field and reference to other data sources was required. This generally occurred when data enterers used standardized responses generated by Site of Care, such as "kidney and bladder," which were too broad to be of utility for these research purposes. The standard phrase "kidney and bladder" was rarely used, but when it was employed it represented maternal conditions ranging from a remote history of uncomplicated urinary tract infection to a renal stent placed during a recent kidney resection for a congenital anomaly.

The process of reasoning, querying multiple search terms, validating, re-coding and data entry was repeated for each of the 126 care processes and maternal and neonatal outcomes examined in the Index, as well as other parameters of interest related to the generic *Medical Problems* field within the Site of Care database. This was a time-consuming and tedious process which could have been avoided if the study site required the use of detailed standardized responses and condition-specific electronic data entry fields rather than a single narrative note to describe all current and historic medical, obstetric, and psychosocial conditions, as well as triage data such as chief complaint and adequacy of labor support.

#### Validation

Although the use of electronic data presented significant challenges, benefits were numerous. In addition to narrative electronic data, many condition-specific field codes were employed and these proved to be useful and highly accurate when compared to data in handwritten medical charts and midwife log books. Data were triangulated whenever possible, particularly for critical parameters including hydrotherapy, provider type, transfers among providers, and transports to intensive care facilities. Discrepancies were manually resolved with review of available data sources and reference to a priori decisions about the hierarchy of accuracy among information sources. Midwife logs were considered the definitive source for midwife-attended water birth data, as were electronic medical records for information about immersion during the first stage of labor subsequent to the introduction of IPI-specific codes halfway through the study period.

Compared with information derived from delivering provider documentation in the standard medical chart, data abstracted from midwife log books and condition-specific electronic medical record field codes were the highest quality and most comprehensive. These data were prospectively entered by nurses during the course of clinical care, by delivering providers in the postpartum period, and by unit clerks during birth certificate application preparation. When data derived from these sources were compared, percent agreement ranged from 94.36% to 99.92%. The validity of electronic data was previously established during quality improvement activities at the site (Main et al., 2004). Prior system-wide initiatives also minimized missing data with successive educational and administrative interventions (Main et al., 2004). For this research, parameters with greater than five percent missing data were not analyzed except duration of ruptured membranes which was missing in 8% of cases. Missing data were less than one percent for most of the 964 remaining variables.

#### Statistical Analysis

After data entry and manipulation were performed with Microsoft Excel software, the SPSS program was used to further transform variables and perform chi-square analyses, one-way analysis of variance testing (ANOVA), analysis of covariance (ANCOVA), and binomial and multinomial logistic regression analyses of data. Analytic details will be provided in subsequent discussions of hypotheses testing but several generalizations can be made. First, as previously described, the alpha level was set at .01 for all analyses. However, most hypothesis testing revealed significant findings with p values <.001. Second, post-hoc testing was performed whenever significant findings were observed. For significant Chi-square analyses, the magnitude of the identified relationship was assessed with Cramer's V values and standardized residuals were examined in lieu of formal post hoc testing. Standardized residuals were converted to z scores for comparison to the critical value (+/-2.58) associated with an alpha level of .01. Significant residuals were revealed when dependent variable frequencies for one study group were greater or lesser than would be anticipated if all groups were equivalent.

Third, analyses requiring independent observations were performed on sub-samples comprised of women who gave birth at the site just once during the study period, and the first birth to women who delivered there more than once. This prevented violation of analytic assumptions of independent observations incurred in prior IPI studies, by transforming longitudinal data into cross-sectional observations without repeated measures (Geissbühler & Eberhard, 2000; Geissbühler et al., 2002; Geissbühler et al., 2004; Zanetti-Dällenbach, Lapaire, Maertens, Holzgreve et al., 2006). Although this transformation resulted in lost information about IPI use during each of the births to women who delivered at the site more than once during the study period, these data were not critical to examinations of primary research questions and outcomes of interest.

The independent variable IPI was operationalized with three levels in each

analysis performed: 1) no immersion, 2) immersion during labor (WL), 3) immersion during birth (WB). Although women who give birth in water typically do so after some period of immersion during labor, labor and birth in water were considered mutually exclusive events for analytic purposes (i.e. women who gave birth in water were not also counted among those who labored in water). In addition to the categorical variable described, several analyses also examined IPI use with a dichotomous variable that differentiated women who labor or birthed in the tub from those who were never immersed.

Analyses involving type of obstetric provider were performed by intention-to-treat (i.e. women who began intrapartum care with midwives were analyzed as midwifeattended even if their care required transfer to an obstetrician for medical or surgical management and delivery). This helped to minimize but not eliminate the bias presented by complicated cases referred to the obstetrician-attended group. The research design precluded identification of women who, for medical conditions or maternal preferences, were transferred to the obstetric caseload prior to intrapartum admission. Thus, the intention-to-treat model only reflects intrapartum transfers of care.

Clinical guidelines in use at the site outline conditions in which women may be independently managed by midwives, those which require midwife consultation with an obstetrician, instances in which an obstetrician must perform a physical exam and collaboratively manage midwife-attended parturients, and circumstances in which an obstetrician must assume care of a midwife patient (see Appendix B). In general, guidelines mandate obstetric care when forceps or vacuum assisted vaginal delivery or cesarean is anticipated, when women require anti-hypertensive medications or insulin, when non-insulin dependent diabetes is poorly controlled, and when women present with unknown risk status by virtue of not having had prenatal care.

Separate guidelines outline conditions which permit or preclude labor or birth in
water (Appendix C), and specify how providers can ensure IPI is offered safely after informed consent is obtained (Appendix D and Appendix E). Guidelines for hydrotherapy at the study site underwent significant changes in late 2001 and late 2003 when waterproof telemetry units for continuous fetal monitoring were purchased and a review of the evidence in support of IPI was performed. As a result of these activities the guidelines were revised with fewer restrictions on hydrotherapy, and instances in which women could labor but not give birth in water were outlined. Previously, guidelines made no distinction between labor and birth in water, so women were either eligible for water birth or ineligible to enter the tub at any time. A complex variable, w*ater birth eligibility,* was created to account for these changes in clinical guidelines during the study period and to identify women who were eligible for some form of hydrotherapy at the time they gave birth. This information was used to consider whether IPI use was related to a woman's clinical condition in addition to presumed preferences for hydrotherapy.

### CHAPTER 5

### **Results:**

Birth Attendants, Demographics, Care Processes and Perinatal Outcomes This chapter will begin with a description of the maternity care providers who attended subjects during labor and birth. Subsequently, sample demographics, care processes, and general biophysical maternal and neonatal outcomes will be described. Findings will be presented with reference to Chi-square analyses of differences in demographics, maternity care practices and outcomes by provider type.

### Birth Attendants

Members of the midwife-obstetrician collaborative practice (including midwives employed by the non-profit partner organization) attended 80% of births at the facility during the study period. As described in Figure 5-1, the remaining births were attended by family practice physicians and residents (19.5%; n=2,615), and by registered nurses in cases of precipitous delivery (0.3%; n=42). Like family practice physicians at the site, midwife-attended births often involved care by students. Obstetrician-attended births were the only cases in which care was consistently provided by licensed and experienced providers rather than those in training. This difference is an additional reason that outcomes of hydrotherapy were evaluated solely within the midwifery clientele.

More than half of women in this sample were attended by midwives intrapartally (58%; n=7,785), with obstetricians caring for a substantially smaller portion (22%; n=2,952). Midwife-attended births were defined as those in which a midwife from either the private or non-profit organization managed a portion of intrapartum care and intended to perform the delivery. Among midwife-attended women, 8% were transferred to physician care prior to birth, including 44 who were transferred for simultaneous births rather than medical indications (14% of transfers). This is consistent with findings from

prior examinations of the site. Among women who received prenatal care from the consortium's non-profit midwifery clinics in 1990 (N=496), 71% were independently managed by midwives, and 8.8% were transferred to the obstetric service in the intrapartum period (Schimmel et al., 1992).

Midwife-obstetrician consultation and collaboration without referral were beyond the scope of this study. However, a study of the 1,634 births that occurred at the facility in 1992 attended by the collaborative midwife-obstetrician practice, found that 12.6% of women required either consultation or referral from midwifery to obstetrician care (Schimmel et al., 1992). Utilizing data from this study and others at the site which suggest a transfer rate of 8-9%, it can be estimated that 4-5% of women require midwifeobstetrician co-management at the facility (Schimmel et al., 1992; Schimmel, Lee, Benner, & Schimmel, 1994; Schimmel, Schimmel, & DeJoseph, 1997).



Figure 5-1. Flow chart: Labor and birth attendants.

### **Demographics**

The study facility serves a diverse and predominantly low-risk population of childbearing families. Tables 5-2 and 5-3 describe the demographic and clinical characteristics of the sample, comprised of 13,394 who gave birth at the site during the period of study. In addition, the tables note whether chi-square analyses identified significant associations between parameters of study and type of delivering provider. These bivariate analyses were performed to identify whether results of subsequent hypothesis testing performed within the midwifery clientele could be generalized to the entire sample.

			i		
	Analysis by	/ Provid	ier Type		I otal Sample
	Chilenijare	4	والدير ير	Percent (r	(14-1-2,-24) (14-1-2,-24)
	74 47	؛ اد	2 0004		
Panty	11.17	~	<10001		
Nulliparous		•		45.4 (3534)	42.4 (5679)
Multiparous		'		54.6 (4251)	57.6 (7715)
Maternal age at delivery	13.39	Ν	.001		
Teen (19 or younger)		'		9.2 (718)	7.7 (1037)
35 years or older		•		13.5 (1051)	15.9 (2130)
Married or living with a partner	57.54	2	<.0001	89.2 (6943)	90.3 (12097)
History of sexual or physical assault/abuse	49.12	2	<.0001	1.8 (139)	1.2 (156)
Domestic violence in index pregnancy	11.86	2	.003	0.5 (38)	0.3 (46)
Race/ethnicity	98.35	2	<.0001		
Non-Hispanic Caucasian		•		41.9 (3265)	45.0 (6030)
Hispanic		•		45.4 (3532)	42.8 (5728)
Language	197.38	2	<.0001		
English		'		59.2 (4607)	63.3 (8472)
Spanish		'		33.3 (2591)	30.2 (4041)
Other		•		7.5 (587)	6.6 (881)
Educational attainment	205.52	2	<.0001		
Less than high school education		'		30.6 (2384)	26.7 (3579)
High school graduate or equivalent		•		23.8 (1853)	23.8 (3190)
Some college or vocational training		•	•	14.3 (1115)	15.8 (2115)
College graduate		•		14.2 (1104)	14.8 (1977)
Partial/completed graduate education		•		16.3 (1270)	18.0 (2415)
Insurance status	729.99	2	<.0001		
Private insurance		'		42.5 (3305)	51.0 (6828)
Government program		•		56.4 (4389)	47.4 (6346)
Prenatal care	106.99	2	<.0001		
Adequate prenatal care		'		55.6 (4331)	59.2 (7926)
Late to care/ Lapse in care		•		8.7 (678)	7.7 (1026)
No prenatal care				0.2 (14)	0.4 (59)

# Table 5-1. Demographic characteristics of the sample.

Analyzed by intention to treat after excludin	Shoulder dystocia	Chorioamnionitis	Non-cephalic fetal presentation	Meconium stained amniotic fluid	Ruptured membranes >24 hours	Gestational age <37 or >42 weeks	Intrapartum complications	Intrauterine fetal demise	Intrauterine growth restriction	Multiple gestation	Diabetes in pregnancy	Sexually transmitted infection	Eclampsia	Pre-eclampsia	Gestational hypertension	Chronic hypertension	Hypertensive disorders	Psychiatric diagnosis and treatment	Drugs	Alcohol	Tobacco	Substance use	Complications of index pregnancy	Prior cesarean	History of baby <2500 grams	Prior preterm birth(s)	Complication of prior pregnancy	Pre-existing major medical condition		Olisiool sosultios
g cesareans perfo		,	891.36	14.51	74.42	207.32	38.52	30.09	34.40	667.01	697.90	22.37	3.0	161.22	20.40	28.0		44.1	9.0	.65	6.8		403.35	1954.50	11.04	47.73	27.59	57.82	Chi-square	Analysis b
ormed p		,	2	2	2	2	2	2	2	2	0	2	2	2	2	2		2	2	2	2		2	2	2	2	2	2	df	y Provid
rior to onset o		ı	<.0001	.001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	ns (.224)	<.0001	<.0001	<.0001		<.0001	ns (.011)	ns (.722)	ns (.033)		<.0001	<.0001	.004	<.0001	<.0001	<.0001	p value	er Type
)f labor (n=12,590)	3.1 (240)	1.5 (117)	1.6 (125)	23.8 (1852)	23.1 (1801)	5.2 (408)	26.4 (2058)	0.2 (19)	0.7 (58)	0.3 (21)	5.2 (404)	5.3 (410)	0.1 (6)	2.8 (215)	0.9 (70)	0.6 (44)		6.2 (482)	1.6 (127)	0.8 (59)	3.0 (231)		23.5 (1832)	3.0 (233)	1.8 (140)	2.1 (160)	8.8 (687)	18.0 (1398)	Percent	Midwife Group
	3.0 (316)*	1.5 (202)	2.9 (368)*	23.4 (2943)*	25.5 (3009)*	6.8 (913)	28.0 (3752)	0.5 (63)	0.9 (118)	2.1 (227)	7.0 (938)	4.5 (607)	0.1 (12)	3.9 (529)	1.1 (154)	0.8 (110)		5.7 (761)	1.5 (198)	0.7 (95)	2.9 (386)		25.7 (3445)	9.1 (1217)	1.6 (221)	2.5 (331)	8.4 (1123)	17.7 (2366)	(Count)	Total Sample

Table 5-2. Clinical characteristics of the sample.

ns = Not statistically significant at an alpha level of .01.

### Parity

Parity was examined with continuous data as well as a dichotomous variable that distinguished between women who were having their first baby (nulliparae) and those with at least one prior birth (multiparae). Multiparae comprised more than half of the sample (57.6%, n=7715), and most had one or two prior children (83.0%, n=6401). Just 2.9% were grand-multiparae who had given birth 5-12 times previously (n=221). Women in midwifery care were more likely to be nulliparous than women in the care of obstetricians or family practice physicians (Chi-square=71.2, df=2, p<.0001). *Maternal Age* 

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Maternal age was examined as continuous data and with a dichotomous variable that distinguished between women of average childbearing age (18-40 years old) and those at the extremes of age (<18 or >40 years). Although the OI-US uses 40 as the upper limit for optimal maternal age at delivery, advanced maternal age is most commonly conceptualized as 35 years or older so data are presented in several ways to allow for comparisons with other samples.

Subjects' mean maternal age was 28.2 years (SD 6.04). Most subjects were 18-40 years old (95.4%), with a range from 13 to 51. There were no significant differences in the age of women cared for by midwives or obstetricians, but family practice physicians were less likely to care for teens and older women than other provider types (Chi-square=13.4, df=2, p=.001).

### Partnership Status

Partnership status was examined using a dichotomous variable that distinguished between women who were married or living with an intimate partner at the time of birth from those who were not. Most women who gave birth at the study site were married or cohabitating (90.3%). Women who received care from family practice physicians were more likely to be partnered than women in the midwifery or obstetric

caseloads, but there was no difference between women in midwifery and obstetric care (Chi-square=57.5, df=2, p<.0001).

### Violence

Violence was examined with two dichotomous variables, *domestic violence* and *history of assault. Domestic violence* identified women who reported physical or sexual abuse by an intimate partner in the index pregnancy, while *history of assault* identified women who reported a lifetime history of physical or sexual abuse or assault by either a stranger or person known to them previously.

Overall, just 1% of women (n=135) had a documented history of assault/abuse. Forty six women (0.3%) reported domestic violence in the index pregnancy, with those in family practice care less likely to do so than women cared for by midwives or obstetricians (Chi-square=11.9, df=2, p=.003). Women were more likely to have a documented lifetime history of sexual or physical abuse or assault if they were in midwifery care rather than family practice or obstetric caseloads (Chi-square=49.1, df=2, p<.0001).

### Racial and Ethnic Origin

Racial and ethnic backgrounds were successively examined with categorical variables containing ten, five, and three levels defined by the sample's largest subgroups. Ultimately, a dichotomous variable was used (non-Hispanic Caucasian vs. other) to examine racial and ethnic origins by provider type.

The sample was predominantly comprised of non-Hispanic Caucasian (45%) and Hispanic (42.7%) women, with smaller racial and ethnic origin sub-groups including Asian/Pacific Islanders (7.6%), African Americans (1.7%), Middle Easterners (1.1%), Native Americans (0.6%), and Africans (0.3%). Compared to expected frequencies in Chi-square analyses, midwives were significantly more likely to care for Hispanic and non-Caucasian women, while family practice physicians were significantly less likely to do so, and no significant differences were observed for obstetricians (Chi-square=98.4, df=2, p<.0001).

### Primary Spoken Language

Review of nominal data revealed that subjects spoke 73 different primary languages. This parameter was further examined with a three level categorical variable defined by the most commonly reported languages (English, Spanish, other languages). Almost two-thirds of the women in this study spoke some English (63.3%), but 30.2% of women spoke Spanish exclusively. Smaller linguistic subgroups included Asian dialects (3.5%), North African/Middle Eastern languages (0.9%), Russian (1.3%), and various other Indo-European languages (0.5%).

Maternal primary language was associated with provider type (Chi-square=197.4, df=2, p<.0001). Midwives were more likely to care for women who spoke languages other than English, while family practice physicians were more likely to care for English-speaking women than anticipated. Obstetricians were less likely to care for Spanish-speaking women, but there were no other significant differences in expected or observed proportions related to maternal language.

### Educational Attainment

Due to inconsistent methods used to report educational attainment by subjects at the study site, these data could not be analyzed continuously (i.e. number of years in school). Instead, education was examined using a categorical variable with five levels: less than a high school education, high school graduate or equivalent, some college or vocational education, college graduate, and at least some graduate education.

Subjects' educational attainment differed from US childbearing women in 2005, with more women reporting both lower and upper extremes of education (Martin et al., 2007). Fewer subjects completed high school than was reported nationally (72.4% vs. 76.5-79.1%) while a significantly greater proportion of the sample had a college degree

(32.8% vs. 23.3-27.8%) (Martin et al., 2007).

Educational attainment was associated with provider type (Chi-square=205.52, df=2, p<.0001). Midwives were more likely to care for women without a high school education and less likely to care for women with some graduate education than was anticipated. Family practice physicians and obstetricians were less likely to care for women without a high school education than expected. Women with some college education were more likely to be attended by family practice physicians, while women with some graduate education were disproportionately cared for by obstetricians. No other differences between expected and observed frequencies were observed for educational attainment by type of provider.

### Insurance Status

Insurance status was examined with a four level categorical variable: No prenatal care (unknown insurance status), self-paid (no insurance), insurance through a government health care program, and private insurance. Roughly half of the sample had private insurance (51.0%) or insurance through a government program (47.4%). Less than 2% of women had no insurance; among them, 41.9% self-paid (n=90) and 58.1% (n=125) had not obtained prenatal care and were likely eligible for insurance assistance programs. Family practice physicians were more likely to care for privately insured women compared to either midwives or obstetricians, while midwives were more likely to care for women receiving care through a government insurance program compared to obstetricians and family practice physicians (Chi-square=730.0, df=2, p<.0001). *Prenatal Care* 

Three fifths of the sample obtained adequate prenatal care (59.2%, n=7926), defined as initiation in the first trimester and at least five prenatal visits. Although eight percent of subjects were late to care, defined as initiation after 20 weeks gestation (n=1026), just 59 women (0.7%) failed to obtain any prenatal care.

Adequacy of prenatal care was associated with provider type, with midwives more likely to care for women who received inadequate care (63.6%) than either family practice physicians (16.3%) or obstetricians (20.1%) (Chi-square=107.0, df=2, p<.0001). When women without prenatal care were analyzed separately, obstetricians were more likely to have provided care than other provider types (50.8%) but midwives (31.2%) and family practice physicians (18.0%) also participated in their care.

### **Baseline Health Status**

### Pre-Existing Major Medical Conditions

One or more pre-existing major medical condition was documented for 17.7% of subjects, including chronic pulmonary disease or asthma (6.0%, n=804); psychiatric diagnoses requiring medication and/or inpatient treatment (5.1%, n=687); thyroid dysfunction requiring medical or surgical management (2.3%, n=304); chronic renal disease (1.2%, n=166); class II-IV heart disease (1.2, n=160); hypertension (0.8%, n=110); history of cancer (0.8%, n=107); diabetes (0.7%, n=90); epilepsy (0.5%, n=64); clotting disorder (0.4%, n=52); systemic lupus erythematosus (0.1%, n=11); irritable bowel syndrome, Crohn's disease or ulcerative colitis (0.1%, n=20); and/or HIV (n=1).

In a crosstabs analysis of prior medical conditions by provider type, obstetricians were observed to care for women with pre-existing medical conditions significantly more often, while family practice physicians did so less often (Chi-square=57.86, df=2, p<.0001). There were no significant findings for women in midwifery care, 18.0% of whom had one or more pre-existing conditions (n=1398).

### Prior Obstetric Complications

Multiparous subjects (n=7715) were examined for a history of significant complications in one or more prior pregnancies. Complications included a history of premature births, stillbirths, small for gestational age infants (<2500 grams) and births by cesarean, each examined with a dichotomous variable (history versus no history). Other

complications were examined with an aggregate dichotomous variable (history of at least one other complication versus no history of obstetric complications).

A history of 1-7 premature births was reported by 4.3% of multiparae (2.5% of sample), who received care from obstetricians more often than anticipated in crosstabs analysis (Chi-square=47.7, df=2, p<.0001). Women with a history of stillbirth comprised 1.7% of the multiparous sample (1.0% of overall sample), and were also more likely to be cared for by obstetricians (Chi-square=15.6, df=2, p<.0001). Standardized residuals did not reveal significant differences in expected and observed frequencies for prior premature birth or fetal demise in either the midwife or family practice group. A history of having a small for gestational age infant (<2500 grams) was identified for 2.9% of multiparae (1.6% of the sample) who were more likely to receive care in the index pregnancy from midwives, and less likely to receive care from family practice physicians (but not obstetricians) (Chi-square=11.0, df=2, p=.004).

A previous cesarean was reported by 15.7% of multiparae (9.1% of sample), who were more likely to be in the obstetric rather than midwife or family practice physician caseload (Chi-square=1954.5, df=2, p<.0001). The study facility ceased to offer vaginal birth after cesarean as an option for childbearing women at the site halfway through the study period, and mandated obstetric care with a repeat cesarean or transfer of care to a tertiary facility in another county for vaginal birth. Thus, the finding that obstetricians cared for disproportionately more women with a history of cesarean demonstrates adherence to clinical guidelines in use at the study facility.

Other historic obstetric complications were aggregated and examined with a dichotomous variable that included one or more of the following conditions: pyelonephritis, Rh sensitization, gestational diabetes, pre-eclampsia, eclampsia, placenta previa, placental abruption, shoulder dystocia, large for gestational age infant, postpartum hemorrhage, and postpartum depression. Women with one or more of these

documented histories were more likely to receive midwifery care in the index pregnancy, and less likely to receive care from family practice physicians (Chi-square=27.6, df=2, p<.0001). There were no significant differences in expected and observed crosstabs proportions for women in obstetric care.

### Pregnancy Interval

The OI-US defines optimal pregnancy spacing as 18-60 months based on data indicating that adverse maternal and neonatal outcomes are associated with closely spaced pregnancies as well as those which are significantly delayed (Conde-Agudelo, Belizán, Norton, & Rosas-Bermudez, 2005). This research operationalized pregnancy spacing with a dichotomous variable (18-60 month interval versus <18 months or >60 months).

More than a third of multiparous women (37.5%) had non-optimal pregnancy spacing and reported a range from 9 months to 37 years elapsed since their last child's birth. Although a significant association was observed between pregnancy interval and provider type (Chi-square=11.0, df=2, p=.004), no statistically significant differences between anticipated and actual proportions were observed within the contingency table. *Complications of Index Pregnancy* 

### Substance Use

Drug testing is not performed routinely at the study site. Women are requested to consent for testing if they disclose use during verbal screenings, are late to care, or if they appear to be under the influence of drugs during a clinical exam. Subjects reported tobacco (2.9%), alcohol (0.7%) and drug use (1.5%) at low levels. Women who reported drug use (n=198) primarily disclosed poly-substance use (59.1%), followed by methamphetamines (13.1%), marijuana (6.6%), and crack/cocaine (5.6%). Small numbers of women also reported using heroin, ecstasy, hallucinogenic drugs, and/or abusing prescription drugs. There were no differences in the rate of tobacco (Chi-

square=6.8, df=2, p=.033), alcohol (Chi-square=.65, df=2, p=.722) or substance use (Chi-square=9.0, df=2, p=.011) documented for women in midwifery, obstetric or family practice care.

### Psychiatric Diagnosis and Treatment

A dichotomous variable was used to determine that 5.7% of the sample was receiving treatment for one or more psychiatric diagnoses in the index pregnancy (n=761), including 248 women on psychotropic medications. Family practice physicians were less likely to care for women with psychiatric diagnoses and treatment documented in the index pregnancy, but there were no other differences between expected and observed frequencies by provider type observed within a contingency table (Chi-square=44.51, df=2, p<.0001).

### Hypertensive Disorders

Pre-existing hypertension and hypertensive disorders of pregnancy were examined with dichotomous variables that indicated whether or not chronic hypertension, gestational hypertension, pre-eclampsia or eclampsia were present in the index pregnancy. In general, women with hypertensive disorders are referred to obstetric care at the study facility, with the exception of women in midwifery care who develop mild pre-eclampsia that does not require anti-hypertensive medications.

Women with chronic hypertension comprised just 0.8% of the sample (n=110) and were significantly more likely to be cared for by obstetricians than midwives or family practice physicians (Chi-square=28.0, df=2, p<.0001). Obstetricians were also significantly more likely to care for 1.1% of women (n=154) with gestational hypertension (Chi-square=20.40, df=2, p<.0001) and 3.9% (n=529) with pre-eclampsia (Chi-square=161.22, df=2, p<.0001). There was no difference in the rate of eclampsia among provider types (Chi-square=3.0, df=2, p=.224), suggesting they were equally unable to predict disease progression in a small number of women (0.1%, n=12).

### Sexually Transmitted Infection

Sexually transmitted infection (STI) was examined with dichotomous variables that indicated whether or not a woman was diagnosed or treated for herpes (2.0, n=263), chlamydia (1.1%, n=141), hepatitis B (0.7%, n=87), condyloma (0.6, n=86), hepatitis C (0.2%, n=33), gonorrhea (0.1%, n=14), trichomonas (<.01%, n=6), or syphilis (<.01%, n=5) during the index pregnancy. Overall, 4.5% of women in the sample had at least one STI.

The diagnosis and treatment of STI was related to provider type in a bivariate crosstabs analysis (Chi-square=22.4, df=2, p<.0001). Women in midwifery care were more likely to have STI than anticipated, while STI observed among women in the care of family practice physicians and obstetricians was less than expected.

### Diabetes During Pregnancy

Diabetes was relatively common among women who received care at the study site. Seven percent of women were diagnosed during pregnancy while 0.9% had a diagnosis prior to becoming pregnant. Among gestational diabetics in the sample (n=940), 63.8% were treated with exercise and dietary changes, 23.7% received insulin, and 1.8% were prescribed oral hypoglycemic agents.

Obstetricians were more likely to care for women with pre-gestational diabetes (Chi-square=63.9, df=2, p<.0001), and diabetes diagnosed in pregnancy (Chi-square=697.9, df=6, p<.0001), compared to either family practice physicians or midwives. This demonstrates adherence to clinical guidelines in use at the study site which directed midwives to refer women with diabetes uncontrolled by diet and exercise to the obstetric service, until the final year of the study period when midwives began caring for women on oral hypoglycemic agents.

