

THE EFFECT OF INDUCTION OF LABOR ON THE
ODDS OF PRIMARY CESAREAN DELIVERY

A DISSERTATION
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BY
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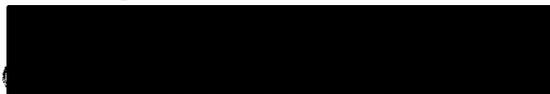
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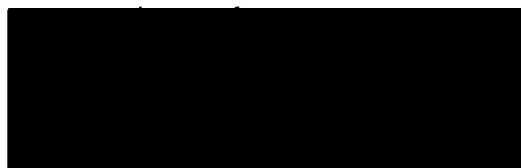
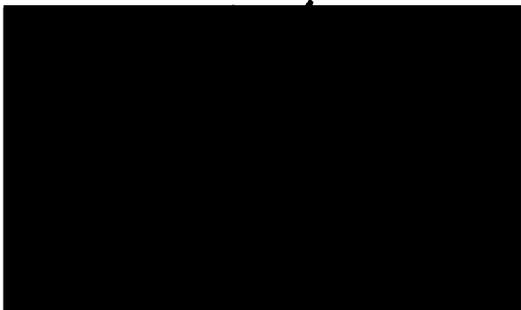
To the Dean of Graduate School:

I am submitting herewith a Dissertation written by Susan McBride, entitled "The Effect of Induction of Labor on the Odds of Primary Cesarean Delivery." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Nursing.



Patti Hamilton, PhD, RN, Major Professor

We have read this Dissertation and recommend its acceptance:



Dean of Graduate School

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DEDICATION

This dissertation is dedicated to the memory of my father and my loving mother, for instilling in me the values of hard work and perseverance. The love, concern, and pride in my work were always a major source of strength and encouragement to me. Their unwavering belief in my ability gave me the confidence to achieve. I am humbled by my doctoral experience, because the real wisdom and ability was passed on from my two wonderful parents.

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Finally, I acknowledge and thank my dear friend, colleague, and coach, Annette Anderson, for her loving support throughout my doctoral studies. Her coaching and mentoring throughout the years provided wisdom to help me see the path to a balanced life, creating the possibility of having it all.

ABSTRACT

SUSAN MCBRIDE, M.S., R.N.

THE EFFECT OF INDUCTION OF LABOR ON THE ODDS OF PRIMARY CESAREAN DELIVERY

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The induction rate in the United States has more than doubled since 1989 to a high of 20.6% (Martin et al., 2003). The purpose of this study was to examine the effect of labor induction on the odds of primary cesarean delivery controlling for factors that confound or modify the effect with a database that provides size and scope.

The study design was a retrospective, explanatory study design, using secondary data analysis with a database comprised of hospital discharge data, birth certificate data, AHA Annual Hospital Survey data, and neonatal intensive care survey data ($N= 160,533$ births). Data from cases with total agreement between the hospital discharge data and the birth certificate data on the two key variables of interest, labor induction and primary cesarean delivery, were used for the analysis. Secondary data analysis of administrative data provided an advantage of having a large volume of demographically diverse cases, thus addressing issues of generalizability and sample size limitations. Multivariable logistic regression methods were deployed as described by Hosmer and Lemeshow (2000) to control for confounding and effect modifying variables that influence the relationship of labor induction on the odds of primary cesarean delivery.

Study findings indicated that the effect of labor induction was confounded by maternal age and teaching status. Additional findings included significant ($p \leq 0.01$) effect modification with six covariates: baby weight, parity, dystocia, medical indication for induction, gestation, and race and ethnicity. The findings indicate that effect modifying covariates interact with the effect of labor induction on the odds of primary cesarean delivery. When labor induction was examined controlling for effect modifiers and confounders, the odds ratio was 1.165 (95% CI: 0.948; 1.430; $p > .05$), indicating that labor induction no longer significantly influenced the effect of labor induction on the odds of primary cesarean delivery, independent of other client and system characteristics. An important conclusion was that labor induction increases the odds of primary cesarean delivery under certain conditions dependent on the level of the effect modifying client characteristics.

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CHAPTER I

INTRODUCTION

This study examined the effect of labor induction on the odds of primary cesarean delivery controlling for variables that confound or modify the effect. It is important to understand the impact of labor induction on the quality and safety of obstetrical delivery, particularly given the reported rise in induction rates. The rate of labor induction in the United States has increased from 9% in 1989 to a high of 19.9% in 2000 across gestational ages including preterm deliveries (less than 37 weeks gestation) (Martin, Hamilton, Ventura, Menacker, & Park, 2002). The induction rate in the national vital statistics report, *Births: Final data for 2002* issued on December 17, 2003 indicated the induction rate had more than doubled since 1989 to a high of 20.6% (Martin et al., 2003).

Recent studies have indicated that high cesarean rates and, conversely, low cesarean rates reflect poor quality (Gould et al., 2004). Yet, the scientific evidence is not clear on how the increasing rates of labor induction across gestational ages may be impacting the cesarean rates, with some studies indicating there is an association between cesarean and induction of labor (Alexander, McIntire, & Levino, 2000, 2001), while others have refuted the association (Sanchez-Ramos, Olivier, Delke, & Kaunitz, 2003). It is important to understand how induction of labor affects the odds of a cesarean delivery to fully understand what constitutes a safe effective delivery.

Quality of care and patient safety are significant issues for the healthcare industry according to two recent reports released by the Institute of Medicine (IOM): *To Err is Human*

(2000) and *Crossing the Quality Chasm* (2001). These two IOM reports call for immediate action to fundamentally change the United States (U.S.) healthcare delivery system in order to address the patient safety and quality concerns outlined in these reports. Factors outlined in the reports impacting patient safety and quality issues primarily deal with the complexities inherent in the healthcare delivery system (Kohn, Coorigan, & Donaldson, 2000). Labor management and the multifactorial relationships that effect a safe delivery for the mother and neonate are important to understand, particularly given the variation in practice patterns for cesarean delivery and the lack of clarity on how this variation may impact quality (Gould et al., 2004).

The nursing profession can contribute significantly to improving the U.S. healthcare delivery system through research examining quality, patient safety, and improving clinical outcomes. This study examined an important domain of patient safety and quality measurement addressing obstetrical outcome research, with a primary focus on the mode of delivery as the key outcome variable. Obstetrical outcomes are complex with multiple factors, including client and system characteristics that impact the measurement process. Additionally, there is considerable debate on what constitutes a safe, effective mode of delivery (Volavka, 2003). It is unclear how the increasing induction rates may be impacting the quality and safety of obstetrical delivery for both the mother and the baby. This study focused on the obstetrical delivery outcome of the mother, examining the effect of labor induction on the odds of primary cesarean delivery.