### Multiple Gestation

Overall, 1.1% of women in the sample gave birth to multiples (n=281) and 2.1%

(n=283) of births in the study were plural, including one set of triplets. Women expecting triplets or higher order multiple births at the study site were transferred to tertiary facilities whenever possible. The triplets in this sample were born after precipitous premature labor at 21.28 weeks gestation and did not survive. Twins were generally cared for by obstetricians at the site although women could be inter-professionally collaboratively managed if they preferred, particularly in instances where the first twin presented in a cephalic position. In accordance with guidelines, multiple gestations were associated with provider type (Chi-square=667.0, df=2, p<.0001). Obstetricians were more likely to care for women with multiples (n=237), while family practice physicians and midwives were less likely to do so (n=18 and n=21 respectively).

### Intrauterine Growth Restriction

Intrauterine growth restriction (IUGR) was operationalized as a dichotomous variable that indicated whether the diagnosis was made in the index pregnancy or not. At the study facility IUGR is generally diagnosed with serial ultrasounds rather than isolated observations, although diagnostic criteria were not examined for this research. Less than one percent (0.9%, n=118) of cases had a prenatal diagnosis of IUGR which was associated with provider type (Chi-square=34.4, df=2, p<.0001). Obstetricians were more likely to care for women with an IUGR diagnosis while family practice physicians were less likely to do so. There were no differences in observed or expected diagnoses among women cared for by midwives.

### Intrauterine Fetal Demise

Fetal death after 20 weeks gestation was reported for 63 cases (0.5% of the sample), with most cases occurring prior to hospital admission (n=56). Fetal demise was associated with provider type (Chi-square=30.09, df=2, p<.0001), particularly care from obstetricians (n=31). In crosstabs analysis, midwives were less likely to care for women with intrauterine fetal death (n=19), but there were no significant differences in

observed and expected frequencies of fetal demise for the family practice physician group (n=12).

### Other Antenatal Complications

Additional antepartum conditions were examined with a dichotomous variable that indicated whether one or more complications were noted. Conditions included anemia at term which was defined as hemoglobin <10 gm/dl (1.9%, n=248), placenta previa (0.3%, n=44), vaginal bleeding in the second or third trimester in the absence of placenta previa (0.7%, n=90), pyelonephritis (0.4%, n=48), cholestasis (0.3%, n=41), Rh sensitization (0.2%, n=33) or other isoimmunization (<.1%, n=6), idiopathic thrombocytopenia defined as platelets <50 x 10<sup>9</sup>/L (0.2%, n=33), thrombophlebitis or thrombosis (<.1%, n=4), infectious diagnoses other than STI or group B beta streptococcus (.1%, n=19), and/or antepartum fetal diagnoses (3.4%, n=455). Among cases with antepartum fetal diagnoses (n=455), most had polyhydramnios defined as an amniotic fluid index (AFI) greater than 20 cm (n=192) or abnormal alpha fetal protein testing (n=185), followed by abnormal fetal anatomy per ultrasound (n=29), oligohydramnios defined as an AFI of 5 cm or less (n=24), fetal tachycardia or arrhythmia (n=19), and suspected umbilical cord structure and insertion anomalies (n=6). Overall, 25.7% of subjects experienced one or more antepartum complication and were more likely to be cared for by obstetricians than either midwives or family practice physicians (Chi-square=403.4, df=2, p<.0001).

### Intrapartum Complications

A variety of intrapartum complications were examined including abnormal gestational age at delivery, duration of ruptured membranes, amniotic fluid color, fetal presentation, chorioamnionitis and shoulder dystocia.

### Premature and Post-Term Births

Infant gestational age was assessed with continuous data as well as a

dichotomous variable that differentiated babies born at term (37-42 weeks) from those who were pre or post-mature. As requested by the OI-US, data were derived from newborn examinations whenever possible. However 44.3% of cases were missing physical exam data, and required the use of estimated due dates to calculate probable gestational age in these instances. This limitation and substitution has been experienced by other Index users (Cragin & Kennedy, 2006).

The range of gestational age observed for this sample was 20.28 weeks (n=2) to 46.85 weeks (n=1), with a mean of 39.71 weeks (SD=1.83). Seven percent of women gave birth prior to 37 weeks or beyond 42 weeks (6.8%, n=912) and were more likely to be cared for by obstetricians than midwives or family practice physicians (Chi-square=207.3, df=2, p<.0001). Among these births, 598 took place prior to 37 0/7 completed weeks gestation (65.6%) and 314 occurred beyond 42 0/7 completed weeks gestation (34.5%). When preterm births were analyzed separately, obstetricians were more likely to have provided care, while midwives were less likely to be in attendance than anticipated (Chi-square=347.4, df=2, p<.0001), and no significant differences between observed and expected frequencies were noted for family practice physicians. When post-term births were analyzed by provider type, midwives were more likely to be involved than anticipated (Chi-square=23.2, df=2, p<.0001), while the opposite was true for family practice physicians, and no significant differences were observed for obsetvricians.

### Prolonged Rupture of Membranes

Prolonged rupture of membranes (ROM), defined as greater than 24 hours between rupture and birth, occurred in more than one-fifth of study births (22.7%). Overall, 89.3% of women in the sample gave birth within 72 hours of ROM despite a range from 0 to 93 days. Women with prolonged ROM were more likely to be cared for obstetricians and less likely to be attended by family practice physicians than anticipated (Chi-square=74.4, df=2, p<.0001). There were no differences in observed and expected frequencies of prolonged ROM in the midwifery clientele, in analysis by intention to treat. *Meconium Stained Amniotic Fluid* 

Meconium stained amniotic fluid was examined with a dichotomous variable that differentiated clear amniotic fluid from fluid with any meconium present. Overall, 22.4% (n=2990) of women in the study experienced some degree of meconium staining. In bivariate analyses these women were more likely to be in midwifery care, while women without meconium were more likely to have received care from obstetricians (Chisquare=14.5, df=2, p=.001) and there were no significant differences in observed or expected frequencies of meconium staining for the family practice physician group. However, the analysis was performed for the entire sample, including women who gave birth by cesarean prior to labor. These births may be associated with decreased meconium stained amniotic fluid and could reduce the frequency observed in the obstetrician group. Further, findings were likely related to the increased gestational age previously observed within the midwifery clientele. As such, multinomial logistic regression was performed to control for gestational age. Although the model was significant overall (Chi-square=423.2, df=3, p<.0001), provider type was not found to be associated with meconium stained amniotic fluid (Chi-square=7.2, df=2, p=.027). Non-Cephalic Fetal Presentation

Fetal presentation was difficult to examine with available data since it was documented only for vaginal births, spontaneous or assisted with vacuum or forceps. Among vaginal births, 4.1% (n=547) were associated with non-cephalic fetal presentations. Of these, 67 were vaginal breech births (.5%), including 7 forceps extractions.

Obstetricians at the study site were more likely to attend non-cephalic births (n=402) than either midwives or family practice physicians (Chi-square=891.36, df=2,

p<.0001), who delivered 125 and 20 malpositioned babies respectively. These findings were anticipated given that non-cephalic presentations are associated with operative delivery performed by obstetricians, and because clinical guidelines at the study site endorse vaginal birth for few specific breech and face presentations.

### Other Intrapartum Complications

Additional complications of parturition were examined with a dichotomous variable that indicated whether one or more of the following conditions were present: chorioamnionitis (1.5%, n=202), intrapartum fever without a diagnosis of chorioamnionitis (2.6%, n=342), umbilical cord prolapse (0.2%, n=28), placental abruption (.4%, n=48), maternal-fetal hemorrhage (<.1%, n=3), and shoulder dystocia (2.5%, n=336). Cord entanglement was noted for 24.7% of births, with nuchal cords wrapped 1 to 6 times, but this finding was not considered an intrapartum complication during aggregate analysis. Overall, 28% of women (n=3740) experienced one or more obstetric complication.

Intrapartum complications were associated with provider type (Chi-square=38.52, df=2, p<.0001). Midwives were less likely to care for women with complications than anticipated, while the opposite was true for family practice physicians. There were no significant differences in observed and expected proportions of the obstetrician caseload with intrapartum complications.

### Care Processes

Care processes in the antenatal, intrapartum and postpartum period were examined as described in Table 5-3. Care processes that differed in Chi-square analyses by provider type are noted.

### Antepartum care processes

*Prescription medication.* Overall, 15.7% of women (n=2073) used or were prescribed medication during the antenatal period. Women in obstetric care were more

likely to use prescription medication during pregnancy, while the opposite was true for women cared for by other provider types (Chi-square=172.7, df=2, p<.0001).

Antenatal testing. Almost half of the sample (44.7%, n=5991) had antenatal testing documented. Although substantial, this may underestimate the actual number of women who experienced formal prenatal assessment of fetal well-being. A significant number of women with diabetes, hypertension, cholestasis and other medical conditions warranting testing per site-specific clinical guidelines were not documented as having experienced assessment. Given general issues with under-representation in this particular type of electronic data (few parameters that were retrospectively entered by lay abstracters employed by the study facility) it was rarely used in this study unless validated with information from other sources. This was not possible for antenatal testing data which will likely contribute to type II error but does not necessarily indicate significant provider and patient non-compliance with clinical guidelines.

Antenatal testing was associated with provider type (Chi-square=219.5, df=2, p<.0001). Obstetricians attended disproportionately more births among women who experienced antenatal testing, while women in the care of family practice physicians were less likely to have had testing than anticipated. There were no significant findings for the women in midwifery care.

Induction of labor. Almost one fifth of subjects (17.2%, n=2168) experienced induction of labor with pharmacologic agents, mechanical cervical dilation (Foley bulb) or artificial ROM. Induction was associated with provider type in crosstabs analysis performed in a sub-sample (n=12,590) that excluded women who gave birth by cesarean prior to labor (Chi-square=302.72, df=2, p<.0001). Women attended by obstetricians were more likely to be induced, while the opposite was true for those in midwifery care. There were no statistically significant differences in expected and observed frequencies for labor induction experienced by women in the care of family practice physicians.

	Analysis by	Provide	er Type	(n=7,785)	(N=13,394)
Care Process	Chi-square	<b>₫</b>	<i>p</i> value	Percent	(Count)
Antepartum					•
Prescription medication	172.60	2	<.0001	13.3 (1038)	15.7 (2066)
Antenatal testing of fetal well-being	219.51	2	<.0001	44.2 (3439)	33.1 (4430)
Induction of labor	302.72	Ν	<.0001	13.2 (1031)	17.2 (2168)*
Intrapartum		'			
Augmentation of labor	124.63	Ν	<.0001	43.9 (3420)	49.9 (6690)*
Artificial rupture of membranes				32.2 (2508)	39.1 (5233)*
Augmentation with Pitocin		'		18.3 (1428)	11.3 (1508)*
Intrapartum medications	447.74	Ν	<.0001	59.2 (4605)	64.8 (8163)*
Pharmacologic pain relief	871.43	2	<.0001	41.2 (3211)	50.8 (6400)*
Epidural/Spinal	1441.59	2	<.0001	20.0 (1554)	28.6 (3595)*
Fetal monitoring type	979.0	Ν	<.0001		
Intermittent		•		56.8 (4421)	49.0 (6175)*
Continuous		•		43.2 (3364)	51.0 (6415)*
Non-reassuring fetal monitoring	213.12	2	<.0001	15.5 (1207)	16.7 (2108)*
Episiotomy	113.67	2	<.0001	2.5 (192)	4.0 (447)*
Method of Delivery	3535.02	12	<.0001		
Spontaneous vaginal birth (cephalic)				92.7 (7217)	84.6 (10007)*
Vaginal breech (spontaneous/assisted)	,	•	,	0.2 (12)	0.6 (66)*
Forceps (cephalic)		•		0.2 (16)	0.2 (27)*
Vacuum (cephalic)				2.0 (156)	3.3 (392)*
Cesarean		•		4.9 (379)	11.3 (1335)*
Maternal postpartum procedures		•		•	
Prescription medication for third stage	1384.97	2	<.0001	7.4 (575)	11.1 (1399)*
Prescription for postpartum condition**	639.30	2	<.0001	29.5 (2293)	33.9 (4263)*
Blood transfusion**	11.09	2	.004	0.5 (36)	0.5 (68)*
Repair of obstetric laceration**	873.86	2	<.0001	54.6 (4249)	47.7 (6373)*
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Table 5-3. Processes of care.

\*Analyzed by intention to treat after excluding cesareans prior to labor (n=12,590).

Table 5-3 (continued). Processes of care.					
	Analysis by	Provid	er Type	Midwife Group	Total Sample
Care Process				(n=7,785)	(N=13,394)
	Chi-square	đŕ	p value	Percent	(Count)
Neonatal procedures			'		
Narcan administered	1.63	Ν	.442	0.8 (64)	0.7 (94)*
Admitted to level I nursery	204.01	2	<.0001	2.9 (225)	4.1 (512)*
Transferred to neonatal intensive care	108.59	2	<.0001	1.7 (130)	2.1 (269)*
*Analyzed by intention to treat after excluding cesar	eans prior to la	bor (n=	12,590).		

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### Intrapartum Care Processes

*Labor augmentation.* Augmentation of labor was examined with dichotomous variables that indicated whether membranes were ruptured artificially or Pitocin was administered intravenously after the onset of contractions, in a sub-sample that did not include women who gave birth by cesarean prior to labor (n=12,590). Half of the sample was augmented (49.9%, n=6690); among these women, 78.2% (5233) experienced artificial ROM and 11.4% (n=1508) received Pitocin. Labor augmentation was associated with type of delivering provider (Chi-square=124.6, df=2, p<.0001), with midwives less likely to augment labor than either family practice physicians or obstetricians.

*Intrapartum medications.* The OI-US includes a dichotomous item that captures any medication received in the intrapartum period, including pharmacologic pain relief. The use of intrapartum medications in this sample was examined among women who did not give birth by cesarean prior to labor (n=12,590). Overall, 64.8% (n=8163) received one or more medications during labor. Half of the sample, 50.8% (n=6400) used medication for pain, and 28.6% (n=3595) had epidural or spinal analgesia.

Use of intrapartum medication was associated with type of provider in a bivariate analysis of this sample (Chi-square=447.7, df=2, p<.0001). Obstetricians were more likely to attend women who received one or more medication during labor, while midwives were less likely to do so, and there were no differences between observed and expected frequencies within the family practice physician group. The same findings were true for overall use of pharmacologic pain relief methods (Chi-square=871.4, df=2, p<.0001), and for epidural/spinal analgesia when analyzed separately (Chisquare=1441.6, df=2, p<.0001).

*Fetal monitoring.* Fetal monitoring was examined with dichotomous variables that identified whether intermittent or continuous electronic fetal monitoring (EFM) was

employed, and whether non-reassuring monitoring was observed among women who labored prior to birth (n=12,590). Roughly half of the sample experienced intermittent (49.0%, n=6175) or continuous monitoring (51.0%, n=6415). Type of fetal monitoring was associated with provider type (Chi-square=979.0, df=2, p<.0001). Obstetricians were more likely to employ continuous EFM, while women attended by midwives were more likely to experience intermittent auscultation of fetal heart tones, and there were no significant differences between observed and anticipated frequencies for fetal monitoring type within the family practice physician group. Non-reassuring EFM findings were present in 16.7% of cases (n=2108) and were associated with the obstetrician caseload (Chi-square=213.1, df=2, p<.0001). The midwife and family practice physician clienteles had abnormal fetal heart rate tracings less often than anticipated.

*Episiotomy*. The use of episiotomy was examined in a sub-sample of women who did not experience cesarean prior to labor (n=12,590). Just 4.7% of births involved episiotomy, a procedure disproportionately experienced by women in the care of obstetricians and family practice physicians compared to the midwifery clientele, in bivariate analyses (Chi-square=113.7, df=2, p<.0001).

*Method of delivery*. The method of delivery experienced by subjects was examined in a sub-sample (n=12,590), after excluding women who gave birth by cesarean prior to labor. The aggregate cesarean birth rate was 15.6%, with a primary cesarean rate of 10.0% (percentage of women having their first cesarean). Among cesareans in this sub-sample, 23 (.18%) involved classical/vertical incisions and 3 (.02%) required hysterectomy. Vacuum (2.9%, n=392) and forceps (.25%, n=34) assisted deliveries were less common than spontaneous vaginal and cesarean births in this sample.

Method of delivery was associated with provider type, despite intention to treat analysis and exclusion of women who experienced a cesarean prior to labor (Chi-

square=3535.0, df=12, p<.0001). A bivariate contingency table indicated midwives and family practice physicians were more likely to attend spontaneous vaginal births than anticipated, while obstetricians were less likely to do so. Women in the care of family practice physicians were more likely to have a vacuum assisted birth, while the opposite was true for women in midwifery care, and there were no significant differences between observed and expected frequencies of vacuum extraction for women in obstetric care. As clinical guidelines suggested, obstetricians were more likely to attend vaginal breech births and cesareans than would have been anticipated if there were no differences among provider types.

### Maternal Postpartum Procedures

Several maternal postpartum procedures were examined including medications administered in the third stage of labor, prescriptions for a condition newly diagnosed in the postpartum period, blood transfusion and repair of obstetric laceration. Examinations were performed on sub-samples that did not include the 804 women who experienced cesarean births prior to labor (n=12,590).

*Prescription medication in third stage labor.* A dichotomous variable was created to identify cases in which women received medications other than oxytocin or local anesthesia during the third stage of labor. Overall, 11% of the sample received other medications in the third stage, a finding that was associated with type of delivering provider (Chi-square=1385.0, df=2, p<.0001). Women in obstetric care were more likely to receive a medication than women in either midwifery or family practice physician caseloads.

Prescription for new postpartum condition. In addition to intrapartum medications, new prescriptions for conditions that presented in the postpartum period were examined with a dichotomous variable. This variable excluded contraceptives, vitamins and iron supplements, vaccines, Rhogam, and analgesics provided over the counter. A third of

women received a new postpartum prescription (33.9%, n=4263), and were more likely to do so if they were in the care of obstetricians (Chi-square=639.3, df=2, p<.0001).

*Blood transfusion.* The blood transfusion rate was identified as 0.5% (n=68). Blood transfusion was associated with provider type, and more common among women in obstetrician care than anticipated within a bivariate contingency table (Chisquare=11.1, df=2, p=.004). There were no differences in observed and expected frequencies for blood transfusion within the midwifery and family practice physician groups. These findings are likely related to the increased cesarean rate within the obstetric group, a method of delivery associated with increased maternal blood loss and incidence of hemorrhage.

*Obstetric laceration repair.* Repair of obstetric laceration was examined in a subsample of women who did not give birth by cesarean (n=10,545). More than half of the sample experienced obstetric laceration requiring surgical repair (56.6%, n=5966), including 5,650 women who experienced mild laceration (first or second degree) and 310 with severe laceration involving the rectum (third or fourth degree). There was no significant relationship between provider type and obstetric laceration requiring repair in bivariate crosstabs analysis (Chi-square=5.9, df=2, p<.051),

### Neonatal Procedures

Neonatal procedures, including Narcan administration and admission to level I or intensive care nurseries, were examined with dichotomous variables among the 12,590 women who did not give birth by cesarean prior to labor. Narcan is generally administered to newborns who are observed to have suppressed respiratory effort and delayed transition to extrauterine life after maternal intrapartum receipt of narcotics for pain relief. In this sample, 0.7% of babies received Narcan (n=94). This parameter was not associated with type of delivering provider, suggesting that providers were equally adept at timing the appropriate administration of pharmacologic pain relief methods (Chi-

square=1.63, df=2, p=.442).

During the study period 4.1% of inborn infants (n=512) were admitted to the level I nursery, and 2.1% were transferred to NICU (n=269). The standard for neonatal care at the study facility was "rooming-in," or nursing care of the mother-baby dyad in the delivery room. Babies were admitted to the level I nursery only if transition to extrauterine life was compromised and individual nursing care was required. If neonates could not be stabilized within four hours of birth, they were transferred to an intensive care unit elsewhere.

In bivariate analyses provider type was associated with both nursery admissions (Chi-square=204.0, df=2, p<.0001) and NICU transports (Chi-square=108.6, df=2, p<.0001). Infants delivered by obstetricians were significantly more likely to be admitted or transferred than anticipated, while babies in midwifery or family practice care were more likely to remain in dyad care. These differences are likely attributable to uncontrolled differences in risk status, care processes and complications experienced among groups defined by provider type.

### **Biophysical Outcomes**

Multiple standard biophysical perinatal outcomes were examined including obstetric laceration, retained placenta, postpartum hemorrhage, birth weight, Apgar scores, congenital anomalies, birth trauma, breastfeeding and death. Table 5-4 describes the maternal and neonatal parameters examined with reference to bivariate analyses by provider type.

Table 5-4. Maternal and neonatal biophysical	outcomes.				
				Midwife Group	Total Sample
Outcomes	Analysis t	oy Providei	Туре	(n=7,785)	(N=13,394)
	Chi-square	ďŕ	ø value	Percent	(Count)
Maternal parameters	•			•	•
Perineal outcomes	3862.45	2	<.0001		
Intact perineum	ı			35.1 (2731)	37.6 (3949)*
First degree laceration			,	29.4 (2289)	26.2 (2749)*
Second degree laceration			,	28.0 (2183)	33.1 (3481)*
Third degree laceration			,	2.1 (163)	2.5 (258)*
Fourth degree laceration		'		0.5 (40)	0.6 (66)*
Retained placenta	11.52	2	.003	2.5 (197)	3.0 (335)
Postpartum hemorrhage	81.58	2	<.0001	11.8 (922)	13.4 (1710)
Other postpartum complications	24.68	2	<.0001	2.8 (220)	2.5 (335)
Maternal death		,	,	0	0
Neonatal parameters	·				
Birth weight <2500 or >4000 grams	293.14	2	<.0001	16.7 (1299)	18.1 (2416)
Five minute Apgar score <7	20.40	2	<.0001	1.1 (86)	1.4 (182)
Breastfeeding at discharge	31.66	2	<.0001	94.0 (7317)	94.5 (12403)
Congenital anomalies noted	2.91	2	.233	0.6 (44)	4.9 (66)
Neonatal complications	39.94	2	<.0001	6.7 (521)	7.2 (955)
Infant death	11.87	2	.003	0.1 (6)	0.1 (18)
* Analyzed by intention to treat after evolution	a cocorcon hitthe	2123 014-40			

\* Analyzed by intention to treat after excluding cesarean births (n=10,545).

### Maternal Parameters

*Perineal outcomes.* Perineal outcomes were examined with a five level categorical variable (intact, first degree, second degree, third degree, fourth degree) in an independent sub-sample after excluding cesarean births (n=10,545). More than a third of women in the restricted sample had an intact perineum (37.6%, n=3949). The second largest sub-group was comprised of women with second degree lacerations (33.1%, n=3481), followed by first degree (26.2%, n=2749), third degree (2.5%, n=258) and fourth degree lacerations (0.6%, n=66).

The relationship between perineal laceration and provider type was then examined. A significant association was observed, with women in midwifery care more likely to experience a first degree laceration, and less likely to have a second degree laceration, compared to family practice and obstetric caseloads (Chi-square=334.3, df=8, p<.0001). There were no differences in severe laceration or intact perineums among women cared for by different providers in this bivariate crosstabs analysis.

Retained placenta. Retained placenta was defined as third stage labor lasting greater than 30 minutes, with or without hemorrhage. By these criteria, 3.0% (n=335) of the sample experienced a retained placenta, with 1.6% (n=217) requiring manual placental removal. Retained placenta/prolonged third stage labor was associated with provider type in this sample (Chi-square=11.5, df=2, p=.003). Women in the care of obstetricians were more likely to experience a retained placenta than anticipated, but there were no other differences within the contingency table.

*Postpartum hemorrhage.* Postpartum hemorrhage was defined as at least 500 cubic centimeters (cc) of estimated blood loss following vaginal delivery, or at least 1000 cc after a cesarean delivery. More than a tenth of women in the sample experienced a postpartum hemorrhage (13.4%, n=1710), with estimated blood loss ranging from 25 cc to 4250 cc overall. Hemorrhage was associated with provider type in a bivariate

analysis, with a higher incidence than anticipated in the obstetrician caseload, and lower than expected frequencies within the midwife and family practice clienteles (Chi-square=81.6, df=2, p<.0001).

*Other postpartum complications.* Additional postpartum complications were examined with a dichotomous variable that identified cases in which one or more of the following complications occurred prior to hospital discharge: elevated temperature or new infectious diagnosis including cystitis, endometritis, mastitis and/or wound infection; wound breakdown; hematoma; urine retention; separation of the symphysis pubis; thrombophlebitis or thrombosis; postpartum depression or psychosis; uterine inversion; unplanned operation after childbirth; or admission to an intensive care unit. Just 2.5% of the sample experienced one or more of these complications. Overall, this parameter was associated with provider type but post hoc testing indicated that the only significant difference within the contingency table was a lower than expected frequency of postpartum complications for the family practice physician group (Chi-square=24.68, df=2, p<.0001).

*Maternal death.* There were no maternal deaths in this sample. Analysis was limited to data recorded by employees of the study facility prior to a woman's hospital discharge (generally 24-72 hours postpartum).

### Neonatal Parameters

*Birth weight.* In accordance with OI-US instructions, birth weight was primarily analyzed with a dichotomous variable that indicated whether or not a baby weighed <2500 grams or >4000 grams versus 2500-4000 grams (appropriate for gestational age). Additional analyses of birth weight were performed using continuous data and a three level categorical variable (<2500 grams, 2500-4000 grams, >4000 grams) to facilitate comparisons with prior research findings.

Birth weight ranged from 230 grams 5610 grams, with a mean of 3487 grams

(SD=535.55 grams). Almost one-fifth of the neonates were either small or large for gestational age (18%, n=2416); among these, just 17% were <2500 grams (n=411). Half of the sample was comprised of infants weighing 3500-3999 grams (34.5%) or 4000-4500 grams (14.7%).

Newborn birth weight was associated with provider type, whether analyzed with continuous, dichotomous or categorical data. In the analysis of categorical birth weight data by type of provider, obstetricians delivered small infants more often than anticipated while the opposite was true for midwives and no differences were observed for family practice physicians (Chi-square=293.1, df=2, p<.0001). Obstetricians were also less likely to deliver infants with appropriate for gestational age birth weights but no other significant differences were observed within the contingency table. These bivariate findings are likely related to the increased frequency of premature infants in the obstetrician group, among other uncontrolled differences by provider type.

*Five minute Apgar score.* Five minute Apgar scores were chosen as one of the primary neonatal outcome measures given the association between scores less than seven and neonatal mortality and morbidity (American Academy of Pediatrics, 2006). Further, the widespread use of Apgar scores facilitated comparison of these data with findings from prior research.

Overall, 1.4% of babies in the sample were assigned Apgar scores less than seven at five minutes (n=182). Scores less than seven were significantly associated with provider type in a bivariate crosstabs analysis, with obstetricians more likely to deliver infants with low scores than was anticipated, while midwives were less likely to do so. There was no difference between observed and expected low Apgar scores among women attended by family practice physicians (Chi-square=20.4, df=2, p<.0001).

Breastfeeding. Infant feeding at hospital discharge was examined with a three level categorical variable (exclusive breastfeeding, breast and formula feeding, exclusive

formula feeding). The overwhelming majority of women with live births were breastfeeding (with or without formula supplementation) at the time of hospital discharge (94%). Most breastfeeding mothers in the sample were doing so exclusively (92%, n=11,465) while a combination of breast and formula feeding was reported by 977 others. Just 6.3% of babies were exclusively formula fed at the time of hospital discharge (n=721), although this was greater proportion than anticipated based on the number of women who reported planning to formula feed upon admission prior to delivery (n=607). Discrepancies between planned and actual infant feeding practices were less pronounced for exclusively breastfed infants (11,498 versus 11,465) and for infants who were both breast and formula feed (943 versus 977). Breastfeeding was associated with type of delivering provider, with women in midwifery care more likely to breastfeed than anticipated, while women in obstetric care were less likely to do so (Chisquare=31.7, df=2, p<.0001).

*Congenital anomalies.* Among babies in the sample, 0.5% (n=70) were observed to have one or more congenital anomalies. There was no statistically significant difference in the frequency of anomalies among groups differentiated by provider type (Chi-square=2.9, df=2, p=.233).

Neonatal complications. Neonatal complications prior to hospital discharge were examined with a dichotomous variable that indicated whether or not a complication listed in Table 5-5 was observed. Of note, drug toxicity was defined by the study facility as maternal drug use, infant withdrawal symptoms, maternal analgesia necessitating infant treatment, or infant Narcan administration.

able 3-3. Neonalaí complications prior to nospital dischar	ge (11-13,394).
Condition	Count (Percent)
Anemia	51 (0.4%)
Apnea	29 (0.2%)
Aspiration other than meconium	1 (<.01%)
Atelectasis	1 (<.01%)
Birth injury, cumulative	299 (2.2%)
Brachial plexus injury	12 (0.1%)
Bronchopulmonary dysplasia	0
Cardiac complications	0
Cardiac failure	0
Cephalohematoma*	151 (1.1%)
Cerebral palsy	0
Clavicle fracture	33 (0.2%)
Conjunctivitis*	18 (0.1%)
Drug toxicity	315 (2.4%)
Electrolyte imbalance	91 (0.7%)
Hypoxic-ischemic encephalopathy	0
Intracranial bleed	0
Intraventricular hemorrhage	0
Jaundice, any etiology*	1074 (8.0%)
Laceration, other than scalp injury	5 (<.01%)
Meconium aspiration syndrome	36 (0.3%)
Necrotizing enterocolitis	0
Neurologic diagnosis, other	2 (<.01%)
Persistent pulmonary hypertension	7 (0.1%)
Pneumonia	39 (0.3%)
Polycythemia	8 (0.1%)
Renal failure	0
Respiratory complications, other	64 (0.5%)
Respiratory distress syndrome	83 (0.6%)
Rh disease	3 (<.01%)
Scalp injury	41 (0.3%)
Seizure	9 (0.1%)
Sepsis	6 (<.01%)
Shock (hypovolemia, hypotension)	0
Skull fracture	0
Subgleal hemorrhage	0
Transient tachypnea of the newborn*	454 (3.4%)

Table 5-5. Neonatal complications prior to hospital discharge (N=13,394).

\*Parameter did not contribute to Optimality Index-United States scores.

Neonatal complications were associated with type of provider, with obstetricians

more likely to be listed as delivering provider than expected (Chi-square=39.9, df=2,

p<.0001). Family practice physicians were less likely to deliver neonates with

complications than anticipated, but there were no differences in observed and expected

complications within the midwifery clientele.

*Infant death.* Infant death between birth and hospital discharge was examined. Overall, 18 infants died (0.1%); among these, 13 died immediately after birth, three died at the study site before transfer or discharge, and 2 died within 72 hours of birth after being transported to another facility. Infant death was associated with provider type for this sample, with obstetricians more likely to be in attendance than anticipated (Chisquare=11.87, df=2, p=.003). There were no differences between observed and expected frequencies of infant death for the midwife or family practice clientele. These bivariate findings are likely due to decreased gestational age and other risk factors experienced in the obstetric caseload.
#### CHAPTER 6

#### **Results: Intrapartum Immersion**

This chapter describes study hypotheses, testing and results. Hypotheses all involved IPI, thus the history and current procedures for use are presented first. Analyses are described subsequently. Methods varied among seven hypotheses and included contingency tables, binomial and multinomial logistic regression, ANOVA, and ANCOVA.

IPI was introduced at the study site in 1997 when two soft-sided, deep immersion Aqua-Doula tubs were purchased. When filled to a depth of 18 inches, the tubs contain 150 gallons of water and can comfortably support a woman submerged to the axillae (AquaDoula, 2005). The tubs are placed upon heating elements which allow clinicians to set and maintain bath water temperature electronically. A separate submersible thermometer facilitates monitoring and documentation of bath water temperature. In addition to features that ease temperature regulation, the tub model was designed to decrease contamination and infection. For example, the tub is lined with a single-use, disposable shell. After use, the liner is removed and discarded before the tub is cleansed thoroughly. The self-contained pools provide a still-water bath, without whirlpool jets or fixtures which would require extensive back-flushing during cleaning procedures. Tubs are filled with an external water supply hose that is not provided by the manufacturer. The manufacturer recommends that a new hose be used for each patient who enters the tub. To prevent contamination of the water supply, the hose should not be submersed in water that has already been used by a woman. These hygienic practices are critical given concerns about transmission of infection during IPI.

Although AquaDoula tubs were designed to be portable, the facility permanently installed them in two rooms remodeled to facilitate privacy and relaxation during hydrotherapy. Curtains can be pulled around the tubs placed on the tiled portion of an

open bathroom. A shower head on a cord can be pulled down from the wall next to the tubs for therapeutic use on the abdomen or lower back during immersion. The bathroom lights are on a dimmer switch and kept low, contributing to a calm and restful environment.

IPI was introduced as a natural extension of the woman-centered and holistic collaborative practice model. During the study period the facility offered a spectrum of choices in maternity care, with a focus on supportive data and informed consent rather than exclusive endorsement of specific care practices. Within this framework, the facility offered dedicated anesthesiology services, a volunteer labor support/doula service and hydrotherapy, in addition to other innovative care practices and programs (e.g. lactation consultants and infant massage classes).

The context in which IPI was provided at the site during the study period is crucial to understanding the phenomenon, and is consistent with descriptions of holistic maternity and midwifery care featuring IPI elsewhere (Balaskas, 1996; Balaskas & Gordon, 1990; Geissbühler & Eberhard, 2002; Lichy & Herzberg, 1993; Odent, 1983, 1998). The context of IPI was difficult to measure for examination but several related hypotheses were tested and will be described subsequently, including tests of association between hydrotherapy and time, provider type and individual care providers. As Table 6-1 describes, 10% of births at the facility during the 10 ½ year study period involved WL or WB.

	Nurse- Midwife	Family Physician	Obstetrician/ Gynecologist	Registered Nurse	TOTAL
No	6,005	2,544	3,509	39	12,097
Immersion	(83.9%)	(97.2%)	(98.2%)	(92.9%)	(90.4%)
Labor in	527	38	56	1	622
Water	(7.3%)	(1.5%)	(1.6%)	(2.4%)	(4.6%)
Birth in	629	35	9	2	675
Water	(8.8%)	(1.3%)	(0.2%)	(4.8%)	(5.0%)
TOTAL	7,161 (53.5%)	2,617 (19.5%)	3,574 (26.7%)	42 (0.3%)	13,394

Table 6-1: Intrapartum immersion and provider type (N=13,394).

## Hypothesis One

The proportion of births involving hydrotherapy will increase over time as providers, childbearing women and the community become more familiar with the practice.

# Hypothesis Testing

IPI was introduced at the site in 1997 but utilization remained very low for several years, as demonstrated in Figure 6-1. WB occurred just 5-18 times annually for the first 3 years it was an option. Between the third and fifth years of availability the number of annual WB doubled and then held for 4 years (76-84 annually). After a slight decrease in 2005 (n=56) and 2006 (n=66) the number of WB doubled during the final six months of the study (n=67).



Figure 6-1. Labor and birth in water over time.

Although these data could not explicate reasons for fluctuations in IPI they support a relationship between IPI utilization and periodicity. There was a small but significant Chisquare association between the six month period of time in which a birth occurred and the incidence of immersion during labor (Cramer's V= 0.171, p<.001) and birth (Cramer's V= 0. 122, p<.001). The strength of this relationship is limited by the small percentage of births involving IPI within the larger sample.

It is likely that periodic fluctuations in the incidence of WB were related to staff turnover, equipment maintenance/malfunction, and patient census among many other potential covariates beyond the scope of this study. With just two birthing tubs on the unit and a range of 1-11 births per 24 hour period, it was not uncommon to see a notation in midwife log books about women's disappointment when no tub was available for their use. Indications that facility and provider factors were related to IPI incidence warranted subsequent examination of the relationships between clinicians and women's decision-making and use of hydrotherapy.

#### Hypothesis Two

Nurse-midwife patients will be more likely to utilize IPI than women cared for by obstetricians or family practice physicians.

## Hypothesis Testing

Chi-square analysis was used to assess the relationship between provider type (by intention to treat) and women's use of warm water immersion during labor or birth at the study site. Hypothesis testing was performed on the sub-sample of unique women who did not give birth by cesarean without labor (n=2086), after excluding births with registered nurses listed as the sole delivering provider (n=42) since they were frequently precipitous deliveries that could not involve IPI. These exclusion criteria resulted in 8,817 remaining cases.

Initially, IPI was dichotomized (yes/no) using aggregated data about immersion during labor and/or birth. In this model 986 births (11.2%) involved IPI and were predominantly attended by midwives (93.7%). Family practice physicians contributed 5.4% of cases while obstetricians attended just 0.9% of births involving immersion. A small but significant association between provider type and IPI was noted (Cramer's V= 0.201, p<.0001). The magnitude of the association was likely limited by the relative rarity of IPI in the sample; just 15.6% of midwife-attended births involved immersion (n=924), compared to 2.7% of family practice physician-attended births (n=53) and 0.9% of obstetrician-attended births (n=9).

When analyses were repeated for IPI distinguished by timing, using a three level categorical variable (no immersion, immersion during labor, immersion during birth), the association with provider type remained significant but decreased in magnitude (Cramer's V= 0.142, p<.0001). This was probably a function of differentiating immersion during labor from underwater birth, which decreased the number of cases analyzed per group. Among midwife-attended births, 7.7% occurred after immersion during labor (n=456) and 7.9% occurred underwater (n=468). In comparison, 6.1% of births attended by family practice physicians occurred after immersion in labor (n=30), and 4.7% (n=23) took place in water. Women attended by obstetricians were the most unlikely to use IPI; just 7 labored in water (1.4% of OB-attended births) and 2 gave birth there (0.4% of OB cases). Observed differences in rate of IPI by provider type are unlikely to be a function of provider differences in documentation rather than incidence since data were triangulated using multiple sources.

#### Hypothesis Decision

Data support hypothesis two. Midwifery care was significantly associated with women's use of hydrotherapy, compared to care from family practice physicians and obstetricians.

### Hypothesis Three

Women's use of hydrotherapy will be significantly associated with the specific midwives and individual nurses who attend them.

### Hypothesis Testing

Chi-square analysis was performed to test for an association between the midwives and nurses in attendance at a woman's birth and her use of IPI. First, midwife-attended births were examined in an independent sub-sample, after excluding births by cesarean section without labor. After exclusions, 6266 births remained with 52 individual midwives in attendance. When IPI was examined as a three level categorical variable, a small but significant association with individual midwives was observed, and 4.4% of the variance in IPI use was explained (Chi-square=554.7, df=102, Cramer's V=.210, p<.0001). As previously noted, the magnitude of association was likely limited by the relative infrequency WL and WB. Seven midwives did not attend women who labored or birthed while immersed; collectively, they attended just 73 births (1.17% of the sub-sample). IPI was examined in detail for remaining midwives, who contributed an average of 137.6 cases to the analysis (range = 3 to 578 births). The mean proportion of births attended by individual midwives was calculated by IPH utilization. On average, 82.96% of midwife-attended births did not involve IPI, with a range from 28.6% (n=2) to 95.0% (n=344). Conventional births after WL comprised an average of 9.55% of midwives' individual contributions to the sub-sample, with a range from 1.9% (n=6) to 36.4% (n=8). WB contributed an average of 11.6%, with a range from 0.8% (n=1) to 50% (n=1).

Crosstab calculations were then performed with data about individual registered nurses present at births attended by any type of delivering provider (n=8,555). As was observed for specific midwives, a woman's use of immersion during labor or birth was associated with her particular labor nurse. This was true whether IPI was analyzed as a dichotomous (Chi-square=384.2, df=108, Cramer's V=0.212, p<.0001) or categorical variable (Chi-square=502.0, df=216, Cramer's V=0.171, p<.0001). The nurse in attendance during a woman's birth explained 2.92-4.49% of variance in IPI use, depending on whether or not IPI was operationalized with reference to the timing of immersion. Among 108 nurses, 34 did not attend births involving immersion in either the first or second stage of labor. The remaining nurses attended conventional births after WL 1.9% (n=1) to 36.4% (n=8) of the time, while WB comprised 2% (n=2) to 100% (n=1) of births attended by individuals.

### Hypothesis Decision

Data support hypothesis three. Women's use of IPI was significantly associated with both the individual midwife and nurse in attendance during birth. Based on measures of association and explained variance, midwives had a somewhat greater influence on IPI use than nurses (Cramer's V =.210 versus 0.171), but each provider type made significant unique contributions.

#### Demographic Predictors of Intrapartum Immersion

#### Hypothesis Four

Demographic characteristics of women who labor or birth in water will differ from other parturients with regard to age, parity, race/ethnicity, primary language, education, type of payment for obstetric services and significant social stressors reported.

This hypothesis was informed by European and Asian IPI literature which suggested that older, multiparous, educated, non-immigrant women without language barriers would be most likely to labor and birth in water (Geissbühler & Eberhard, 2000; Geissbühler et al., 2004; Mack et al., 2005; Richmond, 2003b).

### Hypothesis Testing

For purposes of hypothesis testing, the categorical dependent variable IPI was operationalized with three levels as previously described. Table 6-2 contains eleven independent variables, representing eight demographic concepts, examined in relationship to IPI.

First, each potential demographic predictor was examined for association with clinical eligibility for WB in sub-samples restricted to independent observations, after excluding women who gave birth by cesarean prior to labor (n=10,474). Water birth eligibility (WBE) was operationalized as a dichotomous dependent variable in these initial analyses (eligible/not eligible). The relationships between WBE and dichotomous or categorical independent variables were examined with Chi-square analyses. Quantitative predictors were examined with binary logistic regression. Findings determined whether subsequent tests of association between demographic factors and actual IPI use needed to control for eligibility status (n=3,691). This was important to assess in order to determine whether demographic differences in utilization were simply a reflection of baseline risk factors and disproportionate access to hydrotherapy per adherence to clinical guidelines.

After examining WBE, bivariate approaches were used to identify demographic characteristics significantly associated with IPI utilization. Chi-square analyses were performed for dichotomous and categorical independent variables, and ANOVA was used to examine quantitative independent variables. After review of findings from these bivariate analyses, multinomial logistic regression was employed to examine significant demographic predictors of IPI in a unified multivariate model.

Parameter	Variable type	Details
Maternal age at birth	Quantitative Categorical	Interval data 3 levels Teen 20-34 years old 35+ years old
Parity	Dichotomous	Nulliparae/Multiparae
Racial and ethnic origin	Categorical	10 levels
	Categorical	5 levels Caucasian, Hispanic and non-Hispanic African American and African Asian Mixed/Other Withheld/Unknown
Hispanic origin	Dichotomous	Yes/No
Primary language	Categorical	3 levels English Spanish Other primary language
Educational attainment	Categorical	11 levels
	Categorical	5 levels Less than high school education High school graduate or equivalent Some college or vocational education College graduate At least some graduate education
Insurance status	Categorical	4 levels No prenatal care (no identified payer) Government program Private insurance Self-paid (uninsured)
Psychosocial stress	Dichotomous	Yes/No

Table 6-2. Potential demographic predictors of intrapartum immersion.

*Maternal age.* When examined in an independent sample of 10,474 women, maternal age at delivery was associated with WBE, whether analyzed as a categorical (Chi-square=19.36, df=3, p<.0001) or continuous variable (Wald=25.86, df=1, p<.0001). Crosstabs indicated that women who were at least 35 years old at the time of birth were less likely to meet inclusion criteria for WB than anticipated. This was confirmed in an analysis of continuous maternal age data using binary logistic regression, when increased maternal age was found to be associated with a small but significant reduction in clinical eligibility for WB (OR .983, 99% CI .975-.992, p<.0001). Maternal age explained .19% (Cramer's V= .043) to .3% (Nagelkerke's pseudo  $R^2$ =.003) of variance in WBE, depending on whether categorical or continuous data were used. Despite minimal clinical relevance, these findings conservatively supported the performance of further hypothesis testing in an independent sample restricted to women eligible for WB (n=3690) so as to control for the small reduction in eligibility experienced by older women.

Maternal age was associated with IPI utilization using ANOVA (F=5.95, df 2, p=.003) in the restricted sample. Post hoc testing revealed that the mean age of women who gave birth in water (28.7 years, SD 5.5) was significantly older than women who labored in water (27.5 years, SD 6.0) or were never immersed (27.8 years, SD 6.2). There was no significant difference in the mean age of women who labored in water compared to those who never entered the bath tub (p=.415).

*Parity*. The relationship between IPI and parity was explored using a dichotomous variable that differentiated nulliparae from multiparae in a sample of unique women (n=10,474). First, a statistically significant association between nulliparae and ineligibility for WB was observed (Chi-square=66.6, df=1, p<.0001), but parity explained less than 1% of the variance in eligibility status (Cramer's V=.08). To account for this small but significant difference, the association between parity and actual IPI utilization was examined among independent observations of women who were eligible for WL and WB (n=3,691). Overall, a significant association was observed between parity and IPI (Chi-square=92.0, df=2, p<.0001), with 2.3% of variance in utilization attributable to

differences in number of prior births (Cramer's V=.152). Nulliparae (n=1774) comprised almost half (48%) of the restricted sample but were three times more likely to labor in water than multiparae (11% versus 3.6%). Standardized residuals did not indicate that a significant difference in WB related to parity was present, although there was a modest increase in the proportion of nulliparae who gave birth in water (12.4%) compared to women who had given birth previously (9.3%). The proportion of multiparae who labored and birthed without immersion (45.2%) was greater than expected (42.6%).

Racial and ethnic origins. As described in Table 5-6, maternal racial and ethnic backgrounds were initially operationalized with an 11-level categorical variable but the parameter was collapsed to 5 levels given that 93% of women in the sub-sample of independent observations (n=10,474) were Hispanic or non-Hispanic Caucasians. Crosstabs determined that WBE did not differ by maternal racial/ethnic origin (Chisquare=3.2, df=4, p=519). Accordingly, the same sub-sample was used to examine racial/ethnic background in relationship to actual IPI utilization. Although the overall Chisquare statistic was significant (29.10, df=8, p<.0001), racial/ethnic background did not explain a clinically significant portion (.15%) of the variance in IPI use (Cramer's V=.039, p<.0001). Further, analysis of standardized residuals failed to reveal significant difference(s) within the contingency table at an alpha level of .01.

*Primary language*. Although 73 languages were spoken by women in the sample, primary spoken language was analyzed as a categorical viable with three levels representing the largest linguistic sub-groups: English (63.3%), Spanish (30.2%) and other primary languages (6.2%). The relationship between primary language and WBE was not clinically meaningful in the independent sub-sample (n=10,474), despite statistical significance (Chi-square = 11.19, df=2, p=.004). Just .11% of variance was explained by primary language indicating that WBE was unlikely to contribute to differences in IPI use (Cramer's V= .033). Nonetheless, conservative analyses of

primary language and IPI use were performed in a sample restricted to unique women who were clinically eligible for WB (n=3,691). A significant association was observed in this analysis with 2.28% of the variance in IPI explained by primary language (Chisquare= 169.4, df=4, p<.0001, Cramer's V=.151). English-speaking women were two and a half times more likely have WL (9.3%), and almost five times more likely to give birth in water (15.1%) than Spanish-speaking women (3.6% and 3.4% respectively). Compared to women who spoke other languages, English-speaking women were more than twice as likely to give birth in water (6.6% vs. 15.1%), but no significant differences in use of immersion during labor were observed for these groups.

Hispanic origin. Given the reduced use of WL and WB observed for Spanishspeaking women, the relationship between racial/ethnic origins and IPI was revisited. Hispanic women comprised the second largest racial/ethnic subgroup in the full sample (n=5,728, 42.8%) so a dichotomous variable *Hispanic origin* was created (yes/no). Hispanic origin was first examined in Chi-square analyses of IPI eligibility in a sample restricted to independent birth events (n=10,405). A small but significant association was observed between being Hispanic and WBE, but less than 1% of variance was explained (Chi-square=9.25, df=1, p=.002, Cramer's V=.030, p=.002). These findings supported the conservative use of an independent sample of women eligible for WB for subsequent hypothesis testing (n=3670). Crosstabs examination revealed a significant association between Hispanic origin and IPI use (Chi-square=106.6, df=2, p<.0001, Cramer's V=.170). Post hoc testing of standardized residuals indicated that Hispanic women used WL and WB significantly less often than expected and in comparison to non-Hispanic counterparts. This was surprising in light of prior findings that Hispanic women had disproportionately greater access to IPI given fewer clinical exclusion criteria for WB. Further, Hispanic origin explained slightly more variation in IPI use (2.89%) than was explained by primary language (2.3%) in prior analyses of the same restricted sample.

The potential interaction between Hispanic origin and primary language was explored in a multinomial logistic regression described subsequently.

Maternal education. As for racial and ethnic origins, educational attainment was initially operationalized as an 11-level categorical variable but distilled to 5 levels to enable meaningful analyses of the smallest sub-groups. Education was analyzed in relationship to IPI eligibility in an independent sub-sample (n=10,382) without significant findings (Chi-square=10.25, df=4, p=.036). Thus, it was appropriate to examine the relationship without controlling for IPI exclusion criteria. Hypothesis testing revealed an association (Chi-square=263.6, df=8, p<.0001), and educational attainment explained 1.28% of the variance in IPI (Cramer's V=.113). The likelihood of WL or WB increased with advanced maternal education. Standardized residuals were used to identify significant differences between expected and observed frequencies for each cell within the contingency table, using an alpha level of .01. By these criteria, disproportionately few of the least educated women had WL (2.4%) or WB (1.5%). Among women with a high school education, significantly fewer (3.3%) had WB than expected (4.7%), but there were no significant discrepancies between anticipated and observed frequencies for WL or childbirth without hydrotherapy. Significantly more college graduates and women with at least some graduate education had WL and WB. Detailed information about the relationships between levels of maternal educational attainment and IPI utilization is presented in Table 6-3.

*Significant contribution to the chi-square n (critical value +/-2.58).		Percent of sub- sample (N=10,382)	Total Count Expected Count 2	Std. Residual	Percent	water Expected Count	Birth in Count	Std. Residual	Percent	water Expected Count	Labor in Count	Std. Residual	Percent	immersion Expected Count 2	No Count	educa	high s	Less ti		Table 6-3. Contingency table: Maternal edu
ations	0.0%	7.2%	2822	-0.1*	1.5%	34.5	41	-6.3*	2.4%	41.3	67	ယ ယူ	6.2%	46.1	2714	ion	hool	an a		ation ai
nip between edu	100.0%	23.7%	2461 2461.0	-:	3.3%	117.3	82	-1.6	4.3%	123.3	105	1.1	92.4%	2220.4	2274	equivalent	graduate or	High school		nd intrapartum ir
cation and intrap:	100.0%	16.1%	1668 1668.0	1.6	5.6%	79.5	94	1.8	6.0%	83.5	100	8	88.4%	1504.9	1474	education	or vocational	Some college		nmersion.
artum immersio	100.0%	14.6%	1512 1512.0	ත. දෙ	8.6%	72.1	130	4.2*	7.4%	75.7	112	-2.5	84.0%	1364.2	1270	graduate	College			
on at alpha leve	100.0%	18.5%	1919 1919.0	5.9*	7.7%	91.5	148	4.1*	7.1%	96.1	136	-2.3	85.2%	1731.4	1635	education	graduate	complete	Partial or	
9. 01	100.0%	100.0%	10382 10382.0	ı	4.8%	495.0	495	,	5.0%	520.0	520		90.2%	9367.0	9367	Total				

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*Type of insurance.* The significant relationships between IPI use and the demographic variables analyzed may reflect differences in socioeconomic status. Education is closely correlated with SES, as are language and racial/ethnic origins which may serve as proxies for immigrant status (American College of Obstetricians and Gynecologists Committee on Health Care for Underserved Women, 2006). Unfortunately, women's place of birth was not available for analysis. Instead, data regarding women's health insurance status was used to measure socioeconomic status in relationship to IPI eligibility and utilization.

Payment type at delivery was first examined in a sample of independent observations (n=10,474) and was associated with WBE (Chi-square=17.3, df=4, p=.002). Examination of standardized residuals indicated that the only significant discrepancy between observed and expected frequencies was for women without prenatal care. These women, for whom payment type was unknown, were less likely to be clinically eligible for WB. This finding supports the observation that women without prenatal care often present with high risk conditions, some of which would preclude IPI use (e.g. active sexually transmitted infection, hypertension/pre-eclampsia, or placental abruption) (Friedman et al., 2009). This finding was not considered meaningful given that just 59 of 13,394 women in the full sample (.04%) received no prenatal care. Further, just .17% of the variance in IPI use was explained by having had prenatal care or not (Cramer's V=.041).

Although the small but significant relationship between insurance status and WBE was likely largely a function of the sample size rather than meaningful betweengroup differences, payment type and actual IPI use were conservatively examined in a sample restricted to unique women eligible for WB (n=3,691). The resultant contingency table was significant overall, and 1.64% of variance in IPI use was attributable to type of payment for maternity care (Chi-square=120.9, df=8, p<.0001, Cramer's V=.128).

Despite an increased likelihood that women without prenatal care were ineligible for WB, there was no significant relationship between having had prenatal care (or not) and actually using IPI (or not). Analysis of standardized residuals indicated that significant differences in IPI use were only present among women who had public or private insurance. Women with private health insurance were more likely to have WL (9.0%) or WB (15.7%) than women with insurance through government programs (5.4% WL, 6.0% WB).

*Psychosocial stress.* Psychosocial stress was operationalized as a dichotomous variable that indicated whether or not a woman experienced one or more psychosocial<sup>1</sup> risk factors for poor perinatal outcomes. Stress was assumed for women without adequate prenatal care, who were either late to care (>20 weeks gestation) or received limited care (<5 prenatal visits). Teens were also included as were women with an elementary school education or less, homeless women, planned adoptions, maternal or paternal incarceration during the index pregnancy, current domestic violence, drug abuse (woman or father of the baby), eating disorder or other psychiatric diagnoses requiring medications or inpatient treatment, involvement by Child Protective Services, and women with limited socioeconomic means as reflected by payment type at delivery (no insurance or government health care program).

Significant psychosocial stress was initially examined with a Chi-square analysis in an independent sample of women (n=6,970), which determined that WBE was slightly less likely for women with stressors, although just .07% of variance was explained (Chisquare=7.4, df=1, p=.006, Cramer's V=.027). As such, the sub-sample was further restricted to women eligible for WB (n=3,691) prior to examination of the relationship between social stress and actual IPI use. This relationship was found to be significant,

<sup>&</sup>lt;sup>1</sup> Some "psychosocial" risk factors can also be conceptualized as biomedical in nature, e.g. domestic violence which is related to poor psychologic and physiologic perinatal outcomes.

with 2.02% of the variance in IPI use explained by the presence or absence of psychosocial stressors (Chi-square=74.4, df=2, p<.0001, Cramer's V=.142). Review of standardized residuals demonstrated that significantly more women without stressors gave birth in water than anticipated; conversely, women with stress did so less often than expected. There were no discrepancies in the expected and observed frequencies of WL.

*Multinomial logistic regression.* Bivariate analyses indicated that each demographic independent variable significantly contributed to IPI utilization when examined alone. To explore whether significant relationships would persist when demographic characteristics were examined in relationship to one another, parameters were simultaneously entered into a multinomial logistic regression model and likelihood ratio tests of individual parameters were analyzed. As Tables 6-4 and 6-5 indicate, social stress, payment type, racial/ethnic origin, Hispanic origin and maternal age at delivery were not significant predictors of IPI use, and were removed from the final multivariate model.

Ultimately, the final regression model was limited to maternal educational attainment, primary language and parity. The optimal combination of these significant factors explained 12.6% of variance in IPI use among women in the restricted sample (Chi-square = 340.4, p<.0001, pseudo  $R^2$ =.128). Contributions made by specific parameters are described in Table 6-5, which demonstrates that women with less than a high school education were half as likely to labor in water than women with at least some graduate education (OR=.516, 99% CI=.278-.958), while the likelihood of WB was diminished by a factor of .262 (99% CI= .143-.481).