Problem and Purpose of Study

Cesarean delivery rates have been an issue in healthcare quality debates with payers, providers, and consumers for some time. More recently, the debate has focused on patient safety, with new measures from the Agency for Healthcare Research and Quality (AHRQ) creating patient safety indicators to examine the safety of the obstetrical delivery for mother and baby. AHRQ has released the following measures to examine patient safety in obstetrical delivery:

(a) cases of birth trauma, injury to neonate, per 1,000 liveborn births; (b) cases of obstetric trauma (4th degree lacerations, other obstetric lacerations) per 1,000 instrument-assisted vaginal deliveries; (c) cases of obstetric trauma (4th degree lacerations, other obstetric lacerations) per 1,000 vaginal deliveries without instrument assistance; (d) cases of obstetric trauma (4th degree lacerations, other obstetric lacerations) per 1,000 Cesarean deliveries; (e) cases of obstetric trauma (3rd and 4th degree lacerations, other obstetric lacerations) per 1,000 instrument-assisted vaginal deliveries; (f) cases of obstetric trauma (3rd and 4th degree lacerations, other obstetric lacerations) per 1,000 vaginal deliveries without instrument assistance; (g) cases of obstetric trauma (3rd and 4th degree lacerations, other obstetric lacerations) per 1,000 Cesarean deliveries (AHRQ, 2003, pp. 21-22).

Historically, the primary concern was the escalating cesarean delivery rates in the United States (U.S.) with disagreement on how to resolve key issues in the labor management process. Two areas of concern that have had considerable attention are elective induction of labor and whether or not women should be offered a trial of labor after a previous cesarean delivery. More recently the American College of Obstetrics & Gynecology ([ACOG], 2003) issued an opinion statement addressing the controversy over whether a woman should have the right to elect a cesarean delivery. *Surgery and Patient Choices* (ACOG, 2003) issued the landmark opinion statement regarding a woman's right to choose a cesarean delivery. Central to the issue is the patient's autonomy and the concept of informed consent. Women in the U.S., as well as healthcare providers and payers, all agree that they want safe, cost-effective, and appropriate care, but disagree on what constitutes appropriate care as well as the best way to deliver care (Volavka, 2003).

According to the Center for Disease Control and Prevention's (CDC) most recent report on 2002 births, the overall U.S. cesarean delivery rate has reached an all time high of 26.1%, an

increase of 7% over 2001 (Martin et al., 2003). The report on 2000 births (Martin et al., 2002) indicated the cesarean delivery rate in 2000 increased for the fourth consecutive year to nearly 23% of the total births, the highest rate reported since 1989. An additional report specifically examining cesarean delivery trends was issued by the CDC: *Trends in Cesarean Birth and Vaginal Birth After Previous Cesarean, 1991-1999* (Menacker & Curtin, 2001). The report attributed the increase in cesarean delivery rates to a decrease in vaginal birth after cesarean (VBAC) deliveries, and perhaps more importantly, a 4% increase in primary cesarean delivery (Menacker & Curtin, 2001). This follows declines in the overall cesarean rate between 1989 and 1996.

The primary cesarean rates are perhaps more important because there is significant debate on whether or not VBAC delivery is a safe mode of delivery, with no conclusion to date on the debate. If some proportion of the initial cesareans (primary cesarean) could be prevented, then the need for a trial of labor for women with vaginal birth after cesarean is also decreased. The primary cesarean delivery rate has increased from a 1996-1997 low of 14.6% to 18% for 2002, while the VBAC rate has plummeted from 55% in 1996 to 12.7% in 2002 (Hamilton, Martin & Sutton, 2003). Figure 1 depicts the trend lines for 1989 through 2002 for total cesarean delivery, primary cesarean delivery, and vaginal birth after cesarean delivery, reflecting the steep drop in VBAC rates and the steady increase in total cesarean delivery and primary cesarean delivery rates.

The CDC is by no means the lone institutional voice on the issue of rising cesarean delivery rates. The ACOG and the World Health Organization (WHO) have both established a goal for cesarean delivery rates at $\leq 15\%$. Berwick (1998), of the Institute for Healthcare Improvement (IHI), believes that by drawing on the best available scientific evidence as well as the experiences of countries such as Ireland and the Netherlands where cesarean delivery rates are

less than one-third of the U.S. rate, the ACOG and WHO goals can be safely achieved. *Healthy People 2010* (Department of Health & Human Services, 2000) also has established a goal for cesarean delivery rates at 15.5%. Berwick (1998) points out that, by these standards, over 400,000 cesarean deliveries in the U.S. each year may be medically unnecessary, raising the question as to what can be done to reverse the current trends. It is important to examine these issues in light of the complexities of the labor management process to develop interventions to address the issues. It is unclear at this time how the recent ACOG (2003) opinion statement on elective cesarean delivery may impact these historical recommendations regarding cesarean delivery rates.

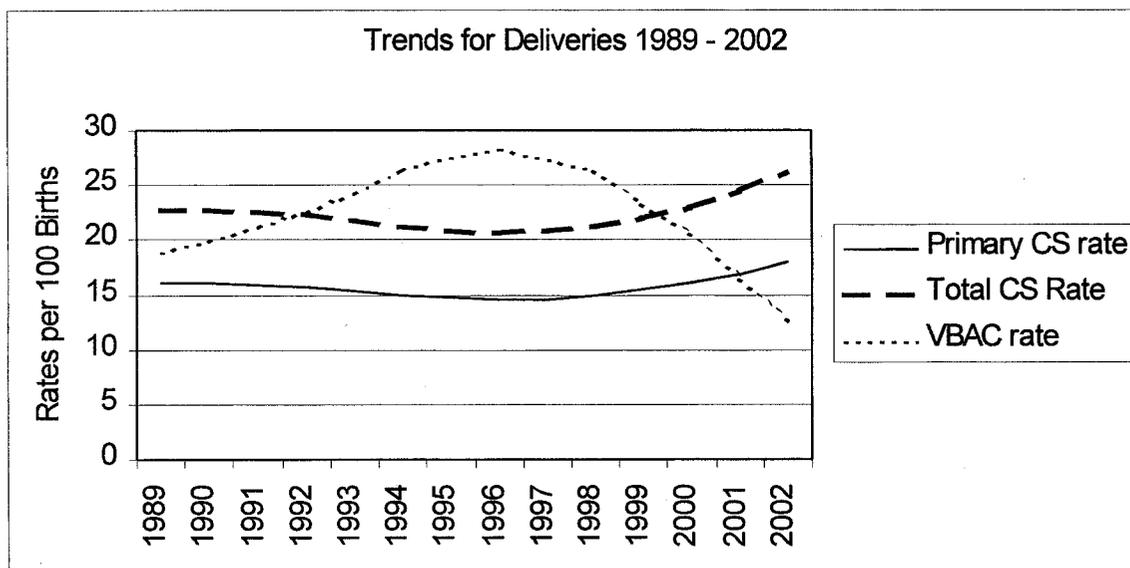


Figure 1. Mode of delivery trends 1989-2002.