	Model Fitting			
Effect	Criteria	Lik	elihood Ratic	Tests
	-	-	Degrees	-
	-2 Log Likelihood	Chi-	of	
	of Reduced Model	Square	Freedom	Significance
Intercept	882.017	.000	0	
Social stress	882.928	.911	2	.634
Maternal education*	918.482	36.465	8	.000
Payment type	889.505	7.488	6	.278
Racial/ethnic origin	897.264	15.247	6	.018
Hispanic origin	882.183	.165	2	.921
Primary language*	910.958	28.941	4	.000
Maternal age	888.220	6.203	4	.185
Parity*	950.286	68.269	2	.000

Table 6-4. Likelihood ratio tests of potential demographic predictors of immersion.

\*Statistically significant predictors included in the final model.

High school graduates were also less likely to give birth in water compared to women with the highest educational attainment (OR=.454, 99% CI=.293-.702) but no other significant differences were observed. Generally, as educational attainment increased, so did the likelihood of WL and WB. Women who spoke English were more likely to experience WL or WB than women who spoke another language besides Spanish. English speakers were 2.9 times (99% CI=1.170-7.142) more likely to have WL than women who spoke another language (excluding Spanish), and 2.6 times (99% CI=1.301-5.175) more likely to have WB. First time mothers were 3.3 times more likely to have WL (99% CI=2.25-4.8) and 1.4 times more likely to WB than multiparae (99% CI=1.02-1.81).

# Hypothesis Decision

Results indicate that educational attainment, primary language and parity are demographic predictors of IPI in this sample, thus data partially support hypothesis four.

						99% CI for	·Exp(B)
		Wald	₽	Sig	Exp(B)	Lower	Upper
Labor in water (a)	Intercept	94.951		.000			
	Less than high school education	7.588	-	.006	.516	.278	.958
	High school graduate	6.062	•	014	.616	.371	1.023
	Some college	.450	·	.502	.872	.515	1.476
	College graduate	1.076	-	.300	.812	.485	1.361
	At least some graduate school (reference group)		0				
	English vs. Janguage other than Spanish	9.144	-	.002	2.891	1.170	7.142
	Spanish vs. language other than English Other language (reference group)	.420		.517	1.290	.469	3.550
	Nullinarae ve multinarae	685 383	<u> </u>	80	3 388	2 <u>250</u>	4 804
	Multiparae (reference group)		0				
Birth in water (a)	Intercept	75.468		.000			
	Less than high school education	32.231 21.775	<u> </u>		.262 454	.143 293	.481 702
	Some college College graduate	1.911		.167 725	.797 1.055	.521	1.217
	At least some graduate school		<b>)</b>				
		40 AO .	، د		олол.	4 2014	л 44 л
	Spanish vs. language other than English	.001	<u> </u>	.976	.990	.430	2.279
	Other language		0				
	Nulliparae vs. multiparae	7.568	-	.006	1.357	1.020	1.805
	Multiparae (reference group)		0				
(a) Reference categ	ory: No intrapartum immersion.						

Table 6-5. Demographic predictors of intrapartum immersion.

#### Pharmacologic Pain Relief Methods

### Hypothesis Five

Women who utilize intrapartum immersion will receive less analgesia and anesthesia compared to women who receive conventional maternity care, controlling for demographic and clinical factors.

#### Hypothesis Testing

Hypothesis testing utilized a dichotomous dependent variable *pharmacologic pain relief method used* (yes/no) that included sedative hypnotics, narcotics and epidural or spinal analgesia/anesthesia. The independent variable (IPI) was operationalized as a three level categorical variable, as described previously. Binomial logistic regression was performed for these variables using the independent sample (=10,474) that excluded women who had a cesarean without labor. Among these subjects were 519 women who had WL (4.95%) and 491 women with WB (4.68%). Parameters examined for covariance are outlined in Table 6-6.

Initially, all potential covariates were entered step-wise into the model, followed by IPI. The exploratory model was significant overall (Chi-square=2211.2, df 21, p<.0001) but maternal age, racial/ethnic origin, Hispanic origin, and payment type at delivery failed to make unique contributions and were removed. In the final model (Table 6-7), the omnibus test of coefficients was significant (Chi-square=2354.7, df 12, p<.0001) and goodness of fit was apparent with non-significant Hosmer and Lemeshow testing (Chi-square 17.5, p=.025). Overall, 28.3% of the variance in pharmacologic pain relief was explained by the optimum combination of parameters analyzed (pseudo  $R^2$ =.283), including 2.5% uniquely contributed by IPI.

	Parameter	Variable type
Independent variable	Intrapartum immersion*	Categorical, 3 levels No immersion Labor in water Birth in water
Dependent variable	Pharmacologic pain relief method use*	Dichotomous Used/Not used
Potential covariates	Maternal age at birth	Quantitative
	Parity*	Quantitative
	Racial/ethnic origin	Categorical, 5 levels Caucasian African American and African Asian Mixed/Other Withheld/Unknown
	Hispanic origin	Dichotomous Yes/No
	Primary language*	Categorical, 3 levels English Spanish Other primary language
	Education*	Categorical, 5 levels Less than high school education High school graduate or equivalent Some college or vocational education College graduate At least some graduate education
	Labor induction or augmentation*	Dichotomous Yes/No
*Circuition at a set in the	Provider type*	Categorical, 3 levels Midwife Family practice physician Obstetrician

Table 6-6. Parameters examined in analyses of pharmacologic pain relief methods.

Significant contributor, included in final binomial regression model.

Pharmacologic pain relief was less prevalent among women who used WL or WB, controlling for other factors in the model. The odds that women in the non-hydrotherapy group used pharmacologic pain relief methods increased by a factor of 5.7 compared to women who gave birth in water (OR=5.71, 99% CI 4.0-6.16). For women who labored in water the odds of using analgesia and anesthesia were increased by a factor of 3 compared to women who gave birth in water (OR=2.96, 99% CI= 1.93-4.54). The odds of using pharmacologic pain relief methods were also increased by induction and augmentation of labor, decreased parity, care from an obstetrician rather than a midwife or family practice physician, and English as a primary language. The odds of using analgesia or anesthesia decreased as educational attainment increased, but there were no significant differences between women who were college graduates and those with at least a partial graduate education.

#### Hypothesis Decision

Data support the hypothesized relationship between decreased analgesia and anesthesia use among women who choose to labor or birth in water, controlling for demographic and clinical factors including provider type.

* Dependent variable coding: 0=No, 1=Yes, phar	Constant	Immersion during labor	(Reference: Water birth)	Induction or augmentation of labor Intrapartum immersion	Parity	Spanish-speaking	English-speaking	Primary language (Reference: Other language)	College graduate	Some college or vocational training	High school graduate or equivalent	Did not complete high school	Education (Reference: At least some graduate school)	Family practice physician	Midwife	(Reference: Obstetrician)	Provider type			
macologic p	2.403	43.003	189.296	750.131	270.984	22.187	10.110	153.595	.373	9.164	40.160	16.523	48.893	238.276	395.703	399.218		Wald		
oain reli	-	<u> </u>	<sup>→</sup> N	د		-	-	2	-	-	-	-	4	-	-	2		đŕ		
ef methi	.121	.000		.000	.000	.000	.001	.000	.541	.002	.000	.000	.000	.000	.000	.000		Sig.		
od used.	1.325	2.963	л 71 л	.282	.693	.618	1.340		1.050	1.268	1.593	1.398		.288	.247			Exp(B)	1	
		4.000 1.934	, 000 -	.251	.655	.474	1.057		.854	1.036	1.318	1.131	ı	.234	.207			Lower	99% CI foi	
		o.104 4.540	0154	.318	.734	.804	1.699		1.291	1.552	1.925	1.729		.354	.297			Upper	r EXP(B)	

Table 6-7. Final binomial logistic regression model: Predictors of intrapartum analgesia and anesthesia.\*

### **Obstetric Laceration**

### Hypothesis Six

Women who utilize immersion during labor or birth will have less severe perineal lacerations than women who receive conventional maternity care after controlling for demographic and clinical factors.

# Hypothesis Testing

Binary and multinomial logistic regression models were used to explore whether obstetric lacerations were predicted by IPI utilization. Parameters examined for covariance in one or more regression models are described in Table 6-8. Analyses were performed with sub-samples of independent women after excluding those who gave birth by cesarean section prior to labor (n=10,351). Among subjects were 491 women who labored in water (4.74%) and 487 who gave birth while immersed (4.70%).

	Parameter	Variable type
Independent variable	Intrapartum immersion*	Categorical, 3 levels No immersion Labor in water Birth in water
Dependent variables	Perineal laceration	Categorical, 5 levels Intact perineum 1 <sup>st</sup> degree laceration 2 <sup>nd</sup> degree laceration 3 <sup>rd</sup> degree laceration 4 <sup>th</sup> degree laceration
	Labial laceration	Dichotomous (Yes/No)
	Periurethral laceration	Dichotomous (Yes/No)
	Vaginal wall laceration	Dichotomous (Yes/No)
Potential covariates	Maternal age at birth*	Categorical, 3 levels Teen 20-34 years old 35 years or older
	Parity*	Dichotomous Nulliparous/Multiparous
	Racial/ethnic origin	Categorical, 5 levels Caucasian, Hispanic and non-Hispanic African American and African Asian Mixed/Other Withheld/Unknown
	Method of delivery	Categorical, 3 levels Spontaneous vaginal birth, vertex Vaginal breech birth Vacuum or forceps assisted, vaginal Cesarean
	Episiotomy*	Dichotomous (Yes/No)
	Fetal heart rate abnormalities*	Dichotomous (Yes/No)

Table 6-8. Parameters examined in relationship to obstetric laceration.

\*Variable was significant contributor to obstetric laceration in one or more analyses.

	Parameter	Variable type
Potential covariates	Infant birth weight	Dichotomous Large/small for gestational age/Average
	Provider type*	Categorical, 3 levels Midwife Family practice physician Obstetrician
43.7.1.1.1	1 10 1 1 1 1	

Table 6-8 (continued). Parameters examined in relationship to obstetric laceration.

\*Variable was significant contributor to obstetric laceration in one or more analyses.

*Episiotomy*. First, binomial logistic regression was performed to explore whether episiotomy differed among women by hydrotherapy utilization, controlling for maternal age, parity, fetal heart rate monitoring type, non-reassuring fetal heart rate monitoring, infant birth weight, and type of provider. The final model (Table 6-9) was significant overall and included each parameter studied except fetal monitoring type (intermittent fetal heart rate monitoring versus continuous electronic monitoring) which did not make a unique contribution after controlling for other factors (Chi-square=456.5, df=9, p<.0001). IPI was retained in the final model but did not make a significant contribution (p=.033). Predictors of episiotomy were non-reassuring fetal heart rate monitoring, nulliparity, increased maternal age and infants who were small or large for gestational age. Provider type was also a significant predictor of episiotomy, holding other variables in the model constant. Women who were attended by obstetricians were 2.6 times more likely to experience episiotomy than women attended by midwives (OR=2.65, 99% CI 1.84-3.81), but there was no difference in episiotomy performed by obstetricians or family practice physicians (p=.916).

					99% CI foi	r EXP(B)
	Wald	₽,	Sig	Exp(B)	Lower	Upper
Non-reassuring vs. reassuring fetal heart rate	168.59	-	.000	.25	.189	.328
Provider type	85.25	2	.000			
Midwife vs. obstetrician	47.19	-	.000	2.65	1.837	3.812
Family practice physician vs. obstetrician	.01	-	.916	.98	.672	1.442
Maternal age	20.72	2	.000		ı	·
Teen vs. 35 years or older	20.06	-	.000	2.78	1.545	5.016
20-34 year old vs. 35 years or older	10.24	-	.001	1.61	1.097	2.349
Nulliparae vs. multiparae	107.93	-	.000	.26	.184	.361
Large/small for gestational age vs. average birth weight	8.56	-	.003	.68	.485	.955
Intrapartum immersion	6.80	2	033			
No immersion vs. water birth	6.79	-	.009	.07	.005	.971
Labor in water vs. water birth	6.55		.010	.07	.005	1.016
Constant	33.38	-	000	364.07		
*Dependent variable (episiotomy) coded: 0=Yes, 1=No.						

aldeT ົກ Þ U 9 10 2517 *Perineal laceration.* Although episiotomy was not associated with IPI in the prior analysis, it was controlled in multinomial logistic regression analyses of perineal laceration and IPI because the procedure is associated with severe laceration involving extension to and through the rectum (American College of Obstetricians and Gynecologists Committee on Practice Bulletins, 2006). In addition to episiotomy, analyses of the same restricted sample (n=10,351) controlled for provider type, racial/ethnic origin, age, parity, birth weight and non-reassuring fetal heart rate monitoring. Racial/ethnic origin and abnormal fetal heart monitoring were removed from the final model (Table 5-14) because they did not make meaningful independent contributions to perineal outcomes. The final model was significant (Chi-square=1538.3, df=36, p<.0001, pseudo  $R^2$ =.177) and explained a 17.7% of the variance in perineal trauma despite limitations related to the relative infrequency of fourth degree laceration in the sample (n=72, 0.7%).

Women who gave birth in water were more likely to experience a first degree laceration versus an intact perineum, and less likely to experience a fourth degree laceration versus an intact perineum, than women who were never immersed, controlling for other factors in the model. There were no significant differences in second or third degree lacerations versus intact perineums between women who gave birth in water and those who did not use hydrotherapy in any phase of labor, nor were there differences between women who labored in water compared to those who gave birth while immersed. As described in Table 6-10, additional factors related to decreased perineal laceration occurrence and severity included multiparity, decreased maternal age, infant birth weight appropriate for gestational age, and not having had an episiotomy.

						99% CI for	·Exp(B)
		Wald	đ	Sig.	Exp(B)	Lower Bound	Upper Bound
1st degree							
(a)	Intercept	6.409	-	.011	,	ı	
	Small or large for gestational age	.508	-	.476	.944	.768	1.162
	Average birth weight (reference)		0	,			
	No immersion	20.028	-	.000	.577	.421	.792
	Labor in water	3.678	<u> </u>	.055	.720	.462	1.120
	Birth in water (reference)	·	0	,	,		
	Midwife	25.812	-	.000	1.676	1.290	2.177
	Family practice physician	1.301	·	.254	.873	.642	1.186
	Obstetrician (reference)		0	,			
	Teen	.602	-	.438	.909	.662	1.248
	20-34 years old	.026	<u> </u>	.871	.986	.789	1.233
	35 years or older (reference)		0			,	
	Episiotomy	50.132	-	.000	.084	.034	.208
	No episiotomy (reference)		0			ı	
	Nulliparae	210.543	-	.000	2.487	2.116	2.924
	Multiparae (reference)		0	,			

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		Mold	4	0 ia		99% CI fo	r Exp(B) Haper Bound
2nd degree		24	·	220	-		-
(a)	Intercept	.917	-	.338			
	Small or large for gestational age	4.132	-	.042	1.160	.961	1.400
	Average birth weight (reference)		0				
	No immersion	5.576	-	.018	.739	.531	1.028
	Labor in water	.543	-	.461	.880	.563	1.375
	Birth in water (reference)		0				
	Midwife	4.634	-	.031	.831	.667	1.037
	Family practice physician	5.406	-	.020	1.246	.977	1.590
	Obstetrician (reference)		0				
	Teen	53.995	-	.000	.414	.304	.564
	20-34 years old	3.459	-	.063	.863	.704	1.058
	35 years or older (reference)		0				
	Episiotomy	.185	-	.667	1.056	.763	1.461
	No episiotomy (reference)		0				
	Nulliparae	622.198	-	.000	4.363	3.747	5.080
	Multiparae (reference)		0				
(a) The refere	nce category is: Intact perineum.						

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		Wald	đ	Sig.	Exp(B)	99% CI fo Lower Bound	r Exp(B) ∪pper Bound
3rd degree (a)	Intercept	66.124	<b>→</b>	.000			
	Small or large for gestational age Average birth weight (reference)	16.747 -	0 -	.000	1.947 -	1.280	2.961 -
	No immersion	1.626	<u> </u>	.202	1.816	.544	6.057
	Birth in water (reference)	- - - +	0 -	- - N	1.000 -		 -
	Midwife Family practice physician Obstetrician (reference)	.075 3.461 -	o → →	.784 .063 -	1.060 1.535 -	.611 .848 -	1.840 2.779 -
	Teen 20-34 years old 35 years or older (reference)	19.198 4.617 -	o → →	.000 -	.274 .654 -	.128 .393 -	.586 1.088 -
	Episiotomy No episiotomy	64.737 -	0 →	.000 -	4.340 -	2.713	6.942 -
	Nulliparae Multiparae (reference)	172.199 -	0 →	.000	10.352 -	6.543 -	16.377 -

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(a) The reference category is: Intact perineum.

		10/014	4	0	Cvp/D)	01 2 % 66	or Exp(B)
4th degree			!	( 	(=\\d\=)		Children Control
(a)	Intercept	1228.94	<b>_</b>	.000			
	Small or large for gestational age Average birth weight (reference)	4.86 -	0 -	.028	1.899 -	.897	4.019
	No immersion Labor in water Birth in water (reference)	1876.17 - -	0	<sup>.</sup> 00	45737678.006 94904812.966 -	16022703.098 94904812.966 -	130560691.077 94904812.966 -
	Midwife Family practice physician Obstetrician (reference)	.002 1.06 -	0	.964 .303	.983 1.503 -	.374 .543 -	2.585 4.160 -
	Teen 20-34 years old 35 years or older (reference)	4.13 .126 -	0	.042 .723 -	.305 .875 -	.067 .332 -	1.376 2.309 -
	Episiotomy No episiotomy (reference)	77.12	0 -	.000	10.426 -	5.242 -	20.738 -
(a) The refer	Nulliparae Multiparae (reference)	40.93	0 -	, <sup>.</sup> 00	8.597 -	3.616	20.442

These data cannot fully explain the finding that women who labored in water had perineal outcomes equivalent to women who were never immersed, while women who birthed in water experienced fewer severe lacerations than non-immersed counterparts, controlling for other variables in the model. Although causality cannot be supported with these data, they do support a hypothesized beneficial effect of hydrotherapy informed by physiologic theory. In considering this hypothetical effect, prior research and other predictors of obstetric laceration, it was clear there was insufficient published data with which to evaluate the relationship between IPI and non-perineal obstetric lacerations. Accordingly, non-perineal obstetric laceration was explored in relationship to WL and WB.

It was hypothesized that different approaches to the management of second stage labor and "crowning" might be necessitated by immersion, since water may reduce a provider's access to the perineum for support and/or peri-clitoral guarding. These differences may not always be countered by the hypothesized effect of reduced edema and increased tissue elasticity resulting from mobilization of extravascular fluid in response to hydrostatic pressure. Hydrotherapy may facilitate perineal stretching but labial and periurethral laceration may not be similarly diminished if flexion of the presenting fetal part, rather than stretching, is the primary determinant of these types of lacerations. Further analyses were performed to examine IPI as a predictor of labial, periurethral and vaginal lacerations.

Labial laceration. The relationship between IPI and labial laceration was examined with binary regression models that included racial/ethnic origin, parity, maternal age, non-reassuring fetal monitoring, method of birth, episiotomy, infant birth weight, and provider type. Maternal racial/ethnic origin, fetal monitoring, method of delivery and birth weight were not significantly associated with labial laceration once episiotomy was added to the models. Similarly, IPI appeared to predict labial laceration

until episiotomy was controlled, likely due to the decreased use of episiotomy in the WB group previously observed. The final model (Table 6-11), although significant overall, demonstrates no relationship between IPI and labial laceration after controlling for other factors (Chi-square=351.3, df=8, pseudo R2=.081, p<.0001). Predictors of labial laceration were nulliparity, decreased maternal age, and episiotomy; in combination, these factors explained 8.1% of the variance. Provider type also significantly predicted labial laceration in this sample. Women attended by midwives were almost twice as likely to experience labial laceration than were women attended by either family practice physicians or obstetricians, controlling for other factors in the model. There were no significant differences observed for labial laceration between family practice and obstetrician caseloads. These data could not explain the reasons for differences in labial laceration observed for different provider types, although differences in management of second stage labor, maternal positioning during birth, and clinical documentation are possibilities.

*Dependent variable (labial laceration) coding	Constant	Water birth vs. no immersion	Water labor vs. no immersion	Intrapartum immersion	Episiotomy vs. no episiotomy	Nulliparae vs. multiparae	20-34 year old vs. 35 years or older	Teen vs. 35 years or older	Maternal age	Family practice vs. midwife	Family practice physician vs. obstetrician	Midwife vs. obstetrician	Provider type			Table 6-11. Labial laceration and intrapartum in
: 0=No; 1=Yes, 1	390.427	7.330	1.907	8.519	23.675	156.946	12.983	14.845	15.637	26.377	.303	18.541	39.720	Wald		mmersion (n=10
labial lace	<b>→</b>	-	<u>ب</u>	2	<u> </u>	<b>→</b>	-	<u> </u>	2	<u> </u>	<u> </u>	<u> </u>	2	đ		), 351).*
eration occ	.000	.007	.167	.014	.000	.000	.000	.000	.000	.000	.582	.000	.000	Sig.		
urred.	.023	1.436	1.202		.260	2.880	1.677	1.924		.591	1.095	1.853		Exp(B)		
	1	1.018	.853	ı	.128	2.317	1.159	1.242	ı	.454	.717	1.281		Lower	99% CI for	
	1	2.027	1.694	ı	.531	3.579	2.427	2.979	ı	.769	1.673	2.679		Upper	EXP(8)	

Table
6-11
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0, 351
Periurethral laceration. The same sample (n=10,351) was used to examine whether IPI could predict periurethral laceration, after controlling for provider type, maternal age, parity, racial/ethnic origin, fetal heart rate abnormalities, method of birth, episiotomy and birth weight. Maternal age, racial/ethnic origin, non-reassuring fetal heart tones, method of birth and infant birth weight were removed from the final model (Table 6-12) for lack of significant contributions. The optimal combination of parity, provider type and episiotomy explained 4.1% of variance in periurethral laceration; adding hydrotherapy to the model increased the percent of explained variance just to 4.7% (Chisquare=140.4, df=6, p<.0001, pseudo R<sup>2</sup>=.047). Women who gave birth in water were almost twice as likely to experience periurethral laceration than women who did not use hydrotherapy, but there was no difference compared to women who were immersed during labor only. As with labial laceration, women attended by midwives were significantly more likely to have documented periurethral laceration compared to women in obstetric care. In this case, laceration was more common in the family practice caseload compared to the obstetrician clientele as well. When the analysis was re-run with midwife as the reference group for type of provider, it was apparent that the family practice group had significantly less periurethral laceration in comparison (Wald 8.7, df 1, p=.003, Exp B .67, 99% CI .47-.95).

					99% EXF	CI for P(B)
	Wald	df	Sig.	Exp(B)	Lower	Upper
Type of provider	26.456	2	.000	-	-	-
Midwife vs. obstetrician	20.301	1	.000	3.029	1.607	5.708
Family practice vs. obstetrician	7.031	1	.008	2.033	1.020	4.049
Multiparity vs. nulliparity	50.234	1	.000	2.110	1.608	2.767
Intrapartum immersion	19.349	2	.000	-	-	-
No immersion vs. water birth	12.187	1	.000	.564	.370	.861
Labor in water vs. water birth	.099	1	.753	.935	.537	1.626
Constant	159.927	1	.000	.023	-	-

Table 6-12 Periurethral	laceration and intr	anartum immersion	(n-10 351)	*
		apartum inimersion	(11 - 10, 331).	

\*Dependent variable (periurethral laceration) coding: 0=No; 1=Yes.

*Vaginal laceration.* The relationship between IPI and high vaginal/vaginal wall laceration was examined with binomial regression modeling that included provider type, maternal age, racial/ethnic background, parity, non-reassuring fetal heart rate monitoring, method of birth, episiotomy and infant birth weight. IPI was not associated with vaginal laceration (p=.108), an outcome which was only predicted by nulliparity by not having had an episiotomy, as described in Table 6-13.

					00.00/	CI for
					99.0%	
					EXF	P(B)
	Wald	df	Sig.	Exp(B)	Lower	Upper
Episiotomy vs. no episiotomy	12.83	1	.000	.274	.108	.695
Nulliparae vs. multiparae	61.03	1	.000	2.255	1.725	2.949
Constant	1486.56	1	.000	.035		

Table 6-13. Predictors of vaginal laceration.

\*Dependent variable (vaginal laceration) coding: 0=No, 1=Yes.

*Obstetric laceration requiring repair.* The relationship between IPI and obstetric laceration that required repair was explored with binomial logistic regression using the same restricted sample of unique women who did not experience cesarean without labor (n=10,351). Provider type, fetal heart rate abnormalities and infant birth weight were examined as potential covariates but they did not predict obstetric laceration requiring repair. As Table 6-14 describes, parameters that were independently and significantly

associated with obstetric laceration requiring repair were parity, episiotomy, maternal age and IPI (Chi-square=922.7, df=6, p<.0001). Nulliparae were three and a half times more likely to require laceration repair than multiparae (OR=3.46, 99% CI= 3.04-3.93). Women who experienced episiotomy were five and a half times more likely to need suturing compared to women who did not have an episiotomy performed (OR=5.65, 99% CI= 3.57-8.95). Women 35 years or older were almost twice as likely to experience obstetric laceration requiring repair than teens (OR=.55, 99% CI= .42-.71, p<.0001) but there were no differences in laceration repair among women aged 20 or older (p=.037). The odds that a woman who did not use hydrotherapy would require repair of an obstetric laceration were slightly lower than those for women who gave birth in water (OR=.72, 99% CI =.56-.94, p=.002), but there were no differences among women who labored or birthed in water (p=.715).

Table 6-14. Predictors of obstetric laceration requiring rep	air.

					33.070	
	Wald	df	Sig.	Exp(B)	EXP	<u>P(B)</u>
					Lower	Upper
Nulliparae vs. multiparae	622.169	1	.000	3.455	3.040	3.927
Episiotomy vs. no episiotomy	93.995	1	.000	5.650	3.567	8.951
Maternal age	39.393	2	.000	-	-	-
Teen vs. 35 years or older 20-34 years old vs. 35 years or	35.263	1	.000	.550	.424	.713
older	4.329	1	.037	.867	.727	1.035
Intrapartum immersion	15.267	2	.000	-	-	-
No immersion vs. water birth	9.826	1	.002	.724	.555	.944
Labor in water vs. water birth	.133	1	.715	.948	.652	1.379
Constant	4.005	1	.045	1.262	-	-

\*Dependent variable (repair of obstetric laceration) coding: 0=No, 1=Yes.

## Hypothesis Decision

Data support the hypothesized relationship between WB and decreased perineal laceration severity. However, WB was associated with an increased need for repair of superficial obstetric laceration and an increased incidence of periurethral trauma.

00.0% CI for

Laceration repair and periurethral laceration did not differ among WL and WB groups. No differences were observed among IPI and non-IPI groups for incidence of labial or vaginal laceration. Overall it is unclear whether and what hypothesized effect of hydrotherapy on obstetric laceration would be supported by these data.

### Perinatal Optimality and Intrapartum Immersion

# Hypothesis Seven

Among women who receive midwifery care, Optimality Index-US scores will be higher for women who used intrapartum immersion than for those who received conventional midwifery care, after controlling for baseline demographic and clinical factors.

# Hypothesis Testing

The relationship between IPI and mean OI-US scores was initially explored in a sample restricted to independent observations of women who began intrapartum care with midwives and were clinically eligible for WB (n=2,777). The sample was restricted in this manner in an attempt to control for potential differences in medical and obstetric risk factors that might be present between groups of women who did and did not utilize hydrotherapy. However, differences in pre-existing risk status (as measured with the PBI portion of the instrument) were observed between hydrotherapy groups despite these restrictions. For this reason, analyses were conducted in a larger sub-sample of women who began intrapartum care with midwives (n=6,273), and pre-existing risk factors including PBI scores were controlled in analyses.

To avoid bias introduced by including the PBI as both a covariate and portion of the dependent variable, a modified OI-US score was calculated that excluded the first 14 Index items that comprise the PBI. Mean scores generated with this modified instrument did not differ from those obtained in confirmatory analyses of the full instrument, whether PBI was identified as a covariate or not.