Note. Data extrapolated from the CDC's National vital statistics reports 49 (13); 51(2); 51(11)

There is evidence that a key factor influencing the rise in primary cesarean delivery rates may be the increase in artificial induction of labor for medical and non-medical purposes (Dublin, Lydon-Rochelle, Kaplan, Watts, & Critchlow, 2000; Seyb, Berka, Socol, & Dooley, 1999;).

When compared with spontaneous labor, induction of labor is typically more costly, requires more resources, and may negatively impact clinical outcomes (Maslow & Sweeney, 2000). The rate of labor induction in the United States has increased from 9% in 1989 to a high of 19.9% in 2000 across gestational ages (Martin et al., 2002). The National Center for Health Statistics (Martin et al., 2002) examined births from 1989, when the induction variable first became available in birth certificate data, to 2000. Figure 2 presents the upward trend from 1989 to 2000 for induction for deliveries across gestational ages. The graph demonstrates induction rate increases across all gestational ages, from less than 32 weeks gestation to 42 weeks gestation and greater. Note that the National Vital Statistics Center opted to plot rates with a log scale. The increase would reflect an even greater visual increase with rates per 1,000 plotted without the log scale.

Research has indicated that successful induction of labor is related to cervical dilation and parity (Alexander et al., 2001). In other words, the earlier the induction of labor, the more likely the woman's cervix will be unready for labor, resulting in a failure to progress in labor and a higher potential for cesarean delivery. Therefore, it is appropriate to explore the effect of labor induction on primary cesarean delivery, particularly for women 40 weeks gestation and less, and to do so with a database with adequate sample size to eliminate sample size limitations. It is important to more fully understand the relationship between induction of labor and cesarean delivery in order to better understand and more efficiently address the rising cesarean delivery rates. In addition, the new Agency for Healthcare Research and Quality Patient Safety Indicators for obstetrics may be helpful in discerning if induction of labor is unsafe in other ways, such as more frequent birth trauma to the infant or complications for the mother.

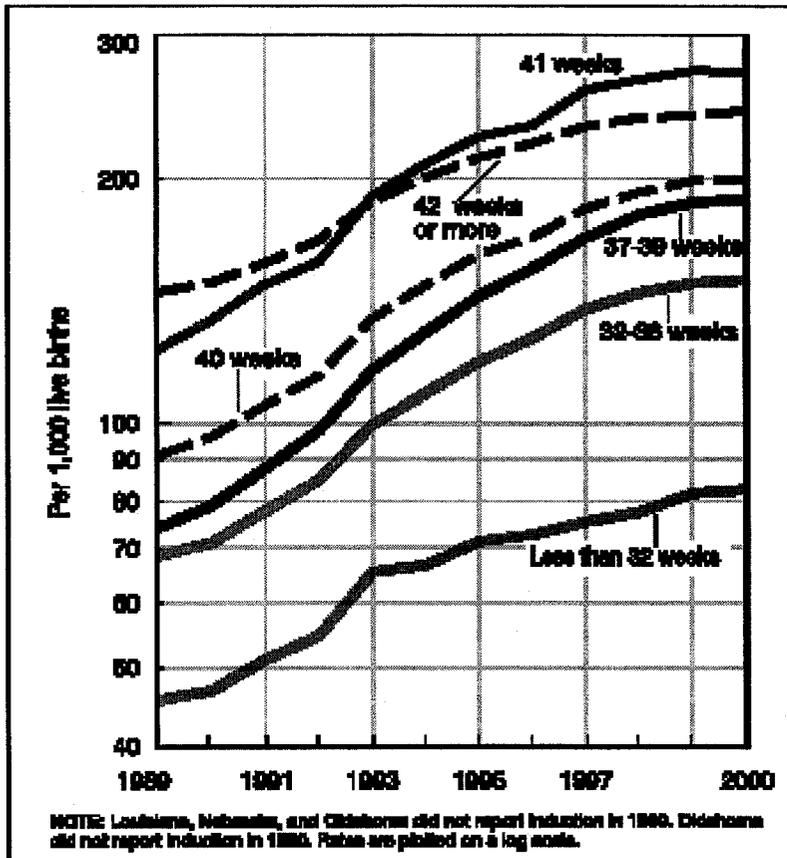


Figure 2. United States log rates of labor induction per 1,000 live births and length of gestation in weeks from 1989-2000.

From Births, Final Data for 2000 by J. Martin, B. Hamilton, S. Ventura, F. Menacker, & M. Park, 2002, *National vital statistics report 50 (5)*, 1-101. Reprinted with permission, see Appendix A. Note: Rates are plotted on a log scale.

Induction is an intervention often used by obstetricians to artificially augment or precipitate labor. There is a variety of methods for inducing labor, including artificial rupture of membranes, intravenous oxytocin, prostaglandin derivatives, and other cervical ripening agents (Cunningham et al., 2001, pp. 323-325). While the overall process of labor management is a complex one, the relationship of cesarean delivery to induction of labor, and how induction of labor might influence maternal and neonatal outcomes is important to consider, particularly given the increase in induction rates since 1989 (Martin et al., 2003).

The purpose of this study was to examine the effect of labor induction on the odds of primary cesarean delivery, controlling for differences in client and system characteristics that potentially influence the relationship, and to do so with a database that provides size and scope. The study utilized a database of merged birth certificate, hospital discharge data, American Hospital Association's ([AHA], 2002) *Annual Hospital Survey*, and neonatal intensive care survey (developed by the Dallas Fort Worth Hospital Council) data to examine the effect of labor induction on the odds of primary cesarean delivery. This study focused on the gap in scientific evidence examining women less than 41 weeks gestation by including women with gestational ages of 37 weeks to 42 weeks as the study population. By including gestational ages of 37 to 42 weeks, the study controlled for the variability across gestational ages to examine the increase in induction rates across the range of gestational ages considered to be term. The study also attempted to clarify the effect of labor induction on the odds of primary cesarean delivery by controlling for patient and hospital characteristics that may influence the effect of labor induction on cesarean delivery, and to do so with a database of adequate size and scope to control for multiple factors thought to influence the relationship. The database represented births from 41 hospitals and was obtained from the Dallas Fort Worth Hospital Council (DFWHC) which is a consortium of hospitals that share data for the purpose of improving quality and clinical outcomes.