The relationship between modified OI-US scores and hydrotherapy was explored with ANCOVA which indicated that perinatal optimality significantly differed among hydrotherapy groups, after controlling for PBI scores (F (2, 6099)=96.6, p<.0001). Adjusted mean scores were highest among women who birthed in water (89.1, 99% CI=88.0-90.2) followed by women who labored in water (83.3, 99% CI=82.2-84.4) and those who were never immersed (82.8, 99% CI=82.5-83.2). Post hoc contrasts identified significantly decreased scores for women who were never immersed compared to those who birthed in water (t(6099)= -13.9, p<.0001), as well as for women who labored in water versus those who birthed in water (t(6099)= -9.5, p<.0001). There were no differences in mean OI-US scores between women who labored in water and those who were never immersed (p=.275).

It was assumed that the association between improved perinatal optimality and WB was primarily related to prior findings that hydrotherapy users employed fewer pharmacologic pain relief methods since use diminishes OI-US scores. Index points assigned to the WB group for less severe perineal laceration would be offset by increased repair of mild laceration. Additional analyses of specific care processes, clinical conditions and maternal and neonatal outcomes were examined to identify parameters contributing to differences in perinatal optimality among groups differentiated by hydrotherapy utilization.

### Processes of Care

## Induction of Labor

Among women in the restricted sample 13.7% experienced induction of labor (n=860). Binary logistic regression was performed to explore whether IPI was significantly associated with this process of care, controlling for PBI scores. The omnibus tests of model coefficients indicated there was no significant relationship at an alpha level of .01 (Chi-square=14.286, df=3, p=.031).

### Labor Augmentation

Binary logistic regression was used to determine that IPI was significantly associated with augmentation of labor and explained 3.3% of the variance in this process of care, controlling for PBI (Chi-square=158.4, df=3, p<.0001, pseudo  $R^2$ =.033). Compared to women who birthed in water, the odds of experiencing augmentation of labor were increased by a factor of 1.27 (99% CI= 2.60-4.88) among women who were never immersed, and by 1.38 (99% CI= 2.70-5.87) among women who labored in water. Augmentation of labor did not differ for women who were immersed during labor and those who did not use hydrotherapy (p=.255).

## Puerperal Antibiotics

Antibiotic administration in the intrapartum or postpartum period was another care process examined. After determining that there was no significant relationship between PBI scores and puerperal antibiotics using multinomial logistic regression (p=.278), the relationship between IPI and administration of antibiotics during parturition was examined with crosstabs analysis and found to be statistically significant overall (Chi-square=55.7, df=6, p<.0001). The association likely has little clinical significance given that less than 1% of variance in antibiotic utilization was explained by IPI (Cramer's V=.067). Review of standardized residuals within the contingency table (Table 6-15) indicated that fewer women in the WB group received therapeutic intrapartum antibiotics and either prophylactic or therapeutic antibiotics in the postpartum period, than was anticipated. Women who used immersion prior to birth were observed to receive prophylactic antibiotics during labor more often than expected. There were no other differences at an alpha level of .01.

Despite minimal clinical significance, findings are likely to make a modest contribution to increased OI-US scores among women who gave birth in water since administration of any medication results in the loss of a potential Index point. Further, if

antibiotics were administered as treatment for infection (e.g. chorioamnionitis), or as prophylaxis against infection following an invasive procedure (e.g. manual placenta removal), further points would be deducted for these specific conditions or care processes. Thus, examination of intrapartum and postpartum antibiotic administration likely served as a proxy for these parameters.

Other clinical indications for puerperal antibiotics do not contribute to OI-US scores, e.g. group B beta strep (GBS) colonization. Direct examination of GBS status was not possible due to missing data and poor documentation of revisions in screening and treatment protocols during the study period. The measure of prophylactic antibiotics administered during labor is hypothesized to primarily represent GBS colonization but other clinical conditions surely contributed (e.g. mitral valve prolapse). The finding that women who labored in water received more prophylactic antibiotics than anticipated could indicate that GBS carriers were more common in this group. Of note, GBS carriers were permitted to both labor and birth in water if they desired hydrotherapy, and antibiotics were administered.

100.0%	4.6%	3.7%	12.6%	79.1%	Percent	
6273.0	288.0	235.0	789.0	4961.0	Expected Count	
6273	288	235	789	4961	Count	TOTAL
	-2.7	-3.0	2.4	.4	Std. Residual	
100.0%	1.9%	1.1%	16.5%	80.6%	Percent	
468.0	21.5	17.5	58.9	370.1	Expected Count	
468	9	5	77	377	Count	Birth in tub
	-1.9	-1.6	4.4	-1.0	Std. Residual	
100.0%	2.8%	2.3%	19.7%	75.2%	Percent	
471.0	21.6	17.6	59.2	372.5	Expected Count	
471	13	11	63	354	Count	Labor in tub
	1.3	1.4	-2.0	.2	Std. Residual	
100.0%	5.0%	4.1%	11.6%	79.3%	Percent	
5334.0	244.9	199.8	670.9	4218.4	Expected Count	
5334	266	219	619	4230	Count	No immersion
TOTAL	antibiotics	postpartum	labor	No antibiotics		
	postpartum	labor and	antibiotics in			
	therapeutic	antibiotics in	Prophylactic			
	Prophylactic or	Therapeutic				

Fable 6-15.
Immersion
and antibi
lotic adminis
stration (n:
=6,273).

### Fetal Monitoring Type

Given that continuous fetal monitoring requires the deduction of a potential point from OI-US scores, an examination of fetal monitoring type in relationship to IPI was indicated. Within the restricted sample of unique women who began intrapartum care with midwives, 54.6% experienced intermittent rather than continuous fetal monitoring (n=3,424). It was hypothesized that a non-reassuring fetal heart rate noticed during intermittent monitoring would necessitate continuous fetal monitoring thereby confounding planned hypothesis testing. Thus, a binary logistic regression of fetal monitoring type and fetal status was performed. Surprisingly, no relationship was observed (Wald= <1, df=1, p=.986) indicating that continuous fetal monitoring was primarily employed for reasons other than abnormal findings, e.g. for observation of fetal status during induction/augmentation of labor or epidural/spinal analgesia/anesthesia. When PBI, reassuring/non-reassuring fetal monitoring, induction/augmentation of labor and epidural/spinal were simultaneously controlled for in a binary logistic regression of fetal monitoring type and IPI, induction/augmentation was the only significant covariate. Thus, the final model of association between fetal monitoring type and IPI included only this parameter (Table 6-16).

The final logistic regression model was significant overall and explained 44.9% of variance in fetal monitoring type, including 2.2% uniquely contributed by IPI (Chi-square= 2561.4, df=3, p<.0001, pseudo  $R^2$ =.449). Women who utilized hydrotherapy were significantly more likely to experience intermittent rather than continuous monitoring compared to women who were not immersed during any phase of labor, holding induction/augmentation of labor constant; for WL the odds were increased by a factor of 1.5 (OR=1.498, 99% CI= 1.09-2.05), while the odds increased by a factor of 5.8 (OR=5.825, 99% CI= 3.83-8.85) for WB.

					99% (	CI for
					EXF	<u> (B)</u>
	Wald	df	Sig.	OR	Lower	Upper
Spontaneous labor vs.	-		-	-	-	
induction/augmentation	1809.56	1	.000	16.67	14.06	19.76
Intrapartum immersion	124.64	2	.000	-	-	-
Labor in water vs. no water	10.91	1	.001	1.50	1.10	2.05
Water birth vs. no water	117.73	1	.000	5.83	3.83	8.85
Constant	880.30	1	.000	.20	-	-

Table 6-16. Predictors of intermittent fetal monitoring (n=6,273).\*

\*Dependent variable coding: 0=Continuous monitoring, 1=Intermittent monitoring.

## Method of Birth

Assisted vaginal deliveries (forceps or vacuum) and cesarean births are considered non-optimal by the OI-US, regardless of medical indication, and result in a loss of potential points toward final scores. This and other factors warranted examination of the relationship between IPI and method of birth. Since women who gave birth in water all experienced spontaneous vaginal deliveries, they were excluded from the analysis and the only the effect of immersion during labor was studied. This reduced the sample of women who began intrapartum care with midwives to 5,805 including 471 women who labored in water (8.1%). A multinomial logistic regression was performed with a dichotomous independent variable labor in water (yes/no). The dependent variable was *method of birth,* initially operationalized as a categorical variable with 5 levels: spontaneous vaginal birth with cephalic presentation (n=5,275; 91%), vacuum assisted birth with cephalic presentation (n=147; 2.5%), forceps assisted birth with cephalic presentation (n=16; 0.3%), spontaneous and assisted vaginal breech births (n=9; 0.2%), and cesareans (n=353; 6%). Given the relative infrequency of vacuum or forceps assisted births and vaginal breech births, these groups were combined. Parameters examined for covariance are described in Table 6-17 and were selected after review of the literature on risk factors for assisted and operative birth (MacDorman, Menacker, & Declercq, 2008).

	Parameter	Variable type	Final model
Independent variable	Intrapartum immersion	Categorical, 3 levels	No
Covariates	PBI Maternal age Parity Gestational age Induction of labor Maternal race/ethnicity Maternal education Prior cesarean	Continuous Continuous Continuous Continuous Dichotomous Categorical, 3 levels Categorical, 5 levels Dichotomous	No Yes No No No No Yes

Table 6-17. Factors examined for relationship to method of delivery.

Labor in water initially appeared to be associated with significant reductions in both operative vaginal birth and cesarean delivery in models that included all other parameters except history of prior cesarean. Once prior cesarean was entered into the model, only maternal age and parity remained significant (final model Chi-square=117.8, df=8, p<.0001). As Table 6-18 describes, increased maternal age was associated with an increased likelihood of cesarean (OR=1.08, 99% Cl= 1.02-1.14, p<.0001) but not assisted vaginal delivery/vaginal breech delivery (p=.018). Similarly, increased parity was associated with significant reductions in the likelihood of cesarean (OR=.674, 99% Cl= .476-.954, p=.003) but not operative vaginal delivery/vaginal breech birth (p=.654). A history of cesarean also predicted cesarean delivery in the index pregnancy (OR=.074, 99% Cl=.039-.140, p<.0001) but not forceps, vacuum or vaginal breech delivery. These findings confirm those from randomized trials of immersion during labor in which no association with method of delivery was observed (Cluett & Burns, 2009).

Table 6-18. Immersion during labor and m Method of delivery (a)	iethod of delivery (n=6,273)	MeiM	₹.	<u>s</u>	Exm(B)	99% CIE Lower Found	<u>xp(B)</u> Upper R∩und
Cephalic forceps or vacuum assisted birth. or any vaginal breech birth	Intercept	15.020	1	.000		ı	
	Maternal age Parity	5.640 201		.018 654	1.089 978	.993 604	1.196 1.426
	No prior cesarean vs. prior cesarean	3.950	<u>ب</u>	.047	.333	.080	1.385
	No immersion vs. labor in water	.000	-	.997	1.004	.070	14.374
	Labor in water (reference group)		0				
Cesarean birth	Intercept	12.726	<u> </u>	.000			
	Maternal age	13.175	-	.000	1.081	1.023	1.143
	Parity	8.548	-	.003	.674	.476	.954
	No prior cesarean vs. prior cesarean	111.036	-	.000	.074	.039	.140
	No immersion vs. labor in water	1.523	-	.217	3.590	.249	51.744
	Labor in water (reference group)		0				

(a) The reference category is: Spontaneous cephalic vaginal birth.

## Maternal Outcomes

# Intrapartum Complications

The relationship between IPI and intrapartum complications was examined using a dichotomous dependent variable (complications, yes/no). Intrapartum complications included one or more of the following conditions: chorioamnionitis, intrapartum fever without a diagnosis of chorioamnionitis, prolapsed umbilical cord, pre-eclampsia and eclampsia, disseminated intravascular coagulation, placental abruption and shoulder dystocia. There were significantly fewer cases with aggregate intrapartum complications associated with both WL and WB compared to childbirth without immersion, after controlling for a myriad of medical and obstetric risk factors outlined in Table 6-19 (Chi-square=294.4, df=11, p<.0001). Specific intrapartum complications were then examined to determine the source(s) of aggregate differences.

			99.0% EXF	CI for P(B)	Included in
	Sig.	Exp(B)	Lower	Upper	Final Model
Perinatal Background Index	.211	1.433	.683	3.005	No
Birth weight	.000	1.000	.999	1.000	Yes
Para	.537	.984	.919	1.053	No
Maternal age	.852	1.001	.988	1.014	No
Gestational age	.346	.980	.927	1.036	No
Induction/ Augmentation	.000	1.332	1.136	1.561	Yes
Pharmacologic pain relief	.758	1.019	.869	1.196	No
Fetal death	.120	2.295	.580	9.078	No
Antepartum complications	.000	1.337	1.128	1.585	Yes
No immersion (reference group)	.000	-	-	-	Yes
Labor in water vs. no immersion	.000	2.711	1.926	3.815	Yes
Water birth vs. no immersion	.000	3.889	2.605	5.805	Yes
Constant	.112	4.580	-	-	-

Table 6-19. Potential predictors of intrapartum complications.

Dependent variable (intrapartum complications) coding: 0=Yes, 1=No.

*Shoulder dystocia.* There was no association between IPI and shoulder dystocia. Among six parameters examined (PBI, gestational age, birth weight, parity, maternal age, and IPI), only birth weight was associated with shoulder dystocia (OR = 1.002, 99%) CI 1.002-1.003, p<.0001).

*Chorioamnionitis.* There was no significant association between IPI and chorioamnionitis examined as a dichotomous variable (yes/no). As Table 6-20 demonstrates, increased obstetric risk factors (measured by the PBI) were positively associated with chorioamnionitis, as were decreased parity, induction or augmentation or labor, pharmacologic pain relief, intrauterine fetal demise, and aggregate antepartum complications.

		_	99.0% CI fo	or EXP(B)
Parameter examined	Sig.	Exp(B)	Lower	Upper
Perinatal Background Index	.008	.099	.010	.928
Birth weight	.094	1.000	1.000	1.001
Parity	.000	.479	.294	.781
Maternal age	.128	1.025	.983	1.068
Gestational age	.257	.923	.770	1.107
Labor induction/augmentation	.000	.210	.099	.443
Pharmacologic pain relief	.000	5.309	2.274	12.394
Fetal death	.521	.485	.027	8.843
Antepartum complications	.692	.919	.531	1.590
Intrapartum immersion	.413			
IPI(1)	.183	.538	.162	1.788
IPI(2)	.993	.000	.000	
Constant	.915	.752		

Table 6-20. Potential predictors of chorioamnionitis.

Dependent variable (chorioamnionitis) coding: 0=No, 1=Yes.

*Postpartum complications.* Postpartum complications were rare in this healthy sub-sample. To enable meaningful analysis, sixteen postpartum complications were aggregated and operationalized as a dichotomous variable (yes/no), including urinary retention, cystitis, uterine inversion, endometritis, hematoma, thrombophlebitis and thrombosis, local infection of perineal sutures or wound breakdown, mastitis and other breast complications, postpartum depression or psychosis (within 72 hours of birth), separation of the symphysis pubis, unplanned operation following delivery, and admission to the intensive care unit in the postpartum period. As Table 6-21 indicates, there was no significant association between IPI and aggregate maternal postpartum

complications, controlling for 12 additional factors, none of which were found to be

significant in the binomial logistic regression model.

			99.0% CI for EXP(B)	
Parameters	Sig.	Exp(B)	Lower	Upper
Perinatal Background Index	.226	2.49	.357	17.399
Birth weight	.026	1.00	.999	1.000
Parity	.015	1.27	.986	1.639
Maternal age	.519	1.01	.973	1.047
Gestational age	.601	1.03	.883	1.207
Labor induction/augmentation	.032	1.44	.928	2.243
Pharmacologic pain relief	.255	.82	.520	1.288
Fetal demise	.999	.00	.000	
Antepartum complications	.180	1.27	.805	1.990
Intrapartum complications	.214	.80	.510	1.265
Postpartum hemorrhage	.010	1.65	1.002	2.722
Cesarean (references group)	.319	-	-	-
Spontaneous vaginal birth vs. cesarean	.401	1.28	.603	2.706
Forceps/vacuum vs. cesarean	.568	.78	.255	2.389
No intrapartum immersion				
(reference group)	.580	-	-	-
No immersion vs. labor in water	.660	.89	.437	1.797
No immersion vs. birth in water	.370	1.40	.531	3.707
Constant	.999	251072280.21	-	-

Table 6-21. Potential predictors of aggregate maternal postpartum complications.

Dependent variable (postpartum complications) coding: 0=Yes, 1=No.

*Postpartum hemorrhage.* There was no association between IPI and excessive postpartum blood loss, controlling for six other potential predictors. Neither maternal age nor gestational age were associated with postpartum hemorrhage, which was predicted by the presence of obstetric risk factors (measured with the PBI), increased infant birth weight and decreased parity (p<.01 for all).

*New postpartum prescription.* New prescriptions for conditions diagnosed in the postpartum period were examined; no relationship with IPI was observed, after controlling for 13 other factors in the binomial logistic regression model described in Table 6-22. Parameters found to be positively associated with new postpartum

prescriptions were decreased parity, induction and augmentation of labor,

pharmacologic pain relief, aggregate antepartum but not intrapartum complications,

postpartum hemorrhage, and cesarean birth versus both spontaneous vaginal birth and

forceps/vacuum assisted vaginal birth.

Table 6-22. Pc	otential predictors	of new post	partum pr	escriptions.

			99.0% CI for EXP(B)		
Parameter	Sig.	Exp(B)	Lower	Upper	
Perinatal Background Index	.033	1.927	.874	4.251	
Birth weight	.200	1.000	1.000	1.000	
Parity	.001	1.108	1.022	1.201	
Maternal age	.025	.988	.974	1.002	
Gestational age	.112	1.037	.977	1.101	
Labor induction/augmentation	.000	1.511	1.275	1.790	
Pharmacologic pain relief methods	.000	.675	.568	.801	
Fetal demise	.773	.838	.173	4.060	
Antepartum complications	.001	1.256	1.046	1.508	
Intrapartum complications	.024	.855	.716	1.022	
Postpartum hemorrhage	.000	1.887	1.513	2.353	
Cesarean (reference group)	.000	-	-	-	
Spontaneous vaginal birth vs. cesarean Forceps/vacuum assisted birth vs.	.000	16.862	10.214	27.839	
cesarean	.000	7.853	4.119	14.973	
Maternal postpartum complications	.000	2.321	1.511	3.567	
No intrapartum immersion (reference					
group)	.034	-	-	-	
Labor in water vs. no immersion	.019	.769	.577	1.026	
Birth in water vs. no immersion	.161	.846	.622	1.150	
Constant	.000	.011	-	-	

Dependent variable (new postpartum prescription) coding: 0=Yes, 1=No.

*Duration of postpartum care.* There were no differences in the length of inpatient postpartum stay related to hydrotherapy observed with a one-way analysis of variance using an alpha level of .01 (F=4.4, df=2, p=.012). In a repeated analysis using an alpha level of .05, women who gave birth in the tub were observed to have had a statistically shorter length of postpartum stay (38.8 hours, SD=14.6 hours) compared to women who labored in the tub (43.1 hours, SD=14.6 hours), but not women who were never immersed (41.0 hours, SD= 22.9). However, this four hour difference was of

questionable clinical significance, and was observed with a bivariate rather than multivariate analysis to control for method of delivery and other predictors of the duration of postpartum care.

Maternal death. There were no maternal deaths in the sample.

### Neonatal Outcomes

## Gestational Age at Birth

Binary logistic regression did not reveal differences in gestational age among groups defined by hydrotherapy utilization (p=.072) within the midwifery clientele restricted to independent observations. Clinical guidelines regarding eligibility for midwifery care during preterm labor and birth changed from 34 weeks to 36 weeks gestation during the study period. Midwives in the sub-sample attended 62 births that occurred prior to 36 weeks gestation (0.99% of sub-sample), including five births prior to 34 weeks, three of which occurred between 21.42 and 27.28 weeks.

### Birth Weight

There were no differences in birth weight observed among hydrotherapy groups using binary logistic regression (p=.475). Birth weight was operationalized as a dichotomous variable indicating whether a baby's weight was small or large for gestation age versus appropriate for gestational age (2500-4000 grams).

### Apgar Scores

There were no significant differences in 5 minute Apgar scores among babies who were born in water, born after labor in water, or born to a woman who did not use immersion (p=0.58), despite reduced frequencies of low scores among babies born in water or following immersion during labor.

# Breastfeeding

It could be hypothesized that women who give birth in water are more likely to breastfeed given that infants are brought to the surface immediately after birth and are

held in close proximity to their mother's bosom. For this reason, the relationship between breastfeeding and immersion was explored within the independent sample of women attended by midwives. An initial crosstabs analysis indicated that breastfeeding was associated with immersion status; women who labored or birthed in water were significantly more likely to breastfeed compared to women in midwifery care who did not use hydrotherapy (Chi-square=27.44, df=2, p<.0001). This bivariate analysis was verified with a significant binomial logistic regression model that controlled for preexisting risk status using PBI scores (Chi-square=84.05, df=3, p<.0001).

					99% CI for	
	Wald	df	Sig.	Exp(B)	Lower	Upper
Perinatal Background Index	49.911	1	.000	51.47	12.23	216.55
No immersion (reference group)	19.201	2	.000			
Labor in water vs. no immersion	10.938	1	.001	4.50	1.40	14.54
Birth in water vs. no immersion	8.681	1	.003	3.41	1.17	10.00
Constant	.612	1	.434	.70		

Table 6-23. Predictors of breastfeeding\* at hospital discharge.

\*Dependent variable (breastfeeding) coding: 0=No, 1=Yes.

As Table 6-23 indicates, women who labored in water were four and a half times more likely to breastfeed than women who did not use immersion, while the odds that women who gave birth in water breastfed were increased by a factor of 3.4 compared to women who were never immersed. When the analysis was run with WB as the reference group, there were no significant in breastfeeding rates between women who labored or birthed in water (p=.651).

The logistic regression was then performed with the addition of planned infant feeding method, as reported by women upon hospital admission prior to birth. Adding planned infant feeding method to the model as a covariate eliminated the unique significant contribution to breastfeeding previously attributed to hydrotherapy (p=.104). These findings suggest that women in midwifery care who planned to breastfeed were more likely to labor or birth in water rather than receive conventional care. These data

do not support the hypothesis that WB facilitates breastfeeding; nor however do they contradict it. At the study facility women were encouraged to exit the tub for delivery of the placenta, thus they did not remain skin-to-skin with their infants in the tub. Instead, women generally handed the infant to a partner or provider while exiting the tub, drying off and walking to the bed where the third stage was completed. During this time infants were dried and either held by a family member and/or examined by a nurse. Thus, the clinical guidelines for immersion at the study site precluded valid hypothesis testing which would need to occur in a facility where the management of third stage labor typically takes place in water. Further, a larger sample would likely be needed given just 4.4% of the midwifery clientele in this study formula fed their infants (n=274), only 11 of whom labored or birthed in water. Among six women who gave birth in water who planned to formula feed, five did so.

# Birth Trauma or Serious Neonatal Complication

Neonatal complications were rare and required aggregation with a dichotomous variable, *neonatal complication* (yes/no), for meaningful analysis. Conditions included in this variable were described in Table 5-5.

No association between IPI and neonatal complications was observed (p=.017) despite reduced frequencies of complications in the immersion groups. In addition to the aggregate neonatal complication variable, attempts were made to examine specific adverse neonatal outcomes mentioned in prior IPI research or case studies. These complications were examined separately, including conjunctivitis, hypoxic-ischemic encephalopathy, admission to level I or intensive care nurseries, and death.

*Conjunctivitis.* Just ten cases of neonatal conjunctivitis were documented in the restricted sample, all of which occurred in babies born to women who did not use hydrotherapy during either labor or birth.

*Hypoxic-ischemic encephalopathy*. No cases of hypoxic-ischemic encephalopathy were documented.

*Nursery Admission (Level I).* There was no significant association between hydrotherapy and admission to the study facility's level I nursery (p=.018) despite an decreased frequency observed in the WL (3.0%, n=14) and WB groups (.85%, n=4) compared to the standard care group (3.6%, n=189). In order to explore whether the clinical course following nursery admissions differed by hydrotherapy utilization, transfers to NICU facilities were subsequently examined.

*Transfer to Neonatal Intensive Care Facility.* There were 115 babies (1.84% of restricted sample) transferred to NICU facilities. As Table 6-24 describes, no differences in transport rates were observed among groups differentiated by immersion when analyzed with binary logistic regression or crosstabs. Two percent of babies born to women who did not utilize immersion were transported (n=105), compared to 1.7% of babies born after maternal immersion during labor (n=8), and 0.4% of babies born underwater (n=2). Since multiple randomized controlled trials have demonstrated no increase in neonatal complications related to maternal immersion in labor, only the transports after WB will be presented in detail (Cluett & Burns, 2009).

One of the two babies transported to a NICU after birth in water was a 2956 gram male infant born after spontaneous labor at 40.57 weeks gestation with clear amniotic fluid on spontaneous ROM and negative GBS screening. No intrapartum medications or complications were noted, and Apgar scores were reassuring (8/9/10). He was transported on the day of delivery, after breastfeeding was established, when an imperforate anus was noted. The second baby, also male, was born at 39.28 weeks gestation after spontaneous rupture of membranes with clear amniotic fluid and negative GBS testing. The mother was healthy except for depression which was being treated with Celexa. A velamentous cord insertion was noted after the birth. The baby weighed

2374 grams, had normal Apgar scores (8/9/10) and breastfed well. The small for gestational age infant was transported on the day of delivery after IV fluid administration for hypoglycemia. He was discharged home in good health the following day.

					99.0% CI for EXP(B)	
	Wald	df	Sig.	Exp(B)	Lower	Upper
Intrapartum immersion	4.780	2	.092	-	-	-
No immersion vs. water birth	4.671	1	.031	.213	.034	1.345
Labor in water vs. water birth	3.092	1	.079	.248	.032	1.913
Constant	59.174	1	.000	233.000	-	-

\*Dependent variable (neonatal transport) coding: 0=Transported, 1=Not transported. \*\* Missing data 0.3% (n=18).

When NICU transport was examined in the entire sample (N=13,394) just 2 additional transports after WL, and one additional transport after WB were identified. The third transport after WB was a baby born via egg donation to a woman with one prior delivery. The male infant weighed 4115 grams and was born at 40.57 weeks gestation after spontaneous labor and ROM with clear amniotic fluid and negative GBS screening. A "mild" shoulder dystocia was resolved with maternal positioning (Gaskin maneuver) and delivery of the posterior arm. Apgar scores were reassuring (9/9/10) but tachypnea was noted within hours of birth. The baby was treated with oxygen while a normal chest x-ray and echocardiogram were performed. He was transported to a NICU on the day of delivery and discharged a day later, with a final diagnosis of "transient respiratory distress of the newborn."

*Neonatal death.* Within the sub-sample of unique women who began intrapartum care with midwives (n=6,273), just three infants died between birth and hospital discharge. None of the neonatal deaths occurred after immersion during either labor or birth. There was no association between hydrotherapy and infant death in the restricted sample (Chi-square=.53, df=2, p=.767). Neonatal death was then examined for the

entire sample (N=13,394) and, among 18 total cases identified (0.13%), none took place following immersion.

# Hypothesis Decision

The hypothesis cannot be rejected. There were differences in mean OI-US scores related to intrapartum immersion within the midwifery clientele. Women who gave birth in water had the highest scores, followed by women who labored in water and those who did not use hydrotherapy. Perinatal optimality was significantly higher for the WB versus non-IPI group, but differences among WL and WB groups were not statistically significant. Observed differences persisted when pre-existing risk status was controlled for in analyses, and may be related to increased use of obstetric intervention in the non-hydrotherapy group including augmentation of labor, intrapartum medications including antibiotics and pain relief, and continuous versus intermittent fetal monitoring. Although severe perineal laceration was significantly less common in the WB group, this would not contribute to improved optimality because laceration repair was also more likely. Other observed differences likely to contribute to improved OI-US scores among women in the WB group were fewer aggregate intrapartum complications and an increased rate of breastfeeding in the IPI groups. However, no additional differences were observed. These findings warrant further examination since differences in perinatal optimality may not be fully explained by these data.

#### CHAPTER 7

## **Discussion and Conclusions**

This chapter will present a synthesis and discussion of primary study findings with comparisons to prior research and national data when available. Study strengths and limitations will be described, followed by conclusions and implications for clinicians, health policy and future research.

### Sample Demographics

Analysis of sample demographics revealed that the study facility serves a community that differs in several crucial ways from larger populations at the state and national level. The women in this study were older, had fewer children and were more likely to be partnered than counterparts in comparative samples. There were also differences in racial/ethnic origins, with subjects less likely to be African American and non-Hispanic Caucasian, and more likely to be Hispanic or Asian than US childbearing populations. These differences have implications for the interpretation of data and application of findings to other settings and childbearing clienteles.

## Parity

Women in this study had fewer children than counterparts at the national level. The sample was comprised of more nulliparae (42.4% versus 39.6%) and fewer grandmultiparae (2.9% versus 4.3%) than comprised the population of US childbearing women in 2005 (Martin et al., 2007). Similarly, less than 4% (3.6%, n=484) were having their fourth or higher order baby compared to 11% nationally (Martin et al., 2007).

Unfortunately, the retrospective study design precluded exploration of factors that may have contributed to differences in parity observed among subjects in the care of midwives, family practice physicians and obstetricians. Since midwives were significantly more likely to care for nulliparae than other provider types, it would have been interesting to determine whether multiparous subjects had experienced midwifery care in

prior pregnancies and decided to change provider type during the index pregnancies. However, it is also plausible that multiparae simply selected the same type of maternity care provider (obstetrician or family practice physician), if not the same individual clinician, as had attended them previously. This possibility is supported by the relative infrequency of midwife-attended births in the US (8-11%) (Martin et al., 2007). *Maternal age* 

A greater proportion of women in the sample were at least 35 years of age (15.9%) than reported at the national level for 2005 (14.4%). When 2005 was analyzed alone, the proportion of subjects 35 years or older was even higher (17.1%), indicating the study site likely experienced trends that were observed nationally over the last 20 years including increased mean maternal age at first birth and a growing proportion of older mothers overall. In 2005, 4.1% of subjects who were at least 35 years old were having their first baby, compared to 3.26% of US childbearing women that year (Martin et al., 2007). This is significant because older nulliparae are at increased risk for some chronic medical conditions and obstetric complications with long-term sequelae and negative implications for perinatal morbidity and mortality (Martin et al., 2007). *Partnership Status* 

There was no ability to distinguish between subjects who were married from those who were living in consensual union, thus comparisons to national data are limited. In 2005, 36.9% of US births were to unmarried women (Martin et al., 2007). Among these, approximately 40% were to women cohabitating with an intimate partner (Chandra, Martinez, Mosher, Abma, & Jones, 2005; Martin et al., 2007). Using these data it can be estimated that 21% of US childbearing women in 2005 were unmarried and not living with a partner, more than twice the rate observed in this sample (8.7%). This is a significant difference given the association between single motherhood and psychosocial and socioeconomic stress, poor mental health, smoking, and premature

birth, among other immediate and long term adverse conditions (Luo, Wilkins, & Kramer, 2004).

# Violence

Prior studies of US childbearing women reported a range of current intimate partner violence from 12% to 24%, and a lifetime history of violence ranging from 12% to 59% (Bohn & Holz, 1996; Sarkar, 2008). Given this context it is likely that women' experiences with domestic violence during pregnancy (0.3%) and history of abuse/assault (1%) were significantly underrepresented in this study of medical record data not expressly collected for the study of violence. This indicates routine assessment and documentation of abuse may not have occurred at the study site, resulting in missed opportunities for counseling women with risk factors for poor maternal and neonatal outcomes (Bohn & Holz, 1996; Sarkar, 2008).

## Racial and Ethnic Origin

The racial and ethnic sample proportions were somewhat different from 2005 US data, and may indicate greater diversity (Martin et al., 2007). The sample contained fewer non-Hispanic Caucasians (45% versus 55%), as well as Alaska natives and American Indians (0.6% versus 1.1%), and women who were African or of African descent (2.0% versus 15.3%). On the contrary, the sample contained greater proportions of Hispanic women (42.7% versus 23.8%) and Asian/Pacific Islanders (7.6% versus 5.6%). It is unclear how an additional 1.1% of the sample classified as Middle Eastern would have been categorized nationally.

# Prenatal Care

Findings related to prenatal care initiation and adequacy are difficult to contrast with national trends given differences in collection and reporting, but some comparisons can be made. Women in this sample may have been less likely to initiate care early, and more likely to present for care in advanced pregnancy, compared to US childbearing

women during the study period. Eight percent of subjects (n=1,026) initiated care after 20 weeks gestation, 0.7% (n=59) failed to receive any care, and 59.2% (n=7,926) both initiated care in the first trimester and had at least 5 prenatal visits. In comparison, 70.2-84.2% of US women who birthed in 2004 and 2005 initiated prenatal care in the first trimester, and 3.5-7.7% did not receive prenatal care or were late to care (Martin et al., 2007).

Clinical guidelines at the study facility assigned women without prenatal care to the obstetric service given their propensity for complications related to substance abuse and other socioeconomic and biophysical risk factors (Friedman, Heneghan, & Rosenthal, 2009). Thus, significant findings from crosstabs analysis of provider type and prenatal care adequacy were surprising (Chi-square=107.0, df=2, p<.0001). Midwives were more likely to care for women who received inadequate prenatal care (63.6%) than either family practice physicians (16.3%) or obstetricians (20.1%). This suggests that midwives served a disproportionately greater number of women who were late to care or received limited care than other providers. When women without prenatal care were analyzed separately, obstetricians were more likely to have provided care than other provider types (50.8%) but midwives (31.2%) and family practice physicians (18.0%) also participated in their care. This may demonstrate poor adherence to the study facility's clinical guidelines or be a function of necessity if women without prenatal care presented with imminent delivery and a midwife or family practice physician was the only provider on-site.

# **Baseline Health Status**

#### Pre-Existing Major Medical Conditions

Almost one-fifth of women in this study had at least one pre-existing major medical condition (17.7%), as did subjects in midwifery care (18.0%). There is a dearth of national data with which to contrast these findings, particularly given differences in

definitions, collection and reporting of data. From 1997 to 2005 the incidence of preexisting medical conditions among US childbearing women increased from 4.1% to 4.9%, excluding psychiatric conditions, those for which insufficient data exists to evaluate effects on perinatal outcomes, and those which present risks to fetuses but not mothers (Berg et al., 2009; Martin et al., 2007). A more appropriate comparative sample was described by Cragin and Kennedy (2006) who used the OI-US to examine women with moderate risk factors in midwifery care. They observed that 20.8% of women had pre-existing chronic medical conditions, after excluding several that were included in this research such as cancer, hypertension requiring medication, cardiac disease, lupus, hyperthyroidism and HIV. Prior studies that utilized the Index to examine low-risk childbearing women reported pre-existing medical conditions in just 0-3% of study samples (Low & Miller, 2006; Murphy & Fullerton, 1998).

#### Complications of Index Pregnancy

### Substance Use

Documented substance use among subjects was less than anticipated. Overall, 2.9% of women were identified as having used tobacco, 0.7% used alcohol and 1.5% used other drugs during the index pregnancy. Although a prior study of birth certificate data for California between 1991 and 1998 found just 1.2% of cases had documented drug or alcohol use, national perinatal substance use appears to be more common (Wolfe, Davis, Guydish, & Delucchi, 2005). The US Department of Health and Human Services does not generally report national data about alcohol or illicit drug use among childbearing women but other studies have indicated that 0.4-27% of US women disclose or are otherwise found to use drugs other than alcohol and tobacco during pregnancy (Bada et al., 2002). In 2005, 10.7-16.2% of US women disclosed tobacco use during pregnancy per birth certificate data (Martin et al., 2007). Substance use is known to be underrepresented by self-report, so it is unclear whether subjects in this study

reported less substance use than national counterparts because actual use was less, or because of differences in patient-provider communication, screening/testing, or documentation at the study site.

## Psychiatric Diagnosis and Treatment

Although a sizable portion of the sample had at least one documented psychiatric diagnosis requiring treatment in the index pregnancy (5.7%), prior studies have identified depression in 7.4-12.8% pregnant women, with other psychiatric disorders affecting additional subjects (Bennett, Einarson, Taddio, Koren, & Einarson, 2004).

### Hypertensive Disorders

Women in this study had slightly less chronic hypertension than was reported for US women in 2005 (0.8% versus 1.0%), but experienced more hypertension related to pregnancy (5.1% versus 4.0%) with associated risks for poor perinatal outcomes including intrauterine growth restriction, prematurity, stroke and death (Martin et al., 2007).

### Sexually Transmitted Infection

The prevalence of STI within the sample was difficult to compare to national data since information about infections during pregnancy is not regularly collected or reported for the population of US women. Data appropriate for comparison were few. For example, among women aged 15-24 who were screened for Chlamydia during prenatal care in 22 states during 2007, 2.0-20.7% were diagnosed with the infection (Centers for Disease Control and Prevention, 2008). However, STI is more prevalent in young women, which limits the utility of comparing these data with this older study sample (Centers for Disease Control and Prevention, 2008).

The finding that women in midwifery care were significantly more likely to be diagnosed with STI during the index pregnancy was interesting but retrospective data precluded further analysis. It is possible that midwives at the study site cared for women

at higher risk for STI, but equally likely that midwives cared for similar populations and utilized routine screening protocols more often than family practice and obstetric counterparts.

# **Diabetes During Pregnancy**

In 2005, 3.85% of US women experienced diabetes during pregnancy, including 0.72% with a pre-pregnancy diagnosis (Martin et al., 2007). Compared to national data, diabetes was disproportionately more common among women who received care at the study site; 7.0% of the sample was diagnosed during pregnancy while 0.9% had a diagnosis prior to becoming pregnant. These findings likely reflect the increased maternal age and large proportion of Hispanic women observed in the sample compared to the national childbearing population.

### Multiple Gestation

Women who gave birth at the study site were twice as likely to have multiple gestation pregnancies than national counterparts. Overall, 1.1% of women in the sample gave birth to multiples (n=281), and 2.1% (n=283) of study births were plural. In contrast, US data for 2005 indicates a national twin birth rate of .32%, while the triplet and higher order multiple birth rate ranged from 0.19% in 1998 to 0.16% in 2005 (Martin et al., 2007). Given that obstetric complications such as prematurity, cord prolapse and operative delivery are more common with multiples, this finding could have implications for care processes and outcomes observed at the study site.

## Intrauterine Fetal Demise

The fetal death rate observed for the study sample (0.5%) was slightly less than observed for the population of US women during most of the study period. Nationally the stillbirth rate ranged from .68% to .62% between 1997 and 2003 (Martin et al., 2007). This finding may be related to the nature of the study site. As a community hospital, women at highest risk for poor perinatal outcomes were transferred to tertiary facilities

prior to birth whenever possible. However, a sizable number of women in the sample had significant risk factors for fetal demise including postmaturity, multiple gestation, diabetes, and hypertension.

# Intrapartum Complications

#### Premature or Post-Term Birth

The preterm birth rate observed in this sample (4.5%) was less than half of that observed nationally, likely because women with premature labor prior to 34 weeks gestation were transferred to tertiary facilities whenever possible. In 2005, 12% of all US births occurred before 37 weeks gestation, with 11% of singletons born premature (Martin et al., 2007). In contrast, women in this study were more likely to give birth on or beyond their due date (56.6% vs. 33.7%) than the national sample in 2005 (Martin et al., 2007). This may reflect a decreased incidence of elective delivery in addition to a decreased premature birth rate and other factors that will subsequently be explored. *Prolonged Rupture of Membranes* 

Prolonged ROM has been identified as a risk factor for intrapartum, postpartum and neonatal infection (Marlowe, Greenwald, Anwar, Hiatt, & Hegyi, 1997; Seaward et al., 1998). However, data suggest the relationship between infection and duration of ROM is mediated by the number and timing of digital cervical exam(s) following rupture (Marlowe et al., 1997; Seaward et al., 1998). As such, the OI-US requests the time elapsed between the first digital exam following ROM and birth but these data were not available for this research. This was a limitation shared by other studies using the Index (Cragin & Kennedy, 2006). With additional review of handwritten chart notes for this sample, information about digital exams could be obtained and analyzed, and missing data about duration of ROM (8.3%) could be located. This undertaking could prove interesting given that delayed and restricted cervical exams were endorsed by clinical guidelines for midwifery management of premature/prolonged ROM in term pregnancies

at the site. Further, site guidelines endorsed a practice of indefinite expectant management of prolonged ROM with daily non-stress testing for half of the study period. These practices differed greatly from community standards of care. It is difficult to determine whether the sizable portion of the sample (22.7%) who experienced prolonged ROM was greater or lesser than observed in other settings since reported rates have varied widely (2.3-33.8%) due to differences in use of expectant versus active management of ROM (Marlowe et al., 1997; Seaward et al., 1998).

### Meconium Stained Amniotic Fluid

Information about the severity of meconium staining was unavailable for this research, thus comparisons to national data are limited. More than one-fifth of subjects (22.4%) had some degree of meconium present in amniotic fluid at the time of birth, while 4.6% of US births in 2005 were associated with moderate or thick meconium (Martin et al., 2007).

## Non-Cephalic Fetal Presentation

The proportion of subjects who gave birth vaginally to breech and other noncephalic babies (4.1%) was similar to the overall rate of abnormal presentations (4.7%) reported for US women in 2005 (Martin et al., 2007). Thus, it appears that subjects may have been more likely to experience fetal malpresentations than national counterparts since fetal presentations were unknown for operative deliveries at the study site, and malpositioned babies are increasingly delivered via cesarean in the US and abroad. Further, women in this study were older than the average US childbearing woman, and increased maternal age is a risk factor for breech presentation.

#### Other Intrapartum Complications

More than a quarter of the sample (28%) experienced one or more intrapartum complication including chorioamnionitis, intrapartum fever without a diagnosis of chorioamnionitis, umbilical cord prolapse, placental abruption, maternal-fetal

hemorrhage, and shoulder dystocia. This proportion was similar to the national rate of 29% from 2000 to 2005 (Martin et al., 2007). Despite similar rates of complications, women in this study were less like to experience technologic care processes and obstetric interventions than US counterparts, as described in the next section.

### Care Processes

#### Antepartum Care Processes

Induction of labor. Women who gave birth at the study site were less likely to be induced than US counterparts. Close to one-fifth of subjects were induced (17.2%), but the proportion was half of what new US mothers reported when surveyed in 2005 (41.0%) (Martin et al., 2007). This survey data is likely more accurate than US birth certificate data for 2005 which revealed an induction rate of 22.3%, only slightly higher than observed in this sample (Declerg et al., 2006).

#### Intrapartum Care Processes

*Labor augmentation.* Women in this study appear to have experienced artificial ROM more often, but received Pitocin augmentation of labor less often, than a national sample. Almost half (47%) of new US mothers surveyed in 2005 reported both pharmacologic augmentation of labor and AROM (Declerq et al., 2006). In contrast, although half of women in this study were augmented (49.9%, n=6690), just 10.6% received Pitocin (n=1428) and 39.0% experienced artificial AROM (n=5233).

Intrapartum medications. Women in this study also received intrapartum medications less often than national counterparts. Overall, 65% of subjects received one or more medication compared to 83% of US women surveyed about childbirth in 2005 (Declerq et al., 2006). The US sample was almost three times more likely to have had epidural or spinal anesthesia then women in this study (78% versus 29%), although the receipt of narcotics/sedatives was comparable (47% versus 51%) (Declerq et al., 2006).

Fetal monitoring. Women in this sample were less likely to experience continuous

electronic fetal monitoring (EFM) than US women in 2005 (51% versus 88%) (Declerq et al., 2006). Continuous EFM is a care process associated with increased operative delivery but not significant improvements in maternal or neonatal outcomes when applied to healthy parturients (Alfirevic, Devane, & Gyte, 2006; Natale & Dodman, 2003). The association between continuous EFM and operative birth is primarily related to difficulties with interpretation of ambiguous and non-reassuring fetal heart tone tracings (Alfirevic et al., 2006; Natale & Dodman, 2003). Thus, professional organizations for US providers of maternity care uniformly recommend the restricted use of continuous EFM (ACNM, 2007; American College of Obstetricians and Gynecologists, 2005). Findings indicate that clinicians at the study site may adhere to such recommendations, and practice evidence based care, more consistently than national counterparts.

Additional notable findings related to fetal heart rate monitoring included differences among provider types for both method and outcome of monitoring. Women in obstetric care were most likely to experience continuous EFM as well as abnormal findings. Bivariate analyses did not permit exploration of these findings further, but it is likely that differences were related to differences in practice styles as well as discrepancies in risk status among women attended by varied provider types. Analyses of provider type by intention to treat ensured that the obstetrician caseload was not biased by inclusion of women who began intrapartum care with family practice physicians or midwives but were transferred to obstetric care after abnormal EFM findings were observed. Thus, potential differences in risk status among women in obstetric versus midwifery and family practice care would reflect appropriate prenatal, but not intrapartum screening. However, differences in the use of continuous EFM have previously been observed among maternity care provider types even when risk status was similar among study groups or controlled in analyses (Janssen, Ryan, Etches, et al., 2007; Storbino, Baruffi, Dellinger, et al., 1988). This supports the likelihood that fetal

monitoring differences observed in this study reflect clinician practice styles in addition to the baseline risk status of parturients.

*Episiotomy.* Women who gave birth at the study site were much less likely to experience episiotomy than US women throughout the study period; 4.7% of sample versus 33% of the national population in 2000 and 19% of US women in 2005 (Martin et al., 2007). Clinical guidelines at the study facility adhere to national guidelines which endorse restricted use of episiotomy, given the strong association with severe perineal laceration (American College of Obstetricians and Gynecologists Committee on Practice Bulletins, 2006). Although the US episiotomy rate declined over the study period, the procedure remained almost four times more likely at the national level than among women in this sample.

*Method of delivery.* Women at the study site were more likely to experience a spontaneous vaginal delivery than US counterparts throughout the study period. Overall, the cesarean birth rate for women in the sample was 15.6%, which is less than national rates of 20.6% in 1996 and 31.8% in 2007 (Hamilton, Martin, & Ventura, 2009; Martin et al., 2007). States and provinces reported cesarean rates ranging from 21.9-48.1% in 2005, with 30.7% of births by cesarean in California (Martin et al., 2007). The primary cesarean rate (percentage of women having their first cesarean) at the study facility was 10.0% compared to 20.3-24.3% of US childbirths in 2005 (Martin et al., 2007), and a national target rate of 15% set by the Centers for Disease Control and Prevention and the Health Resources and Services Administration for the year 2010 (Wright, 2007).

Forceps and vacuum assisted births also occurred less frequently in this sample than in national birth certificate data. During the study period the US vacuum- assisted birth rate declined from 6.2 in 1997 to 3.9 in 2005, but remained greater than the overall rate of 2.9% observed in this sample (Martin et al., 2007). The use of forceps among

subjects (0.25%) was also less than national levels which declined during the study period from 2.8% in 1997 to 0.9% in 2005 (Martin et al., 2007).

# Maternal Postpartum Procedures

*Obstetric laceration repair.* Obstetric laceration requiring repair was common among subjects (56.6%), and unrelated to provider type in bivariate crosstabs (Chisquare=5.9, df=2, p<.051). However, parity was uncontrolled which introduces bias related to the increased nulliparity previously observed among women in midwifery care. However, the increase in perineal laceration anticipated among nulliparae could have been offset by the decrease in episiotomy performed by midwives.

### Summary

Despite an increase in some risk factors for poor perinatal outcomes, this sample experienced fewer technologic care processes and obstetric interventions than national samples. These differences should be considered during the subsequent review and discussion of the excellent biophysical maternal and neonatal outcomes experienced by subjects.

### **Biophysical Outcomes**

## Maternal Parameters

*Perineal outcomes.* Overall, perineal outcomes for this sample compare favorably to US birth certificate data. Severe lacerations (third or fourth degree) involving the anal sphincter occurred in 3.1% of the sample compared to 3.5-4.4% of US women who birthed between 1999 and 2004 (Berg et al., 2009; Callaghan, MacKay, & Berg, 2008; Martin et al., 2007).

Although there was no difference in the incidence of obstetric laceration requiring repair among women cared for by varied provider types, there was a significant difference in the severity of laceration. Women in midwifery care were more likely to have first degree rather than second degree lacerations, compared to women in the care of family practice physicians and obstetricians. However, this bivariate analysis did not control for factors associated with perineal laceration including nulliparity, increased maternal age, specific racial/ethnic origins, episiotomy, and instrumental delivery. These factors would need to be included in multivariate analyses to better understand the relationship between perineal laceration and provider type in this sample.

Retained placenta. The rates of retained placenta (3.0%) and manual removal (1.6%) in this sample were equivalent to those previously reported for similar populations. Retained placenta occurs in 1% of births in developing nations and 3% of births in developed nations; similarly manual removal of the placenta occurs in 1-3% of births regardless of setting (Weeks, 2008).

*Postpartum hemorrhage.* When measured with estimated blood loss, postpartum hemorrhage was more common in this sample than in national estimates. In contrast to 13.4% of the sample, just 2.6% of US women experienced postpartum hemorrhage from 2001 to 2005 per National Hospital Discharge Survey data (Berg et al., 2009). Given the subjective nature of blood loss estimations, objective measures such as calculated change in hemoglobin or hematocrit would have been preferable but were not available for this research. Without such data it is difficult to assess the apparent disparity between hemorrhage observed in this sample and others; however, it does not appear that the incidence of severe postpartum hemorrhage differed. The blood transfusion rate in this sample was 0.5%, while the national incidence increased from 0.3% to 0.5% between 1991 and 2003 (Berg et al., 2009; Callaghan et al., 2008; Weeks, 2008).

*Maternal death.* There were no maternal deaths in the sample, although analysis was limited to data about subjects' inpatient stay (usually 24-72 hours after delivery). This presents challenges for comparisons to national data which report maternal death related to childbearing in the first year postpartum. The US maternal death rate was 13.1-15.1 per 100,000 during the study period, making it possible although unlikely that
a maternal death would be observed in this sample despite the large size (Berg et al., 2009; Callaghan et al., 2008; Martin et al., 2007). This likelihood was reduced by the sample's general good health and relatively low operative delivery rate, despite the probability that maternal death is under-reported in the US by a factor of 1.3-3 (US Department of Health and Human Services, 2000; Wright, 2007).

# Neonatal Parameters

*Birth weight.* Infants born at the study facility were larger than counterparts at the national level during the study period; mean birth weights were 3,487 grams and 3,307 respectively (Martin et al., 2007). The proportion of subjects who were small for gestational age (3.1%) was less than expected, based on 2005 national birth certificate data which indicated 8.2% of US births (6.4% of singleton births) were to small infants that year (Martin et al., 2007). Further, half of this sample was comprised of infants weighing 3500-3999 grams (34.5%) or 4000-4500 grams (14.7%), compared to one-third of US babies born in 2005 (27% and 7% respectively) (Martin et al., 2007). Differences in birth weight between the sample and US data likely reflect discrepancies in risk factors for small and large for gestational age infants including pre and post-term deliveries, hypertension and diabetes.

*Five minute Apgar score.* Apgar scores less than 7 at five minutes of life were comparable among subjects (1.4%) and US babies born 2000-2005 (1.2-1.5%) (Martin et al., 2007). Although midwives were significantly less likely to deliver infants with low scores compared to obstetricians, this finding likely reflects differences in risk status and care processes uncontrolled in bivariate analyses.

*Breastfeeding.* The sample breastfeeding rate was superior to US estimates; 94% of subjects were breastfeeding at hospital discharge compared to 77% of national samples from 2005 and 2006 (McDowell, Wang, & Kennedy-Stephenson, 2008). This finding may be related to differences in demographics and obstetric care processes

associated with initiation and duration of breastfeeding, including socioeconomic status, race/ethnicity, lactation education/support from care providers, method of delivery, and other variables beyond the scope of this study.

*Congenital anomalies.* The percentage of study infants with congenital anomalies (0.5%) was twice the national rate in 2005 (0.2%), although comparison is limited because birth certificate data only account for anomalies related to anencephaly, spina bifida, omphalocele/gastroschisis, cleft lip/palate, and down's syndrome (Martin et al., 2007).

Infant death. The sample infant death rate (0.1%) was one third of that reported for US live born infants in 2003, 0.37% of whom died before seven days of life (Martin et al., 2007). This apparent discrepancy may reflect differences in sample risk status and complications, as well as operational definitions, since study data were limited to inpatient stay (generally 24-72 hours of life).

*Conclusion.* Subjects experienced excellent biophysical outcomes and reductions in technologic care processes despite an increased incidence of some significant perinatal risk factors in comparison to national childbearing samples. One of many potential explanations for findings is the use of IPI at the study facility. Although rates of WL and WB at the site were comparable to national data from midwife-attended births, they were likely greater than rates of IPI use in most US facilities (CNM Data Group, 1996). National IPI prevalence is largely unknown, but 6% of US women surveyed in 2005 reported having used a tub or pool in labor, and few were likely to have had WB given they were primarily attended by obstetricians in inpatient settings (Declerq & Sakala, 2006). Analyses were undertaken to explore potential effects of IPI among subjects through tests of association informed by seven hypotheses.

# Hypotheses Testing

Seven hypotheses were tested and each was supported by study data. Hypothesis One

The proportion of births at the study site involving WL or WB increased over time but not linearly. Instead, the percentage of facility births involving IPI maxed at just under 20% in the final six months of study when the number of WL and WB were close to double that observed in other periods of study. Data were not able to fully explain these findings which warrant further examination. However, testing of the second and third hypotheses indicated that IPI use was significantly associated with provider factors *Hypotheses Two and Three* 

IPI was strongly associated with provider type, and midwives attended 93% of women who had WL or WB. IPI use was also associated with the individual midwife and labor nurse in attendance at a woman's birth. These findings suggest that fluctuations in IPI use were likely at least partially related to provider factors.

Although study design and analytic technique preclude establishing causality, data indicate that the discussion and encouragement or discouragement of IPI provided by midwives as a group, and by midwives and nurses as individual clinicians, are likely related to childbearing women's utilization of hydrotherapy at the study site. These findings are consistent with prior literature demonstrating variation in other obstetric interventions attributable to type of birth attendant or specific maternity care provider, including ultrasonography, analgesia/anesthesia, induction and augmentation of labor, episiotomy, and cesarean section (Main, 1999; Main et al., 2004; Main et al., 2006).

Quantitative evaluation of providers' contributions to IPI utilization has not been described previously, although limited qualitative data from England and Taiwan suggest that midwifery care and counseling were related to participants' decision-making for use (Hall & Holloway, 1998; Richmond, 2003b; Wu & Chung, 2003). The nature of this

relationship has not been explicated and was beyond the scope of this study. Future inquiries should consider examining prenatal and intrapartum education and informed consent, continuity of care, staffing ratios, and unit census data as potential provider contributions to IPI utilization. An individual clinician's experience with IPI and familiarity with supportive literature are also likely to be involved and should be examined. Similarly one must consider the culture or philosophy of the maternity unit or practice setting within geographic and sociopolitical contexts, particularly the degree to which evidencedbased care practices are promulgated and system-level supports for physiologic childbirth are implemented and valued.

At the study site a midwife or nurse's ability to spend time with laboring women to discuss and implement comfort measures like IPI surely vary by patient census and acuity. One can envision a decrease in IPI, particularly WB, during the busiest shifts when intermittent fetal monitoring, labor support and comfort measures often used in conjunction with immersion may be precluded by increased staff-patient ratios, especially when individual staff members are not experienced or comfortable with IPI. These factors may have been involved in the temporary decrease in WB incidence observed in late 2004 through 2006. During this time five senior midwives left the practice after commonly attending births involving IPI. Collectively they attended a third of all WL (36.7%) and WB (33.2%) during the study period. The decrease in WB incidence also coincided with the period of time in which the unit census was highest and when women attended by midwives were most likely to be transferred to physician care at the time of delivery because their midwife was attending a simultaneous birth. Interestingly, the number of women who labored but did not birth in water dramatically increased during this time period. It is possible that the increase in WL and decrease in WB were related, although these data could not evaluate this additional hypothesis.