Rationale for the Study

Inferences drawn from the 2001 *Births* report from the CDC provide the rationale for this study. They indicate that one of the key factors *believed* to be responsible for the escalating primary cesarean delivery rates may be the increasing number of labor inductions (Martin et al., 2002). The CDC's final report on births for 2002 states "increasing induction rates may be related, in part to an increase in elective induction of labor (defined as: induction of labor with no medical or obstetrical indication)" (Martin et al., 2003). Although some studies have shown that

induction of labor increases the odds of primary cesarean delivery (Alexander et al., 2001; Dublin et al., 2000; Maslow & Sweeney, 2000; Seyb et al., 1999), other studies have refuted the relationship (Sanchez-Ramos et al., 2003), creating debate on the issue. This study provided information to further explain the effect of labor induction on the odds of primary cesarean delivery, controlling for risk factors that often confound or modify the effect.

Evidence is Unclear on the Relationship of Labor Induction to Cesarean Delivery

Previous investigators of the effect of labor induction on the odds of primary cesarean delivery frequently used clinically abstracted data. These studies were often limited by sample size issues (Alexander et al., 2000, 2001; Maslow & Sweeney, 2000; Seyb et al., 1999; Xenakis, Piper, Conway, & Langer, 1997). Several of these studies indicated there is a significant increased odds of cesarean delivery for induced deliveries often dependent on client characteristics (Alexander et al., 2000, 2001; Seyb et al., 1999). Alexander et al. (2000) examined the relationship between induction of labor and primary cesarean birth for 40 weeks gestation and beyond in a population of n = 56,317 pregnancies and found an increased incidence of operative delivery associated with induction of labor at 40 weeks without demonstrated improvement in neonatal outcomes.

Alexander et al. (2001) reported findings from a subsequent study using similar methodology. They examined 1,325 post-term (41-42 weeks gestation) women. They reported a 40% increase in the number of primary cesarean deliveries in women whose labor was artificially induced compared to women that went into spontaneous labor. However, this increase was attributed to client characteristics of nulliparity, gestational age, undilated cervix, and epidural anesthesia rather than induction of labor per se. One limitation noted in the second study was the small size of the population sample and the lack of power to adequately establish “no relationship” of labor induction to cesarean deliveries. The 2001 Alexander et al. study reported a

power analysis using a β of .8 and an α of .05 that indicated they would have needed approximately 5,200 patients to demonstrate no effect of labor induction on primary cesarean delivery. These two studies were done with an extensive and detailed clinical database developed by researchers at an academic research center and with data prospectively collected by a well-trained research team. The data needed to complete this study required comprehensive support and rigorous training methods to consistently assess the cervix and collect the data.

Unfortunately, both studies focused on 40 weeks gestation and beyond and were unable to specifically address induction of labor in women prior to 40 weeks or elective induction of labor.

Dublin et al. (2000) used a database of Washington state birth certificate and hospital discharge data to examine the phenomenon of elective induction of labor. This team concluded that induction of labor is associated with increased risk of cesarean delivery for nulliparous women, but not for multiparous women. However, a recent meta-analysis by Sanchez-Ramos et al. (2003), examining 16 randomized controlled trials refutes the causal relationship between induction of labor and cesarean birth for women whose gestational age exceeds 41 weeks, reported that induction of labor was not associated with increased odds of cesarean delivery. This analysis provided some evidence that induction of labor may not increase the odds of cesarean delivery. This is contrary to the findings of Alexander et al. (2001), Dublin et al. (2000), and Seyb et al. (1999) indicating that induction of labor increases the odds of a primary cesarean delivery for nulliparous women when intrinsic patient characteristics are taken into account. Not only do research reports conflict, but the incidence of induced labor in women prior to 40 weeks gestation is rising and may pose an increased risk of cesarean delivery, making the findings of this study of value to researchers, healthcare providers, and consumers (Martin et al., 2002).

Complex Interactions of Client and System Characteristics Impact the Relationship

The study of bivariate relationships in obstetrical outcomes is hampered by the complex interactions of maternal and fetal factors including the parity of the mother, demographic characteristics, gestational age, neonatal anomalies, medical risks, and intra-partum complications (Balit, Dooley, & Peaceman, 1999). Alexander et al. (2001) created an ideal approach for examining the effect of labor induction on primary cesarean delivery, but their research was limited by the size and scope of demographic characteristics in their database, creating doubt on the validity of the findings. The study population was a homogenous population from one institution with a large proportion of Hispanics. This raises additional questions concerning the generalizability of the study beyond the sample. Many of the factors examined by Alexander and colleagues are now available in large administrative data sets which utilize birth certificate data and the maternal hospital discharge data. These data sets can be utilized to overcome some of the limitations originally encountered by Alexander and team and allow a researcher to control for the multiple factors that impact the relationship of labor induction on cesarean delivery, including factors that interact with the effect of labor induction on the odds of cesarean delivery.

Electronically Stored Data Provides Scope and Volume of Cases

Hospital discharge data and birth certificate data are two readily available electronic data sources often used in lieu of clinically abstracted data to analyze clinical outcomes. This study used administrative data sources along with the AHA's Annual Survey and a Neonatal Intensive Care Survey developed by the Dallas Fort Worth Hospital Council. The data were used to examine the effect of labor induction on primary cesarean delivery while controlling for variables that often modify the effect on the relationship (e.g., comorbidities of both the mother and the baby, fetal distress, and failure to progress or hospital characteristics). Because abstracting clinical data is an expensive process, secondary data analysis of readily available electronic data

is attractive from a cost efficient standpoint. Combining the data set of hospital discharge data, birth certificate data, and AHA and DFWHC NICU survey data (2002) provided a large volume of demographically diverse cases so that demographics and some practice pattern variation could be examined and controlled for statistically. This addresses the issue of generalizability of the study. As discussed previously, sample size often has been identified as a limitation of studies investigating obstetrical outcomes using clinically abstracted data. Secondary data analysis is considered a viable and advantageous alternative, providing heterogeneous large samples at a lower cost (Dublin et al., 2000; Iezzoni, 1997). This study examined births to postterm women (41 to 42 weeks), as was done in the Alexander. et al. (2001) study and the Sanchez-Ramos et al. study (2003). In addition, the study addressed the gap in the scientific evidence relating to the effect of labor induction on the odds of primary cesarean delivery for women 37 to 40 weeks gestation, as well as greater than 40 weeks gestation. The investigation of deliveries at 40 weeks or less is important due to the increasing trend in early induction of labor (Martin et al., 2002).