The significance of provider contributions to women's IPI decision-making was underscored by review of CNM log books. Some narrative midwife notes described providers involvement in women's IPI decision-making, e.g. "[She] was panicky- I suggested she get in tub while waiting for anesthesia. She tried it and decided she didn't need epidural after all." Prior European and Asian IPI literature indicated that women with a prenatal intention to labor and birth in water would be most likely to use hydrotherapy. This may also be true in this sample but examination of prenatal intentions was precluded by the limitations of retrospective data. Hypothesis testing and midwife logbook entries indicated that provider factors are involved in women's use of IPI, regardless of any additional contributions made by maternal prenatal intensions and preferences.

It is commonly perceived by providers in settings where labor and/or birth in water are not permitted, that the practice is not desired by women who "choose" to give birth there. Although subject preferences for IPI and selection of maternity care settings were beyond the scope of this study, data do indicate that the decision to labor or birth in water cannot be attributed solely to maternal factors but involves periodicity and the relationship between a woman and her care providers. These findings contribute to the emergent understanding of complexities inherent to informed choice in childbearing, notably limited by socioeconomic disadvantage (Craven, 2007). Recognition of these complexities will assist providers as they evaluate existing or proposed maternity care practices including IPI at institutional and macro levels.

# Hypothesis Four

In contrast to the first three hypotheses, the fourth hypothesis was only partially supported by data. Analyses of the relationships between demographic factors and clinical eligibility for WB failed to demonstrate clinically meaningful differences, despite statistical significance observed for tests of association involving parity, primary

language, Hispanic origin, and type of insurance. Nonetheless, these findings informed subsequent hypothesis testing in samples limited to independent observations of eligible women. Restricting the sample for analyses of the relationships between demographic factors and IPI utilization minimized the possibility that any small effect of parity, primary language, Hispanic origin, and type of insurance exerted on IPI eligibility would not bias findings. Although each demographic characteristic appeared to significantly contribute to IPI use when examined alone, multivariate modeling indicated only educational attainment, language and parity were associated. Women who utilized IPI were significantly more likely to be nulliparous, English-speaking women with increased educational attainment than counterparts who did not utilize hydrotherapy. The disparate findings from bivariate and multivariate analyses highlight the limitations of prior IPI research in which analytic methods were exclusively univariate.

Parity. Future IPI research should further explore the finding that nulliparae were less likely to be eligible for WB but more likely to actually have WB than multiparae. This finding was surprising since multiparae were less likely to use pharmacologic pain relief methods than nulliparae overall. Although beyond the scope of this study, it would be interesting to examine the effect of prior childbirth experiences on decision-making and preferences for IPI and pain relief in general. How did multiparae cope with labor if they did not use either IPI or pharmacologic pain relief options? Did multiparae select "natural childbirth" without hydrotherapy or pain medications, or were their labors too quick to permit desired IPI or analgesia/anesthesia? Multi-level modeling could be utilized to analyze parity and IPI in the full sample, including women who gave birth in at the site more than once during the study period. These women may have had access to birthing tubs in more than one pregnancy, depending on clinical conditions experienced each time. The effect of prior experience with IPI on subsequent deliveries has not been explored to date, although existing data suggest repeat use is likely. When queried

following experiences with WB, English women reported being satisfied with the practice and desirous of use in future pregnancies (Richmond, 2003b).

Future longitudinal study of IPI and parity should also include preferences for comfort measures and pain relief methods identified in the prenatal period because maternal preferences are not represented by actual hydrotherapy use (Mack et al., 2005; Woodward & Kelly, 2004). The discrepancy between intended and actual IPI use described in prior research was supported by multiple midwife log book entries that described multiparous women who had intended to use hydrotherapy but gave birth before tubs could be readied. This suggests that differences in IPI attributed to parity are not explained by experience or preference alone. Since nulliparous and multiparous labors differ, particularly with regard to the rapidity of progress in active labor, it is plausible that physiology contributes to the variation in IPI use by parity. This may help to explain why nulliparae contributed disproportionately more WL and WB than multiparae despite an increased likelihood of clinical ineligibility.

Language. The diminutive magnitude of association between primary spoken language and IPI use was surprising given an underlying assumption that women experiencing language barriers would balk at the use of novel obstetric interventions like IPI, if they could not directly or comprehensively discuss them with health care providers. The strength of the association between primary spoken language and IPI use was likely limited because providers at the site are either bilingual in English and Spanish, or generally have access to Spanish interpreters. Interpreter services for languages other than English and Spanish are limited to translation via phone which likely decreased patient-provider conversation experienced by 6.6% of the sample with a primary language other than English or Spanish.

Nonetheless, study findings support the previously reported negative association between patient-provider language discrepancies and IPI utilization (Geissbühler &

Eberhard, 2000; Geissbühler et al., 2004). Neither racial/ethnic origin nor Hispanic origin made unique contributions to the multivariate model of demographic predictors of IPI use, indicating they may have served as a proxy for primary language when found to be significant in preliminary bivariate analyses. Bivariate data indicated that Spanish-speaking women were significantly less likely to use WL than anticipated, while women who spoke any language other than English were less like to give birth in water. In the multivariate model, English speaking women were more likely to have WL or WB than women who spoke any other language. These findings are particularly interesting given that no significant differences in pharmacologic pain relief method utilization were observed among linguistic subgroups (Chi-square=5.214, df=2, p=.074). English-speaking women were not more likely to give birth without analgesia/anesthesia than counterparts who spoke other languages; English speaking women were simply more likely to utilize hydrotherapy during an unmedicated birth. The relationship between IPI and pharmacologic pain relief methods was explored further during additional hypothesis testing.

# Hypothesis Five

Testing related to the fifth hypothesis revealed that women who experienced WL used pharmacologic pain relief three times as often as women who had WB, while women who did not use IPI did so almost six times as often. This analysis controlled for parity, language, education and provider type, in addition to other parameters not found to be significantly related. Findings support those from 11 prior RCTs of WL and previously published observational WB data.

### Hypothesis Six

Obstetric laceration also differed among groups differentiated by hydrotherapy. Women who are interested in WB should be counseled that these data suggest WB is associated with increased superficial perineal and peri-urethral laceration requiring

repair, and a decrease in severe perineal laceration (4<sup>th</sup> degree). Although data cannot demonstrate causality, these are significant findings not previously observed in IPI research.

Physiologic theory had suggested that reduced edema resulting from hydrostatic pressure during immersion could improve perineal tissue elasticity thereby decreasing the incidence and severity of obstetric laceration. These data support this possibility with regard to the perineum. However, periurethral lacerations were more common among women after WB suggesting that any effect of hydrotherapy on tissue integrity differed in this region. The previously hypothesized difference in the management of second stage labor and "crowning" necessitated by maternal positioning or other factors during immersion is supported by these data and warrants further inquiry. Observation of management strategies in the second stage of labor, particularly perineal guarding, flexion/control of the presenting part, and the "hands-off/hands-poised" versus "hands-on" technique could shed light on these findings (de Souza Caroci da Costa & Gonzalez Riesco, 2006; Mayerhofer et al., 2002).

There were no meaningful differences in obstetric lacerations between women after WL and WB, yet there were several differences between women who had WB and those who never used IPI. This suggests that any effect of IPI on obstetric laceration may increase as duration of immersion increases, although retrospective data precluded measurement of time that hydrotherapy was used. It is possible that some women with documented WL tried immersion therapy briefly before deciding to try another comfort measure or request pharmacologic pain relief. Because the duration of immersion could not be analyzed, it is unknown if any effect of immersion was diminished by including some number of women who were not immersed for a significant length of time. Future IPI inquiries should examine women's use of IPI in greater detail including duration and patterns of utilization.

# Hypothesis Seven

Differences in pharmacologic pain relief methods and obstetric laceration observed in testing of hypotheses five and six contributed to significantly improved perinatal optimality associated with WB (higher OI-US scores) in testing of the seventh hypothesis. However, increased OI-US scores related to decreased severe perineal laceration in the WB group were offset by increased obstetric laceration repair. Other contributors to higher scores among women with WB were decreased labor augmentation, fewer intrapartum medications including antibiotics, more intermittent versus continuous fetal monitoring, fewer aggregate intrapartum complications, and higher breastfeeding rates. No additional differences were observed.

The finding that labor augmentation did not differ between women who labored in water and those who did not use hydrotherapy was surprising in light of previously reported randomized trials demonstrating immersion to be equivalent to Pitocin augmentation for the resolution of labor dystocia (Cluett et al., 2001; Cluett, Pickering et al., 2004). This, and physiologic theory about improved uterine oxygenation and contractility in water, lends credence to the idea that any effect of hydrotherapy could have been diluted if women were included in the WL group even if they used hydrotherapy for short periods of time. It is unfortunate no information about duration of immersion was available for this research.

# Provider Type

IPI utilization was not the only parameter to differ among women in the care of various provider types. As described in Tables 5-1 through 5-4, there were a number of differences in care processes and outcomes experienced by women and infants in midwifery care compared to those who received care from family practice physicians or obstetricians. Differences were observed in simple bivariate analyses and should be re-analyzed with reference to multiple demographic and clinical parameters previously

observed to be associated with maternity care practices and outcomes.

Fewer differences were seen between women in midwifery and family practice caseloads than were observed between women who received care from midwives versus obstetricians. This suggests that the clientele and care practices among midwives and family practices are similar, or at least less dissimilar than care provided by midwives and obstetricians. Compared to care from obstetricians but not family practice physicians, women attended by midwives were significantly less likely to be induced or experience continuous electronic fetal monitoring, and were less likely to receive medications in the intrapartum period including narcotics and sedatives, and epidural or spinal anesthesia. Retained placentas, blood transfusions, level I nursery admissions, five minute Apgar scores less than seven, and formula feeding were significantly more frequent within the obstetrician caseload compared to that of midwives, but there were no differences between the midwife and family practice groups for these parameters.

Factors that differed among midwife and family practice groups as well as the obstetrician group included prescription medications in the antepartum period, preeclampsia, non-cephalic fetal presentation, non-reassuring fetal heart rate monitoring, augmentation of labor, artificial rupture of membranes, chorioamnionitis, episiotomy, perineal laceration incidence and severity, postpartum hemorrhage, and medications during the third stage of labor or postpartum period. In each instance, midwife-attended women experienced the care process or adverse condition less often than women attended by family practice physicians, and women in obstetric care experienced the dependent variable most often. For method of delivery, midwifery care was associated with fewer assisted vaginal births and cesareans than expected in bivariate crosstabs analysis. The rate of spontaneous vaginal birth among women attended by family practice physicians was lower than anticipated, after excluding women

who experienced cesarean prior to labor.

Of note, the relationships between type of provider and both maternal and neonatal complications were significant because maternal-fetal dyads attended by family practice physicians experienced fewer aggregate complications than those attended by either midwives or obstetricians. However, the family practice caseload appears to have had fewer specific risk factors for technologic care processes and adverse outcomes compared to both midwife and obstetrician groups. Women in family practice care were significantly less likely to have serious pre-existing medical conditions and were more likely to be Caucasian, English-speaking, educated, privately insured and married or partnered than anticipated. The family practice caseload also included significantly fewer nulliparae, teens, women at least 35 years old, women who previously gave birth to a small for gestational age infant, and women with a psychiatric diagnosis, prolonged ROM or meconium stained amniotic fluid in the index pregnancy.

There were no differences in aggregate complications experienced among women or babies cared for by midwife and obstetrician members of the collaborative practice. This is surprising considering the assumption that midwives care for women with fewer risk factors for adverse outcomes, and should therefore experience fewer complications. Indeed, obstetricians were more likely to care for women without prenatal care, women with closely spaced pregnancies, and those with some pre-existing medical conditions including chronic hypertension. Although there were no differences in aggregate prior obstetric complications experienced by women in midwifery and obstetric care, the obstetrician caseload reported some specific obstetric risk factors more frequently than anticipated, including prior cesarean section, and a history of preterm birth, fetal demise and/or small for gestational age infants. Further, babies born in the care of obstetricians were significantly more likely to have died in utero, and arrive premature or post-mature, and/or small or large for gestational age. They were also disproportionately more likely

to be multiple gestations or experience complications that required transfer to intensive care facilities compared to babies delivered by either midwives or family practice physicians.

Observed differences in processes and outcomes of care surely reflect differences in provider training and practice as well as pre-existing medical conditions and obstetric complications experienced by women in the care of different provider types. The collaborative practice model and clinical guidelines in use at the site ensure that obstetricians care for disproportionately fewer healthy women than either midwives or family practice physicians. The effect of this inherent bias may be limited by the sample's case-mix which primarily consists of healthy childbearing women who were clinically eligible for care at a community hospital without perinatology or neonatology services. Nonetheless, maternal-fetal dyads who received midwifery care generally had fewer biophysical medical and obstetric risk factors and adverse perinatal outcomes than those in the care of obstetricians.

However, the midwifery clientele did experience some sociodemographic and biophysical risk factors for obstetric intervention and poor perinatal outcomes disproportionately more than anticipated, including nulliparity, non-Caucasian racial/ethnic origin, a history of antepartum complications (when analyzed as a dichotomous aggregate of significant histories), and sexually transmitted infection in the index pregnancy. Women in midwifery care were also more likely to have psychosocial risk factors including inadequate prenatal care, a primary language other than English, decreased educational attainment, prenatal care obtained through a government program and other proxies for low socioeconomic status. Further, in comparisons with family practice and obstetrician caseloads, the midwifery clientele included disproportionately more women with a documented history of sexual or physical assault/abuse and/or domestic violence in the index pregnancy. It is unknown whether

some of these differences would remain significant in multivariate analyses and, if so, whether they would reflect increased incidence within the midwifery clientele or differences in provider-patient communication and documentation of psychosocial and socioeconomic data.

Bias introduced by midwifery care eligibility and selection was not apparent in other bivariate examinations. There were no significant differences among women with different maternity care provider types for demographic and clinical characteristics including tobacco, alcohol and drug use in the index pregnancy, labor augmentation with Pitocin, eclampsia, shoulder dystocia, neonatal administration of Narcan, and infant death prior to hospital discharge.

# Strengths

This project explored care processes and outcomes of an inter-professional maternity service that serves an ethnically and socioeconomically diverse clientele. The study is a significant contribution to the IPI literature as well as knowledge of non-pharmacologic pain relief methods and midwifery care practices. When published, it will be the first to describe outcomes of WB in a US setting. WB in a freestanding birth center was described previously but reports were limited to incidence and descriptive statistics without comparative analyses. In contrast, this study utilized Chi-square, binomial and multinomial logistic regression, ANOVA and ANCOVA analytic techniques. This is a significant advance in IPI research, US or otherwise. The multivariate approaches were particularly progressive, and allowed for the control of predictors of poor perinatal outcomes. As such, this study provides a better measure of association between hydrotherapy and outcomes of interest than provided by most prior IPI studies, despite its descriptive design. Controlling for parameters as basic as parity and maternal age was a significant step forward, and the number and breadth of variables utilized in this study are previously unparalleled.

Demographic and baseline clinical factors were critical to examine in order to describe the sample, ensure appropriate contrasts among subjects, and to assess whether data could be generalized to other settings and populations. The standard biophysical outcomes measures of morbidity and mortality were essential to understand whether IPI was associated with adverse effects which would warrant restricting use. However, the care processes examined both within the OI-US and separately, were equally important contributions and certainly the most novel. Describing, analyzing and controlling for maternity care processes in addition to other parameters, is essential in the evolution of general perinatal research, as well as an important next step in the systematic analysis of the context in which IPI is provided.

# Limitations

Although there were many study strengths, there were also limitations. Weaknesses are primarily related to the retrospective descriptive design which limited parameters available for study and required the use of onerous data management software employed by the study site. Although missing data were minimized among parameters selected for study due to prior quality improvement activities at the site, additional variables would have been included if inconsistencies in data entry had been avoided. For example, electronic information about the duration of each phase of labor could not be used since comparison to handwritten medical records revealed gross inconsistencies. These data, as well as five missing OI-US items could have been collected with a prospective design. These particular parameters would have been significant additions to the study given the high quality of supportive evidence (e.g. skinto-skin contact between mother and child) and potential for significant association with IPI in light of prior study findings and physiologic theory (e.g. labor lengths).

In addition to restricting particular parameters of study, the retrospective design limited this evaluation to what was documented rather than what actually occurred.

Although multiple data sources were triangulated when possible, in some instances there was no way to confirm that documentation accurately represented clinical care or outcomes. This was particularly true for the absence of documentation which was presumed to indicate a parameter of interest was not present in the index case.

Additional limitations are related to the sample and unusual model of care at the study site. The collaborative practice model limits the generalizability of findings, even to other sites where midwifery and WB are options. Although most outcomes evaluations were performed within the midwifery clientele, some included the entire sample. It should not be overlooked that one fifth of women were attended by family practice physicians and residents. The study facility's relationship with a public university and family practice residency program surely contribute to the unique model of care provided at the site.

Details about perinatal risk factors and outcomes in relationship to provider type are critical when considering whether findings from hypothesis testing performed for subjects who received midwifery care can be generalized to maternity care by other provider types at the study site, or maternity care experienced by women in other settings. Given the meaningful differences in risk factors and outcomes observed between dyads in midwifery care and both obstetric and family practice caseloads, it cannot be assumed that observed associations between IPI and midwifery care processes and outcomes would remain significant if analyses were performed for subjects in the care of other types of providers. Similarly, it would prove difficult to generalize findings to maternity care at other facilities unless the sample demographics and case-mix are representative of populations cared for in other institutions. Both the patient population and collaborative inter-professional practice model would need to be similar before findings could be generalized to another setting.

The collaborative practice's emphasis on nursing and midwifery care is highly unusual from a national perspective. Presumably this difference indicates selection bias

which further limits generalizability of findings. However, selection bias is likely limited by the multi-generational community familiarity with midwifery care as well as the number of other maternity care services in the region. Local options for childbearing women include three urban tertiary facilities staffed by obstetricians and obstetric residents within 30 miles of the study site, a midwife-obstetrician collaborative practice in another suburban community hospital (10 miles), a free-standing birth center operated by nurse-midwives (12 miles), a freestanding birth center operated by licensed midwives (18 miles), and home birth services by a physician assistant, nurse-midwives and licensed midwives. Given the spectrum of maternity services available in the immediate area, it is difficult to hypothesize about selection bias and factors impacting a woman's choice to give birth at the study site. Such selection must differ from that which occurs when women choose to receive care from inpatient collaborative practices in regions without other options for midwifery care or obstetric services from family practice physicians. These choices warrant further examination as does the model of care at the study facility, particularly given differences observed in preliminary analyses of study variables by provider type.

# Study Implications

# **Clinical Practice**

This study provides data that will be reassuring to clinicians and childbearing women who utilize IPI for obstetric pain relief. The study demonstrates that outcomes of IPI in a self-selected, low risk population are excellent with adherence to clinical guidelines and hygienic protocols. Although not conclusive, findings do add to a significant body of literature that supports immersion during both labor and birth. Dissemination of results and the foundational review of the literature should increase awareness of practice safety and efficacy, inspire dialogue among clinicians, and increase provider-patient communication about options for effective non-pharmacologic intrapartum pain control. Findings support a significant association between a woman's

use of IPI and her individual midwife and nurse, underscoring the importance of such communication. To this end, initial and continuing education of maternity care providers should include IPI. By increasing knowledge among clinicians, the study could result in increased use of hydrotherapy. This is particularly true for immersion during labor given the conclusive experimental data previously published (Cluett & Burns, 2009).

# Health Policy

Although it is unlikely that this study will singularly contribute to a radical reconceptualization of IPI within US maternity care, thorough dissemination should provoke a re-evaluation of ill-informed reactions to the idea of maternal immersion or newborn emergence in water. This study could serve as the basis for evidence-based position statements issued by US maternity organizations and inspire an update of the policy previously issued by the American Academy of Pediatrics (Batton et al., 2005). Guidelines issued by the Royal College of Obstetricians and Gynecologists, and the Royal College of Midwives provide a template, as does the Cochrane Collaboration review of IPI research updated in 2009 (Alfirevic & Gould, 2006; Cluett & Burns, 2009). It would behoove perinatal clinicians to review these data given the ethical mandate to provide informed consent and respectful facilitation of maternal autonomy within the provision of health care (American College of Obstetricians and Gynecologists, 2004; American Medical Association, 2008a, 2008b).

#### Future Research

*Hydrotherapy.* With this study, IPI research has reached the point where a RCT would be an appropriate next step. Woodward and Kelly (2004) demonstrated the feasibility of such an endeavor, however costly and complicated. However, the ethics of such a trial are in question, particularly in Europe where IPI is widely available (Cluett & Burns, 2009). Although US prevalence remains largely unknown, it does not appear to be so prevalent as to preclude such a trial.

In future IPI research, experimental or otherwise, there are critical parameters that must be included. In addition to factors examined in this study, researchers should include information about length of labor, GBS status, prenatal intentions for IPI, maternal and provider perceptions of the practice, relaxation and coping strategies used in conjunction with IPI, and specifics of hydrotherapy provision including timing and duration of immersion, and water temperature, volume and depth. Long term follow-up and the use of objective measures including biomarkers would also enable significant advances in understanding of the phenomenon.

*Model of care*. In addition to outcomes of IPI, this study described a unique model of care that warrants further exploration. The collaboration between obstetricians and midwives at the site has been described previously but data from this study period were not included (Schimmel et al., 1992; Schimmel et al., 1994; Schimmel et al., 1997). The model has been credited with reducing regional operative and assisted vaginal delivery rates, and facilitating physiologic birth with midwifery care practices including labor support and a spectrum of pain relief and comfort measures. Further, the collaborative practice structure is perceived to enable obstetricians to provide care to a greater number of women through reliance on nurse practitioners and midwives, while focusing on gynecologic and obstetric complications requiring medical and/or surgical management, including lucrative outpatient procedures (IGaskin, 1996a; Gaskin, 1996; Gaskin, 1996b). These perceptions should be evaluated given potential to improve public health and health care financing.

*Health policy.* These themes are the primary study implications for health policy. Data indicate that the inter-professional practice achieved outcomes superior to those observed nationally, using fewer technologic care processes including induction and augmentation of labor, continuous fetal monitoring, and assisted vaginal and operative deliveries. The use of IPI, and concomitant decrease in pharmacologic pain relief

methods utilization, were significant contributors. Findings cannot be solely attributed to the population served by the facility given the sample's ethnic and socioeconomic diversity. Further research at the study site and geographic surrounds, in combination with existing midwifery outcomes data, could inform public health policy thereby expanding access to collaborative maternity care. This is likely to result in a greater emphasis on individualized care, the judicious use of expensive technologies and medications, and a greater incorporation of non-pharmacologic pain relief and comfort measures including IPI.

# Conclusions

This project demonstrated that midwifery and nursing provision of hydrotherapy during labor and birth were associated with optimal perinatal outcomes when used in accordance with clinical guidelines among healthy women who self-selected use with informed consent. The study was the first to describe such outcomes in an inpatient US setting, and one of few to use multivariate statistical approaches to IPI outcomes analysis. The research also provided important new information about the characteristics of providers and childbearing women who use IPI and associated care processes. The collaborative model and content of care described in this study could provide an exemplar for necessary perinatal health care reform.

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Appendix A

The Optimality Index- United States

Available at:

http://www.acnm.org/documents/OptimalityUSCodebook\_June2009.pdf

# THE OPTIMALITY INDEX - US The Perinatal Background Index The Optimality Index Patricia A. Murphy, Dr.P.H., CNM Judith T. Fullerton, Ph.D., CNM, FACNM CODING AND SCORING GUIDELINES August 2008

GENERAL CODES:
8 = General missing (data that will never be found in these records, and will not be collected for this particular purpose) 9 = Missing data (data that should be present, but are not found on this particular record)
SPECIAL NOTES:
<ol> <li>It may be the case that a practice guideline has been established that advocates "charting by exception", i.e., the guideline specifies that an item will be charted <i>only in the event</i> that it is present or is observed. Abstractors should always seek guidance from the PL Abstractors may be advised that "if [specific item] is <i>not noted</i>, outcome = optimal."</li> <li>In the instance of multiple births, re-enter mother's data for each baby</li> </ol>
SCORING:
Numerator = sum of all items coded as "1" (optimal) Denominator = Remainder of total N= 55 optimality items after deletion of all items coded as 7 (not applicable) or 8 (general missing)
MINIMUM NUMBER OF ITEM REQUIRED FOR USE OF THE TOOL:
The OI-US is a clinametric index. There are no subscales. The index items are, nevertheless, ordered within logical clinical domains. Each item is coded as Essential or Nonessential. A valid application of the tool is possible ONLY if
a) there are one or more items present within each clinical domain (i.e., no clinical domain is secored entirely as system missing - code 8), and b) each of the items designated as Essential is generally available for scoring (i.e., codes 7 and 9 are acceptable reasons for missing data).
PROCESS VERSUS OUTCOME VARIABLES
Each item is coded as a <b>P</b> (rocess), <b>O</b> (utcome) or <b>P</b> /O (indicating that the item can be considered either a measure of process or a measure of outcome) variable. Users of the OI-US should confirm their understanding of the nature of each measurement item in the context of their own investigation.

INDEX ITEM	PROCESS OR OUTCOME VARIABLE THE P	ESSENTIAL OR NONESSENTIAL (preliminary ratings) PERINATAL BACK	GUIDELINE GROUND INDEX
	THE P	ERINATAL BACK	GROUND INDEX
		Social and medical I	background
1. marital status	Р	v	<b>OPTIMAL = Married or living in con</b>
2. ethnic minority	Р	Е	OPTIMAL = White - non Hispanic
3. smoking	P	E	<b>OPTIMAL</b> , = <b>No use of any</b> smoking sin pregnancy)
4. alcohol	P	Е	<b>OPTIMAL</b> = <b>No use of any</b> alcohol sinc pregnancy)
5. drug use	P	Е	<b>OPTIMAL</b> = No abuse of any prescription substances since conception (during index
6. pre-pregnancy body mass index (weight [in kg] / height [in meters] <sup>3</sup> )	P	ti Ti	Record weight in pounds Divide weight in pounds by 2.2 to yield w Record height in inches Divide height in inches by 2.54 to yield he Compute formula
			OPTIMAL = 18.5 to 24.9 [WHO standards] Abstrators Note: Confirm the standard prior to calculation and coding. Several available.
7. age	Р	E	OPTIMAL = age 18 - 40 at the time of t
8. preexisting, major, chronic, disease	P	E	<b>OPTIMAL</b> = <b>There is no evidence</b> of an health history
- Advantantian Construction In Proceedings			

<ul> <li>pyclonephritis</li> </ul>	pre-eclampsia	<ul> <li>placenta abruption</li> </ul>	placenta previa	celampsia	diabetes	14. other serious antepartum complications (history of)	<ol> <li>previous baby &lt; 5 ½ pounds at birth</li> </ol>	12. previous Cesarcan section	11. previous intrauterine fetal death	<ol> <li>previous preterm delivery &lt; 37 weeks</li> </ol>	9 inter-pregnancy interval between index pregnancy and previous viable birth > 18 months and < 60 months	<ul> <li>major psychiatric history (treated with drugs or inpatient therapy)</li> </ul>	Hypertension	HIV antibody positive	<ul> <li>heart disease class II-IV</li> </ul>	<ul> <li>diabetes (non-gestational)</li> </ul>
						P	P	Р	P	P	P					
						E	E	Е	Е	E	N					
			Abstractors Note: Code N/A if index pregnancy is the first pregnancy.	provider.	Definition: preeclampsia is defined as blood pressure of 140/90 and proteinuria 1+ or greater in same visit OR use of this term by eare	OPTIMAL = There is no history of any of these conditions in a prior pregnancy.	OPTIMAL = No (All prior infinits weighed at least 5 1/2 pounds at birth.) Abstractors Note: Code N/A if index pregnancy is the first pregnancy.	OPTIMAL = No (All prior infants were born vaginally.) Abstrators Note: Code N/A if index pregnancy is the first pregnancy.	OPTIMAL = No (No prior infant died in utero, prior to birth.) Abstrators Note: Code N/A if index pregnancy is the first pregnancy.	OPTIMAL = No (No prior infant was born before 37 weeks of pregnancy.) Abstractors Note: Code N/A if index pregnancy is the first pregnancy.	<b>OPTIMAL = Yes</b> (There were at least 18 months and < 60 months between previous five birth and index pregnancy. SAB/TAB are not counted as viable pregnancies.)					