This study examined the effect of labor induction on primary cesarean deliveries using a modified version of the Quality Health Outcomes Model (Mitchell, Ferketich, & Jennings, 1998). The original model is depicted in Figure 3. In addition to a modified version of the Quality Health Outcomes Model, the researcher also used the scientific literature surrounding cesarean deliveries and induction of labor, and obstetrical data from 41 hospitals in north-central Texas.

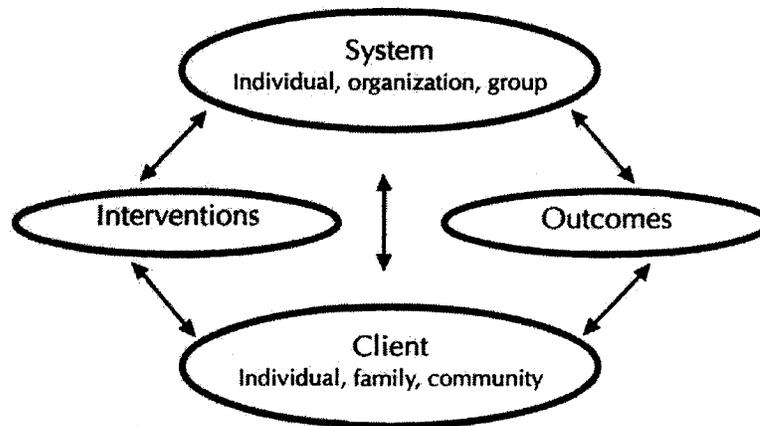


Figure 3. Quality health outcomes model.

From "Quality health outcomes model," by P. Mitchell, S. Ferketich, & B. Jennings, 1998, *Image Journal of Nursing Scholarship*, 30(1), 43-46. Individual under system characteristics refers to individual hospitals; and individual under client characteristics refers to the individual patient or client. Reprinted with permission, see Appendix B.

Conceptual Framework

The Quality Health Outcomes Model originally proposed by Donabedian (1966, 1982) and modified by Mitchell et al. (1998) provided the conceptual framework for this study and is depicted in Figure 3. Donabedian's classical framework identifies three overriding dimensions of health care evaluation: structure, process, and outcome. In this model, these dimensions and the attributes of the dimensions define quality. Donabedian's model is considered to be a linear model supporting the thought that structure and process precede or affect outcomes. According to the model, health care quality is organized as structure, process, or outcome with structure referring largely to qualifications of the practitioner or institution (e.g., number of beds, teaching versus non-teaching, rural versus urban, and ownership). Process refers to the means by which

practitioners deliver care. In this study, induction of labor is the key process variable under examination. Finally, outcome refers to what happened subsequent to the care received; in this case whether or not the mother delivered by primary cesarean delivery or vaginal delivery.

Mitchell et al. (1998), extending Donabedian's model in their work with the American Academy of Nurse Expert Panel on Quality Health Care, proposed that dynamic relationships exist and act reciprocally upon each other. The researchers emphasized the importance of multiple contextual variables that influence health care delivery and outcomes. "Interventions affect and are affected by both system and client characteristics in producing desired outcomes ... and no single intervention acts directly through either system or client alone" (Mitchell et al., 1998, p. 44). Alexander et al. (2001) controlled for client characteristics of maternal age, race, parity, gestational age, cervical dilation, and epidural anesthesia to determine how the populations differed for women who were induced compared to women who were not induced prior to examining the effect of labor induction on primary cesarean delivery. In keeping with the health outcomes model, the Alexander team found that variables intrinsic to the patient, rather than the intervention of labor induction itself, are the cause of increased primary cesarean delivery with induced deliveries.

The difference in Donabedian's initial model and Mitchell and associates' (1998) model is that Donabedian's original model is a traditional linear model. Mitchell et al. (1998) expanded the model, suggesting one that is dynamic and demonstrates the complex relationships between system characteristics, interventions, client characteristics, and outcomes. Mitchell and her colleagues (1998) took into account system and client characteristics. Their model does not directly link interventions and processes to outcomes in a linear manner, but instead addresses the dynamics occurring when client and system characteristics mediate (confound) and modify (interact with) the effect of the interventions on outcomes (Mitchell et al., 1998). Mitchell and

colleagues stated that the model extends previous models by positing dynamic relationships with indicators that not only act upon, but also reciprocally are affected by, the various components.

In this study, multivariable logistic regression analysis was used to examine the dynamics of the relationships between client and system characteristics, and the impact of the characteristics on the effect of labor induction on the odds of primary cesarean delivery. Logistic regression controlled for variables that either mediate (confound) or modify (interact with) the effect of labor induction on primary cesarean delivery. A variable that would mediate the effect is a variable that accounts for or explains the relationship between the independent variable (induction of labor) and the dependent variable (primary cesarean delivery) (Ocker, 2002). A mediating variable means the independent variable of induction affects primary cesarean delivery not just directly, but also indirectly through client and system characteristics. This type of covariate is referred to as a confounder. A variable that would modify the effect is a situation in which the covariate and the variable of interest interact and “modify” or change the effect on the outcome with variability across different strata. The effect of the variable is not constant across all levels of another variable. This type of covariate is referred to as an interaction term. For example, the relationship of labor induction on primary cesarean delivery is different across gestational ages. Multivariable logistic regression methods were deployed as described by Hosmer and Lemeshow (2000) to determine if either the client or system characteristic was a modifying or mediating variable and adjusted for that effect (described in the Chapter III in the Analysis Section) on the odds of primary cesarean delivery. Figure 4 depicts the researcher’s modified Health Outcomes Model to illustrate the potential for effect modifiers on the effect of labor induction on the odds of primary cesarean delivery.

This model proposes relationships among components that are two dimensional, with interventions acting through characteristics of the system and of the client, and vice versa. The

effect of an intervention in this study (e.g., induction of labor) is either mediated or modified by client and system characteristics and, according to the Mitchell et al.'s (1998) model, has no independent direct effect on the outcome. An example of these relationships with primary cesarean delivery is that the effect of labor induction varies across parity and gestational age. Alexander et al.'s study (2001) supports the Mitchell et al. (1998) model in that their findings indicated that client characteristics including nulliparity, gestational age, undilated cervix, and epidural anesthesia rather than induction of labor per se increased the odds of primary cesarean delivery. Figure 3 highlights Mitchell and colleagues' Health Outcomes Model and Figure 4 shows the researcher's modified version of the model. This model created an excellent foundation for examining the effect of labor induction on primary cesarean delivery.

The researcher's modifications of the model extended the model further to address the dynamic effect of labor induction on primary cesarean delivery mediated or modified by client characteristics and hospital characteristics. The interrelationships of the concepts in the Quality Health Outcomes Model provided the framework for the researcher to examine the influence of system and client characteristics upon the effect of labor induction on the odds of primary cesarean delivery. System characteristics were represented by the hospital characteristics of bed size, ownership, rural or urban location, teaching or non-teaching facility by AHA criteria, and payer type. Client characteristics were represented by the parity, gestation, race, ethnicity, maternal age, dystocia, and medical indication for induction. In this study, the intervention under examination is induction of labor, and the effect of labor induction on the outcome of interest, primary cesarean delivery (see illustration depicted in Figure 4). This model was used to conceptually guide the analysis of the large hospital database to further clarify the effect of labor induction on the odds of primary cesarean delivery in a population of women 37 to 42 weeks gestation. The model in Figure 4 illustrates the researchers' investigation of the effect of induction

of labor on the odds of primary cesarean delivery controlling for confounding (depicted by solid arrows) and modifying effects (depicted by dashed arrows) of client and system characteristics. The researcher did not examine the direct effect of client and system characteristics on the odds of a primary cesarean delivery.

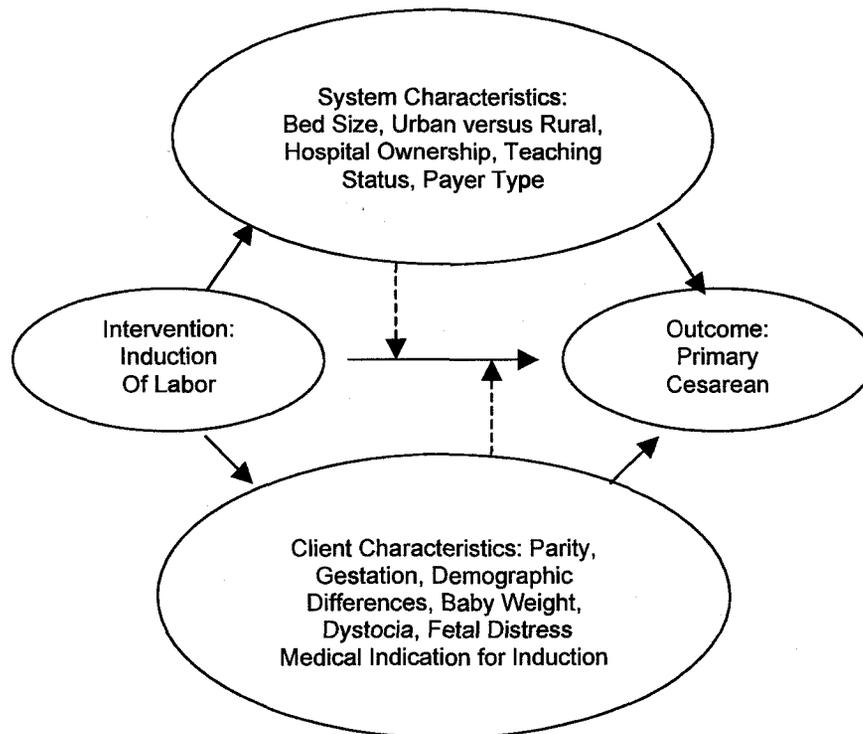


Figure 4. Health outcomes model for examining the effect of labor induction on the odds of primary cesarean delivery.

Note. The dashed arrows represent interaction referred to by Mitchell et al. as “effect modifiers” whereas the solid arrows depict confounding effects referred to by Mitchell et al. as “effect mediating.”

It is important to address the practical application of this conceptual model, particularly with regards to the reciprocal relationships depicted in the original model. Reciprocity is present in some cases between the various components of the model, but with practical application that may not always be the case. For example, induction of labor impacts some client characteristics,

in that induction of labor may actually precipitate a failure to progress or fetal distress phenomenon. Additionally, the client influences induction of labor with co-morbidities and other non-medical reasons that may increase the likelihood that the woman will be induced. However, in the case of parity, primary cesarean delivery does not influence parity, yet nulliparity increases the likelihood of a primary cesarean delivery. So, in the relationship between parity and primary cesarean delivery, the relationship is not a clear reciprocal relationship. Additionally, it is important to emphasize that this study did not attempt to test all of the relationships between client, system, interventions, and outcomes depicted in the conceptual model in Figure 3. This study focused strictly on the effect of labor induction on the odds of primary cesarean delivery, controlling for client and system characteristics that confound or modify the effect and the researcher's practical application for that purpose is depicted in Figure 4.

Research Question

Six studies have shown a significant effect between induction of labor and the odds of cesarean delivery, suggesting that induction of labor increases the odds of a cesarean delivery (Alexander et al., 2001; Dublin et al., 2003; Hefner et al., 2003; Johnson et al., 2003; Maslow & Sweeney, 2000; Seyb et al., 1999). However, the research has historically focused on postterm deliveries and more often has been limited in sample size. With the induction rates increasing across gestational ages, it is important to examine the effect of labor induction for women 40 weeks gestation and less, as well as postterm women greater than 41 to 42 weeks gestation. This research inquiry was designed to either confirm or refute the claim that induction of labor significantly increases the odds of primary cesarean delivery, and determine under what conditions one might expect the odds to increase or decrease. The key research question addressed in this study is: What is the effect of labor induction on the odds of a primary cesarean delivery after controlling for confounding and effect modifying variables that influence the

relationship? This information is important for understanding the trends in rising rates of primary cesarean delivery and to determine if the early induction of labor for medical and non-medical reasons may be increasing the odds of primary cesarean delivery. With clearer information regarding the relationship of labor induction, primary cesarean delivery and the variables that influence that relationship, better interventions can be developed to address increasing rates of primary cesarean delivery and determine under what circumstances induction of labor provides a safe effective intervention for delivery.

Definition of Terms

Utilizing the Mitchell et al.'s (1998) modified Quality Health Outcomes Model as a framework, the definitions of terms fall into four categories including: outcome, intervention, client characteristics, and system characteristics.