Rh sensitization     Press
15. intrauterine fetal demise
16. domestic violence (includes intimate partner)
17. other serious antepartum conditions /complications (current pregnancy)
Anemia
<ul> <li>diabetes diagnosed in pregnancy</li> </ul>
<ul> <li>major psychiatric history (formal diagnosis or treated with drugs/inpatient therapy)</li> </ul>
<ul> <li>multiple birth (twins or higher number of births anticipated)</li> </ul>
<ul> <li>placenta pracvia</li> </ul>
<ul> <li>precelampsia (diagnosed in antepartum period)</li> </ul>
<ul> <li>pyclonephritis</li> </ul>
Rh sensitization
<ul> <li>vaginal bleeding in 2<sup>nd</sup> or 3rd trimester, from cause other than placenta pracvia.</li> </ul>
18. prenatal care: initiation in first trimester and minimum of 5 visits
19. amniocentesis

20. nonstress test/contraction stress test/biophysical profile	0	N	OPTIMAL = No procedure
21. medication use	P	E	OPTIMAL = No medications (prescribed or OTC) are taken during pregnancy. EXCEPTION: Iron or vitamins can be taken, with or without prescription.
		Parturiti	00
22. period of time between first digital examination following rupture of membranes and birth	P	м	OPTIMAL = 24 hours
23. amniotic fluid	0	Е	OPTIMAL = Clear
24. induction/augmentation of labor	P	rs.	OPTIMAL = No Definition: In the absence of onset of spontaneous labor ANY pharmacologic (including herbals and homeopathic) intervention to induce or augment labor. Does not include nipple stimulation, membrane stripping. Abstractors Note: If index patient has an elective primary or repeat C- section, without labor, code this item as N/A.
25. anniotomy	P	Е	OPTIMAL = No
26. oral or injectable (IM or IV) medication during first or second stage of labor	P	E	OPTIMAL = None
27. epidural analgesia for labor and/or birth	P	Е	OPTIMAL = No Abstractors Note: If index patient has an elective primary or repeat C- section, without labor, code this item as N/A.

OPTIMAL = Yes	N	P/O	32. delivery occurred in the place originally intended at the onset of labor
OPTIMAL = Yes Definition: <u>Non-directed</u> pushing refers to a pattern of maternal bearing down in second stage labor characterized by <i>both</i> the following: a) initiated by the mother and b) neither directed or instructed (either verbally or nonverbally) by the provider. <u>Directed pushing refers</u> to prolonged valsalva, closed glottis pushing. <u>Abstrators Note: <u>May use</u> supportive language, "e.g., good job." <u>Abstrators Note: This may be "code \$"</u> in this setting.</u>	z		31. non-directed pushing
OPTIMAL = Yes	в	P	30. presence of a support person during labor (other than care provider)
<ul> <li>OPTIMAL = No recording of FHR abnormality that altered management of the labor process.</li> <li>INCLUDING: <ul> <li>abnormal baseline variability (absent, minimal or marked)</li> <li>bradycardia</li> <li>late or prolonged decelerations</li> <li>tachycardia</li> </ul> </li> <li>Abstractors Note: Fetal scalp sampling is not scored in the OI-US.</li> </ul>	E	0	29. fetal heart rate abnormalities
OPTIM AL = Yes Abstractors Note: If index patient has an elective primary or repeat C- section, without labor, code this item as N/A. Abstractors Note: If index patient has received an "admission strip", code this item asoptimal. (An admission strip is considered the equivalent to the intermittent EFM during labor.)	ra	P	28. fetoscope, Doppler or intermittent electronic monitoring used during labor, rather than continuous electronic fetal monitoring

0. medication (other than oxytocin or scal anesthetic for perincal repair) uring the third stage of labor	9. 3rd or 4th degree extension of O ther an episiotemy or a 1" or 2nd egree laceration	8. 1st or 2nd degree laceration of O crineum or perineal tissue <i>requiring</i> <i>tures</i> (including sulcus and cervical icerations)	7. episiotomy P	6. Cesarean section P/O	5. instrumental (vaginal) delivery P/O	4. presentation at birth O	
E		R	ra T	Е	E	Е	
OPTIMAL = No	OPTIMAL = No Abstrators Note:: It is assumed that the lacerations and extensions will be sutured. Abstrators Note:: The point deducted for this 3rd or 4th degree extension is <i>a addition</i> to the point or points lost for an intentional episiotomy (if applicable) and an unintended 1st or 2nd degree laceration (if applicable).	OPTIMAL = No Abstrators Note:: IF the woman also experiences a 3rd or 4th degree extension, this item is still also coded as not optimal (one point deduction).	OPTIMAL = No Abstractors Note: If index patient has a C-section, code this item as N/A. Abstractors Note: It is assumed that episiotemics will be sutured.	<b>OPTIMAL = No</b> <b>Abstrators Note:</b> If index patient has a vaginal delivery (either spontaneous or instrumental), code this item as N/A.	OPTIMAL = No Abstractors Note: If index patient has a C-section, code this item as $N/A$ .	OPTIMAL = Cephalic	Definition #2: (if degree of head elevation is noted). Any position other than flat on back, or back lying (including lithotomy) with less than 45 degree of head elevation. Abstractors Note: This may be "code 8" in this setting.

L ondition	Neonatal co		- annument ny annum
			<ul> <li>shoulder dystocia</li> </ul>
			<ul> <li>placental abruption</li> </ul>
			<ul> <li>pre-eclampsia present during intrapartum period</li> </ul>
in the maternal score (see related items)			eclampsia
antibiotic use for prophylactic treatment			<ul> <li>cord prolapse</li> </ul>
Tool Users Note: GBS infection is not			<ul> <li>chorioamnionitis</li> </ul>
OPTIMAL = No evidence that any the	Е	0	45. other serious intrapartum complications
OPTIMAL = No	Е	0	44. blood transfusion
Tool Users Note: The OI-US does not i the third stage of labor (AMTSL) as ap item is a complex variable (3 independe strategy is not widely used in the U.S. T international adaptations of this measure	5		
Vaginal Deliveries: OPTIMAL = prov did not occur; or estimation of blood lo C-section: OPTIMAL = provider's do occur, or estimation of blood loss < 100	E	0	43. postpartum hemorrhage
Abstractors Note: If delivery is by C-s			
OPTIMAL = No	Е	0	<ol> <li>placental retention (≥ 30 min)</li> </ol>
Definition: Placement of the unwrapped contract with maternal skin as immediate following birth; both infant and mother conservation cover/blanket. Abstractors Note: This may be "code 8	(unless code 8)		
OPTIMAL = Yes	m	P	41. skin-to-skin contact

0 0/d 0 0
0 E 0 E P/O E E E

OPTIMAL = No Abstractors Note: Recorded through time of mother's discharge from the birth site or the transfer setting.	н	0	56. maternal mortality
OPTIMAL = No Exception: Analgesic medications at over-the counter dosages (OTC), iron and vitamins, oral contraceptives, RhoGamO, rubella vaccine Abstractor Note: Some OTC medications may be written as prescriptions, for insurance purposes. These medications are still "exceptions," as noted above.	rī.	o	55. prescription medications for conditions newly identified in IP or PP period
			mastitis
			<ul> <li>local infection of sutures</li> </ul>
			hematoma
			<ul> <li>endometritis</li> </ul>
			Cystitis
<b>OPTIMAL = No evidence</b> that any of these conditions are present.	E	0	54. fever (100.4 degrees F or higher) while mother remains in the birth setting, OR provider diagnosis of infectious process or major complication
h facility or from provider's care (up to 72 hours)	harge from birt	nother prior to disc	Condition of the r
<b>OPTIM AL</b> = No (time period birth: up to 72 hours of age).	Е	0	53. perinatal death:
OPTIMAL = Yes at time of mother's discharge from birth facility or up to 72 hours postpartum. Abstractors Note: Any evidence of breastfeeding is acceptable; does not have to be exclusive.	E	0	52. breastfeeding

Ар	pendix	В
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## Midwife Labor Management Guidelines at Study Site

•	•			•		•			•		•		•			•		•		•				
> 35 weeks gestation	IUPC	risk ladjurs	48 nours without other	SRUM without labor for <	NSVD	Anesthesia requests for		presence of reassuring	Therapeutic rest in	treatment	UTI, diagnosis and	according to protocols	GBS prophylaxis	rate pattern	reassuring fetal heart	Meconium with	monitoring	Internal and external fetal	controlled	Gestational diabetes, diet			Management	CNM
		•		•		•	•		•	•		•		•		•	•		•	•				
		Amnioinfusion	in labor	≧42 weeks gestation, not	finding	AP testing with abnormal	≥48 hours ROM	hours)	Prolonged 2 <sup>nd</sup> stage (> 2	Arrest of labor	in labor	ROM with meconium, not	1 30/90 with normal labs	Mild pre-eclampsia of	of therapeutic rest	Second consecutive night	Labor induction	100.5	Temperature in labor ≥	Pitocin augmentation	Consultation	With MD	Management	CNM
								•	•	•		•		•		•				•				_
							dystocia	Suspected shoulder	Failure to descend	Mal-presentation	labor	Significant bleeding in	pattern	Non-reassuring FHR	abnormal labs	PIH not on MgSO, with	medication	requiring change in	medical condition	Exacerbation of		Exam	With MD Note and/or	NM/MD Collaboration
•	•	•	•	•	•	•	•		•		•		•	•	•	•	•	•	•	•				
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## Appendix C

## Study Facility Hydrotherapy Protocol

Sutter Davis Hospital Birthing Center Policy and Procedure Manual Page 1 of 6

## Birthing Tub, Use of Hydrotherapy for Labor

## Policy:

It is the policy of Sutter Davis Hospital to support all safe pain management options for the labor & delivery process. Labor and delivery in water is available as a choice for women at the discretion of the attending physician or midwife. Hydrotherapy may be used to increase relaxation and decrease pain during labor when requested by patients and upon approval of their healthcare provider.

#### Purpose:

The purpose of this policy is to provide nursing actions for use of the birthing tub and criteria for patients and conditions appropriate for its use.

#### Supportive Data:

Hydrotherapy can provide the following:

- A. Enhance the normal physiologic process of birth.
- B. Assist in the restoration of control of the birth process to the mother.
- C. Enhance the mother's relaxation and minimize the need for medical intervention, recognizing two major concepts:
  - 1. Her relative weightlessness in water provides comfort and relief;
  - 2. With relaxation less Adrenalin is produced while endorphin and Oxytocin production are increased.
- D. Provide a more gentle transition to the world for the newborn.

## **Objectives:**

- A. Provide laboring women with a safe alternative to delivery in a bed.
- B. Assist in the perceived control of the birth process by the mother.
- C. Enhance the normal physiologic process of birth.
  - 1. Relative weightlessness in water facilitates relaxation and comfort.
    - 2. With increased relaxation less adrenaline is produced while endorphin and oxytocin production is increased.
    - 3. Warm water immersion may increase oxygenation of the uterus, placenta and fetus through increased maternal relaxation, maintenance of maternal normotension, and slightly increased maternal pulse.
    - 4. In some studies of hydrotherapy the length of labor, perineal trauma, operative delivery rates, and maternal requests for pain medication are reduced.

## Birthing Tub, Use of Hydrotherapy for Labor

#### Procedure:

- A. Determine eligibility:
  - 1. Women are eligible to use hydrotherapy during labor and delivery with attending physician or midwife approval and consideration of the following criteria:
    - a. The woman requests hydrotherapy.
    - b. Consent for hydrotherapy during labor and/or delivery is signed.
    - c. Patient agrees to follow the instructions of the provider, including exiting the tub if asked to do so.
    - d. Maternal vital signs are within normal limits as determined by provider.
    - e. FHR is being adequately monitored externally (either intermittently with a Doppler or continuously with a telemetry unit) per condition-specific protocols.
    - f. Patient does not object to maternal and fetal monitoring as outlined in section E.
    - g. Greater than or equal to 36 0/7 weeks of gestation.
    - h. Active phase labor: spontaneous, induced or augmented.
    - The patient has not received narcotic medication less than 1 hour prior to tub entry.
    - j. The spa is cleaned prior to use according to standard written procedures.
    - k. A positive GBS culture does not preclude hydrotherapy for labor or birth if prophylactic antibiotics are administered per protocol.
    - Women desiring intrapartum hydrotherapy should be encouraged to have HIV, hepatitis B and hepatitis C testing during pregnancy. If negative results are not documented in antepartum notes, the individual physician or midwife may assess the patient's risk factors and make patientspecific decisions about tub entry for labor and/or delivery.
  - 2. <u>Conditions In Which Labor But Not Birth In Water Are Permitted Include:</u>
    - a. Multiple gestations or breech presentation when a vaginal birth is anticipated and FHT tracing is performed per condition specific protocols.
    - b. Meconium staining.
    - c. Anticipated shoulder dystocia.
    - d. Documented maternal infection with hepatitis B, hepatitis C, HIV or other blood borne pathogens as determined by the attending physician or midwife.
  - 3. <u>Contraindications To Tub Entry Include</u>:

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## Birthing Tub, Use of Hydrotherapy for Labor

- a. Medical or obstetric conditions that require continuous monitoring of FHR *unless* a telemetry monitoring unit is available and providing adequate continuous FHT tracing.
- b. Fetal scalp electrode use.
- c. The use of an IUPC for uterine activity monitoring or amnioinfusion.
- d. Magnesium Sulfate administration.
- e. Intrathecal or epidural anesthesia administration.
- f. No one with open skin lesions may enter the tub.
- B. Operating the Birthing Tub
  - 1. Keep electrical equipment out of and away from the immediate vicinity of the tub.
    - a. May use IV pump in battery mode only.
    - b. May use electronic fetal monitor on telemetry mode only.
  - 2. Be sure disposable liner is in place.
  - 3. Connect hose to the "fill" spout on wall and place free end of hose in tub.
    - a. Use metal brace to anchor hose to inside edge of tub.
    - b. Approximate fill time 20-30 minutes.
    - c. Adjust hot and cold output to achieve desirable temperature.
  - 4. When tub is at least half full, plug in cord to heating element.
    - a. Be sure heating element is in place beneath tub.
    - b. Heating element is set to not exceed safe temperature limits.
    - c. Heater may remain on indefinitely as long as the tub is filled.
      - i. Do not run heater on an empty tub as this may damage the element.
    - d. When patient is completely finished with the birthing tub, unplug heater.
  - 5. Patient may use the shower head over the birthing tub prior to using the tub:
    - a. Position tub as close to wall as possible prior to turning on shower.
    - b. Have patient stand or sit in the tub while using the shower.
    - c. Tub will become half-filled in approximately one hour of showering.
    - d. Water pump can be used to drain tub if it becomes too full with use of shower.
    - e. Heater may be plugged in when tub is filled to maintain warmth of water until mother can use tub.
- C. Precautions during use of tub:
  - 1. Observe universal precautions:

Staff and MD/AHP will follow procedures for universal precautions for all deliveries. These include face shields, waterproof gowns, if indicated, and gloves. In addition, shoulder length gloves will be available for staff to use during water labor and deliveries.

## Birthing Tub, Use of Hydrotherapy for Labor

2. No one (including support person) with open lesions can enter the water.

#### D. Regulate water temperature:

- 1. Temperature may be regulated to maternal comfort in labor, but may not exceed 38 degrees C to prevent maternal and fetal tachycardia.
- 2. At the time of delivery under water, the temperature should be regulated to 37-38 degrees C, or 90-101 degrees Fahrenheit, to prevent premature stimulus to breathe from cooler temperatures and resultant risk of water inhalation by the newborn.
  - a. Document initial temperature setting of heater and when any changes to settings occur.
- 3. If mother experiences sudden dizziness, rise or drop in blood pressure and/or rise in pulse or respirations, assist her in getting out of the tub immediately and into bed.
- E. Assess the following parameters during water labor and/or birth and document in appropriate areas of the patient record:
  - 1. Status of membranes and color of amniotic fluid.
  - 2. Cervical dilation and effacement.
  - 3. Position and presentation of the fetus(es).
  - 4. Progress of labor, including contraction pattern. If contractions decrease in frequency, length and intensity, the patient should be instructed to exit the tub to walk. The patient may reenter the tub once an active contraction pattern is reestablished either spontaneously, with nipple stimulation or with the administration of oxytocin.
  - 5. Maternal vital signs:
    - Blood pressure and pulse should be monitored per protocol for Care Of The Laboring Patient unless otherwise ordered by the patient's provider.
    - b. Maternal temperature: every hour while the patient remains in tub.
    - c. Dizziness, hypotension, hypertension and tachycardia require exiting the tub, at least temporarily.
  - 6. Fluid intake:
    - a. Encourage maternal intake of PO fluids as warm water immersion facilitates diuresis and may cause dehydration.
    - b. Water immersion does not preclude IV hydration.
  - Fetal well being:
    - a. FHR will be auscultated per protocol for **Care Of The Laboring Patient** or more frequently if ordered by the patient's provider or

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## Birthing Tub, Use of Hydrotherapy for Labor

warranted by patient's condition. Telemetry units may be used to continuously monitor FHR inside the tub if needed.

- F. Observe the following precautions during second stage of labor and delivery:
  - 1. Since rapid delivery may occur after tub entry, the MD/CNM and RN should be appropriately prepared to ensure the safety of the mother and baby. Have all infant resuscitation equipment set up and ready for use prior to delivery.
  - 2. See prior eligibility requirements.
  - 3. The mother may adopt any desired position that is comfortable for her provided the MD/CNM can safely facilitate the birth and the infant emerges entirely submerged. This will help to prevent premature stimulation of the first breath and water inhalation which may occur if the vertex is partially exposed to cooler room air during crowning and delivery.
  - 4. Manipulation of the vertex is not usually required to achieve delivery.
  - 5. If meconium is first visualized in the second stage RT should be paged immediately. Meconium first presenting prior to or with the delivery of the vertex necessitates delivery out of the water so that suction of the mouth, oropharynx and hypopharynx of the newborn can occur. If delivery is imminent when meconium is observed, and the mother is unable to exit the tub, she should be asked to stand (with assistance) so that the newborn can be suctioned above the water level.
  - 6. When a newborn is delivered underwater, the head should be brought to the water's surface immediately. The newborn's supported body should remain underwater to maintain its warmth. The infant may rest on the mother's chest while initial assessments are performed.
  - 7. Breastfeeding should be immediately encouraged to assist with uterine contraction and placental expulsion.
- G. Care of the newborn:
  - 1. Infant may rest on mother's chest while oropharynx and nares are suctioned if necessary and APGAR scores are assigned.
  - 2. Maintain thermoregulation of infant.
  - 3. If any signs/symptoms of respiratory distress or tachycardia are present, infant should be removed from the tub and taken to radiant warmer.
  - 4. Suction when indicated.
  - 5. Encourage breastfeeding immediately (see F 7 above).
- H. Delivery Of The Placenta:
  - 1. Delivery of the placenta out of water should be attempted:

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### Birthing Tub, Use of Hydrotherapy for Labor

- a. Umbilical cord is clamped and cut.
- b. Baby is handed to a family member if vigorous, or to the nurse if close assessment or treatment is indicated.
- c. Mother is assisted out of the tub, either to bed or to a squatting position over towels on the floor.
- d. Mother is dried and wrapped in warm blankets.
- 2. Delivery of the placenta in the tub:
  - a. The primary goal is delivery of the placenta out of the tub to minimize the theoretical but undocumented risk of water embolism. However, at times delivery of the placenta in the tub is unavoidable. If this occurs, the following procedure will be followed:
    - i. Clamp and cut the umbilical cord or facilitate physiologic placental delivery.
    - ii. Have the mother stand or squat in the tub to facilitate the placental delivery if necessary.
    - iii. Estimate blood loss according to darkening of the water.
  - b. IM oxytocin may be administered while the mother is in the tub for PPH prophylaxis. If PPH is noted, the mother must be helped to exit the tub to facilitate emergency measures.
- I. Mother should be taken to the bed for perineal/ vaginal examination and repair.
- J. Cleaning of the Spa: Refer to Birthing Tub, Draining and Cleaning policy.

Originating	
Department:	Birthing Center
Distribution:	Birthing Center Policy
	and Procedure Manual

Origination Date: 3/98 Review Dates: 11/04 Revision Dates: 1/02, 9/04, 5/05 Next Review Due: 5/08

APPROVED BY:			
Committee	Date	Committee	Date
Pharmacy &		Quality	5/05
Therapeutics Committee			
Department Manager	1/02	MEC	5/05
Obstetrics	1/30/02	MAC	5/05

## Appendix D

## Study Facility Hydrotherapy Consent Form

Sutter Davis Hospital Birthing Center Policy and Procedure Manual Page 1 of 2

## Birthing Tub, Guidelines and Consent

#### **GUIDELINES FOR PATIENTS DESIRING WATER LABOR AND BIRTH:**

- The birthing tubs may be used for labor and/or birth at the patient's request contingent on tub availability and approval from their midwife or physician.
- The patient must be at least 36 0/7 weeks pregnant.
- Patients or labor support people with open skin lesions are not allowed in the tub.
- The patient must agree to follow instructions from the nurse, midwife, or physician, including getting out of the tub if instructed to do so.
- Patients may not enter the tub within one hour of narcotic medication administration. Restrictions on tub entry may also apply after the use of other sedating medications per midwife or physician discretion.
- Some medical conditions allow for labor in the tub but preclude waterbirth. These conditions include: anticipated birth complications, infections with blood borne pathogens, breech presentations, and twins. Water labor but not waterbirth is permitted with meconium staining of the amniotic fluid only if an amnioinfusion is not required.
- Other conditions preclude entering the tub during any phase of labor. These conditions include high blood pressure requiring magnesium sulfate administration, and epidural or intrathecal anesthesia.
- Maternal vital signs and fetal heart rate monitoring will be continued in the tub per standard protocols. If adequate monitoring is not possible in the tub, the patient must exit the tub to facilitate monitoring and ensure safety.
- Adequate fetal heart rate monitoring must be obtainable externally (either intermittently with a waterproof doppler or continuously with a waterproof telemetry unit as deemed appropriate by the midwife or physician according to patient's condition). If internal fetal monitoring is required (with a fetal scalp electrode) the patient must exit the tub.
- Patients must wait for active labor before entering the tub. If labor fails to progress after tub entry, the patient must get out of the tub, at least temporarily, until active labor is reestablished. If internal monitoring of labor contractions is required (with an intrauterine pressure catheter) the patient may not reenter the tub.
- The tub is cleaned and lined prior to use according to written standard procedures.

## CONTRAINDICATIONS FOR USE OF WATER LABOR AND BIRTH:

### Contraindications To Tub Entry Include:

1. Medical or obstetric conditions that require continuous monitoring of FHR *unless* a telemetry monitoring unit is available and providing adequate continuous FHR tracing.

- 2. Fetal scalp electrode use.
- 3. The use of an IUPC for uterine activity monitoring or amnioinfusion.
- 4. Magnesium Sulfate administration.
- 5. Intrathecal or epidural anesthesia administration.
- 6. No one with open skin lesions may enter the tub.

#### Conditions In Which Labor But Not Birth In Water Are Permitted Include:

1. Multiple gestations or breech presentation when a vaginal birth is anticipated and FHR tracing is performed per condition specific protocols.

- 2. Meconium staining.
- 3. Anticipated shoulder dystocia.
- 4. Documented maternal infection with hepatitis B, hepatitis C, HIV or other blood borne pathogens as determined by the attending physician or midwife.

Page 2 of 2

\$ <i>Sutter Davis</i> <i>Hospital</i> A Sutter Health Affiliate	Birthing Tub, Guidelines and Consent
2000 Sutter Place Davis, CA 95616 (530) 756-6440	<u>Consent for Water Labor and Birth:</u> <u>Patient:</u>

1. I have voluntarily chosen to use the tub for water immersion in labor. I have made this decision after being informed that in the course of childbearing, which is a normal function, medical problems may unexpectedly arise which may present a hazard to myself and/or my unborn child(ren).

2. As my labor progresses, should potential problems arise, I am aware of the necessity for and hereby consent to immediately follow the instructions of the nurse, midwife, or physician regarding delivery in or out of the tub, including getting out of the tub if directed. If my labor progresses normally, the monitoring of myself and my unborn child(ren) remains reassuring, and underwater delivery continues to be my desire and is deemed safe by my physician or midwife, I voluntarily choose to deliver my child in the tub.

3. I have received the "Birthing Tub Guidelines." I have read these guidelines and this consent form and understand both.

Date	Time	Patient's Signature
Date	Time	Witness

## Appendix E

## Study Facility Tub Cleaning Protocol

Sutter Davis Hospital Birthing Center Policy and Procedure Manual Page 1 of 2

## Birthing Tub, Draining and Cleaning

## Policy:

The Birthing Tub utilized for water labor and delivery will be drained and cleaned after each patient use.

#### Procedure:

#### Equipment:

Aqua Doula Jacuzzi pump and drain hose (stored in Dirty Utility Room) Hospital Disinfectant Disposable liner

## A. Make sure heater is <u>unplugged</u> before draining tub.

- B. Clean outside of "fill hose" with hospital disinfectant.
- C. Detach "fill hose" from water inlet and rinse inside of hose thoroughly with hospital disinfectant.
- D. Drain "fill hose" of any excess water, coil, and reattach to water inlet on wall.
- E. Draining Tub:
  - 1. Be sure drain hose that is attached to drain pump is securely placed in Drain (lower box on wall).
  - 2. Submerge the pump in the tub (after being sure the drain hose is securely placed in drain)
  - 4. Plug pump plug into safety switch plug and safety switch plug into the wall outlet. Draining of tub will automatically and immediately begin.
  - 5. Pump will automatically shut off when 2 inches or less of water is left in tub.
  - 6. Remove pump plug from safety switch plug, and plug pump directly into outlet. At this point you must remain in the room to oversee the draining of the last 2 inches of water from the tub.
  - 7. Once water is drained from tub, unplug pump and remove the pump from the tub. Place unit on a towel on the floor.
  - 8. Remove the disposable liner being careful not to spill excess water on the floor.
  - 9. Place used liner in a red bag and dispose of per policy.

## Birthing Tub, Draining and Cleaning

- 10. Place 4 quarts of HB Quat 25 into the tub. Add a few inches of water.
- 11. Disinfect all surfaces by wetting them with the cleaning solution and allowing them to remain wet for 5-10 minutes.
- 12. Follow steps 1-4 to drain the tub of the water with the cleaning solution.
- 13. Remove the pump and place it on a towel outside the tub.
- 14. Dry the interior of the tub thoroughly.
- 15. Wipe all surfaces of tub with Disinfectant and allow to air dry.
- 16. Make sure blue non-disposable liner is pulled down in place prior to applying the disposable liner.
- 17. Place a clean disposable liner on the tub.
- 18. Place black circular cover in spa to help keep spa dust free.
- F. Storage of drain pump:
  - 1. Dry the water drainage pump and "milk" hose of any excess water into the drain before being coiled up for storage.
  - 2. Place pump and hose in white plastic storage box.
  - 3. Return pump and hose to Dirty Utility Room.

Originating			
Department:	Birthing Center	<b>Origination Date:</b>	5/97
Distribution:	Birthing Center Policy and	<b>Review Dates:</b>	5/05
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	Environmental Services		

APPROVED BY:			
Committee	Date	Committee	Date
Pharmacy &	1/02	Quality	5/05
Therapeutics Committee			
OB Nurse Manager	5/05	MEC	5/05
Environmental Services	8/04	MAC	5/05

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Date