Outcome of Interest

The primary outcome of interest is defined as primary cesarean delivery versus vaginal delivery, operationalized as follows:

1. *Primary cesarean delivery*: Primary cesarean delivery was defined as the delivery outcome for a woman who has not had a previous cesarean delivery and delivered the current pregnancy by cesarean delivery. Primary cesarean delivery was operationalized by identifying cases coded with ICD-9-CM procedure codes of 74.0, 74.1, 74.2, 74.4, or 74.99. Primary cesarean delivery was measured by excluding women with a history of cesarean delivery identified by ICD-9-CM codes of 654.20-654.23. Primary cesarean delivery was identified by the ICD-9-CM procedure information, or if primary cesarean delivery is indicated under obstetrical procedures as “yes” on the birth certificate. The primary cesarean delivery variable was defined as a dichotomous variable indicating the woman had a primary cesarean delivery, coded as 1 for “yes,” otherwise 0 for “no.”

2. *Vaginal delivery*: Vaginally delivery is defined as any delivery that delivered vaginally as opposed to birth via cesarean delivery. The cases were identified as those cases that are not coded as a cesarean delivery by ICD-9-CM procedure codes 74.0, 74.1, 74.2, 74.4, or 74.99. Vaginal delivery was identified by the ICD-9-CM procedure information, or if vaginal delivery was indicated under obstetrical procedures as “yes” on the birth certificate. The vaginal delivery variable was defined as a dichotomous variable indicating the woman had a vaginal delivery, coded as 1 for “yes,” otherwise 0 for “no.”

Intervention of Interest

The intervention of interest was defined as induction of labor versus spontaneous onset of labor, and was operationalized as follows:

1. *Induction of labor*: Induction of labor is defined as a medical procedure that intervenes in the natural process of labor and uses artificial means to initiate labor. Methods for induction of labor might include membrane stripping, amniotomy, administering oxytocin, misoprostol, or prostaglandin E analogues (ACOG, 2000). Induction of labor is coded on the medical record by use of the procedure codes and the diagnosis codes. The procedure data capture induction of labor as either a surgical or medical procedure. Artificial rupture of membranes is coded as a ICD-9-CM procedure code as 73.01. Medical induction is coded as 73.4. Insertion of prostaglandin suppository is coded as 96.49. Failed medical induction of labor is coded with a diagnosis code of 659.10, 659.11, or 659.13. Failed mechanical or surgical induction of labor is coded as 659.00, 659.01, 659.02, or 659.03. Induction of labor was identified by any of the previously noted ICD-9-CM procedure or diagnosis codes, or if induction of labor was indicated under obstetrical procedures as “yes” on the birth certificate. The induction of labor variable was defined as a dichotomous variable indicating the woman had a medical or surgical induction of labor during the course of her hospital admission, coded as 1 for “yes,” otherwise 0 for “no.”

2. *Spontaneous onset of labor*: Spontaneous onset of labor is defined as a woman who goes into labor without artificial rupture of membranes or medical induction of labor.

“Spontaneous onset of labor” was measured by the absence of labor induction noted on either the hospital discharge record or the birth certificate record, assuming that if the delivery was not induced that the delivery was a spontaneous onset of labor.

Client Characteristics

Client Characteristics were defined as gestational age, medical indication for induction, parity, dystocia, fetal distress, risk factor present (exclusion criteria), history of prior cesarean delivery (exclusion criteria), maternal age, race/ethnicity, and baby weight were operationalized as follows:

1. *Gestational age*: Gestation is the period between conception and birth of a baby, during which the fetus grows and develops inside the mother's uterus. Gestational age was operationalized using the birth certificate field for gestational age, which is documented by hospital personnel recording the clinical estimate in completed weeks. The estimated gestational age is a clinically estimated gestational age reported to be more accurate than a calculated menstrual gestational age that can be derived from birth certificate data fields including date of birth and date of last menstrual period (Mustafa & David, 2001). The variable “gestational age” was handled as a categorical variable, with 1 coded as 37 weeks, 2 coded as 38 weeks, 3 coded as 39 weeks, 4 coded as 40 weeks, 5 coded as 41 weeks, and 6 coded as 42 weeks.

2. *Medical indications for induction*: Medical indications for induction is defined as any condition identified as a medical indication for induction by the ACOG. The factor was identified by ICD-9-CM codes, indicating one of the medical indications for induction was present on the coded medical record. The factors were identified by review of the scientific literature and supported by the ACOG’s *Clinical Guidelines for Induction of Labor* as medical indications for

labor induction. The factors are listed as follows with the respective ICD-9-CM codes: septicemia during labor/infected amniotic cavity (658.41, 659.31), pregnancy-induced hypertension (642.31-642.32), premature rupture of the membranes (658.11, 658.21), maternal medical conditions [including diabetes mellitus (648.01-648.02, 648.81-648.82), gestational diabetes (648.81-648.82), renal disease (646.21-646.22), essential and other forms of hypertension (642.01-642.02, 642.11-642.12, 642.21-642.22, 642.91-642.92), transient hypertension of pregnancy (642.31-642.32)], severe fetal growth restrictions (656.51), mild unspecified pre-eclampsia (642.41-642.42), preeclampsia (642.71-642.72), eclampsia (642.61-642.62), and severe eclampsia (642.51-642.52). The ICD-9-CM codes identifying these factors were coded as 1 for “yes” (a factor was present in the hospital discharge data), otherwise 0 for “no.” Detailed definitions for the individual ICD-9-CM codes are listed in Appendix C for all factors categorized under “Medical Indication for Induction.”

3. *Nulliparous*: Nulliparous is defined as never carrying a pregnancy to viability (other than the current pregnancy recorded) or beyond the stage of abortion (Cunningham et al., 2001). For the purpose of this study, nulliparous was operationalized as a dichotomous variable, “yes” if the woman was nulliparous and “no” if the woman was not. The birth certificate fields of 26a (number of live births now living), 26b (number of live births now dead), plus one birth for the current pregnancy was used to calculate gravida. The gravida was in turn used to calculate the nulliparous variable, with any woman a gravida 1 or less operationalized as nulliparous “yes,” otherwise, “no.”

4. *Dystocia*: Dystocia is a condition of labor that is diagnosed when the woman fails to progress normally during labor into a vaginal delivery. It is a subjective diagnosis made by the physician and includes any of the following conditions: shoulder dystocia (660.41), deep transverse arrest and persistent oblique presentation (660.31), cephalopelvic disproportion

(653.51), and prolonged labor (662.01, 662.11, 662.21) (Clark, Xu, Porter, & Love, 1998; McCloskey, Petitti, & Hobel, 1992). All of the previously listed conditions often are coded in the medical record as clinical reasons for a woman failing to progress to a normal vaginal delivery. These cases were identified by ICD-9-CM codes and coded as a dichotomous variable with 1 for “yes” the woman had a failure to progress condition, otherwise 0 for “no.” Detailed definitions for the individual ICD-9-CM codes are listed in Appendix C for the factors categorized within the dystocia variable.

5. *Fetal distress*: Fetal distress is a broad term including non-reassuring fetal status based on fetal heart rate patterns (Cunningham et al., 2001). Experts disagree on definition, with consensus consistent surrounding extremes of normal fetal heart rate patterns and severely abnormal patterns (see Table 1 for further definition). For the purpose of this study, fetal distress was operationalized as any case that is coded with a diagnosis code indicating fetal distress (656.31). 656.31 is defined as “fetal metabolic acidemia” (PMIC, 2002). If the factor was present the case was coded as 1 for “yes” fetal distress was indicated in the discharge data, otherwise 0 for “no.”

Table 1

Fetal Distress Defined by Abnormalities of Fetal Heart Patterns

Abnormalities of Fetal Heart Patterns	
Pattern	Interpretation
Normal	Baseline 110-160 bpm* Variability 6-25 bpm* No decelerations present
Intermediate	No consensus
Severely abnormal	Recurrent late or variable decelerations with zero variability Substantial bradycardia with zero variability

Note. Derived from 1997 NICHD Fetal Monitoring workshop, Interpretation of Fetal Heart Rate Patterns. Reported in *Williams Manual of Obstetrics* by K. Leveno, F. Cunningham, N. Gant, J. Alexander, S. Bloom, B. Casey, J. Dashe, J. Sheffield, & N. Yost, 2003, New York: McGraw Hill.

* "bpm" denotes beats per minute.

6. *Risk Factor for Cesarean:* Risk factors were defined as comorbidities or complications that the ACOG (2000) indicates provide reasonable justification for a cesarean delivery.

Conditions identified as predisposing a woman to cesarean delivery are:

- abnormalities of the uterus and cervix
- placenta abruption, placental hemorrhages
- hemorrhage with coagulation defects,
- unstable lie of fetus
- breech presentation without version
- disproportion or obstruction and abnormality of bony pelvis
- inlet and outlet contraction

- placenta previa with and without hemorrhage
- history of prior cesarean, congestive heart failure
- congenital abnormalities of the uterus
- delayed delivery of 2nd twin, triplet, etc.
- fetal abnormalities causing disproportion
- transverse or oblique lie
- face or brow presentation of fetus
- fetal or intrauterine death
- obstruction caused by malposition of fetus
- fetal maternal hemorrhage
- genital herpes
- human papilloma virus
- cervical incompetence (presence of Shirodkar suture)
- locked twins
- prolapsed arm or other malposition/malpresentation
- multigestation with malpresentation (ACOG, 2000; Cunningham et al., 2001).

The risk factors were identified by ICD-9-CM codes listed on the mother's hospital discharge data. The ICD-9-CM codes considered as risk factors are listed in Appendix C. If the woman had one or more of these factors, the risk factor variable was coded as dichotomous data with "yes" one or more of the factors were present, or "no" the factors were not. This factor was used as exclusion criteria to assure that the study sample would be considered at low risk for cesarean delivery.

7. *History of prior cesarean delivery*: History of prior cesarean delivery is defined as a woman who has had the surgical delivery of a baby by an incision through the mother's abdomen and uterus. History of prior cesarean delivery was operationalized by identifying cases that were coded with ICD-9-CM codes 654.20-654.23 and identified as “yes” history of prior cesarean delivery, otherwise “no.”

8. *Maternal age*: Maternal age is defined as the age of the mother at discharge and was calculated in the research data set from the mother's date of birth and the date of discharge. This variable was examined in this study as both a continuous variable from 11 years of age to 53 years of age, and a categorical variable. The decision to introduce the variable as a continuous versus a categorical is discussed in Chapter III in the Methods section.

9. *Race/ethnicity*: Race/ethnicity is defined as a sociological designation, identifying a population of individuals with similar characteristics culturally and physically (Stevens, 2003). Race and ethnicity was derived from two fields reported on the hospital discharge data. The two data fields are captured during the admission process within a hospital and are statutorily required for reporting to the Texas Health Care Information Council ([THCIC], 2003). for the inpatient public domain Data Initiative. The fields were mapped to the following categories: 1 was coded as “Hispanic,” 2 coded as “Black,” 3 coded as “White,” and 4 coded as “Other.”

10. *Baby's weight*: The baby's weight was defined as the birth weight in grams reported on the baby's birth certificate.

System Characteristics

System characteristics were defined by hospital characteristics of bed size, urban versus rural, ownership type, teaching status, and payer type, operationalized as follows:

1. *Bed size*: Bed size was defined as the number of licensed beds reported in the AHA Annual Survey. Bed size was treated as a categorical variable with the groupings for bed size

defined as follows: less than 80 beds coded as 1, 81 to 260 beds coded as 2, and equal to or greater than 261 beds coded as 3 (grouping determination is discussed in the Methods section of Chapter III).

2. *Urban*: The hospital's location was defined as either rural or urban. Rural was defined according the Texas Department of Health definition of "rural" area. According to the Texas Department of Health definition, "rural area" is a county that had a population in the most recent decennial United States census of 150,000 or less, or that part of a county with a population of greater than 150,000 that is not delineated as urbanized by the United States Census Bureau (Ellison, 2002). The hospital was designated as urban if the hospital was not located in a rural area. The variable was coded as a dichotomous variable, with 1 for "yes" if urban, otherwise 0 for "no." The information regarding the population of the county was obtained from the address location listed in the AHA annual survey data and the total population was obtained from the recent 2002 US Census reporting total population by county (U.S. Census Bureau, 2003).

3. *Ownership type*: Ownership type was defined as a categorical variable with the categories reported by the hospital in the AHA's Annual Survey and reported in the 2003 *Guide to American Hospital Association Hospitals*. The categories were coded as follows: 1 for "For Profit," 2 for "Non-Profit," and 3 for "Public." "Public" hospitals are county hospitals; "For-Profit" are hospitals operated for profit by individuals, partnerships, or corporations; and "Non-Profit" hospitals are operated by a church or other nonprofit organization (AHA, 2002).

4. *Teaching status*: Teaching status was operationally defined as an institution identified by the American Medical Association approved to participate in residency training by the Accreditation Council for Graduate Medical Education, and was identified by using the 2003 hospital approval codes from the *American Hospital Associations Guide 2003-2004* (2003). The

facility was designated in terms of teaching status and coded as 1 for “teaching” and 0 for “non-teaching.”

5. *Payer type*: Payer type was defined as the group primarily responsible for the payment of services and was used as a proxy to socioeconomic status. The researcher was interested in controlling for whether or not the woman was insured by private insurance, or receives Medicaid, Medicare or has no form of payment. Payer type was treated as an aggregated variable combining the standard and non-standard payer codes to represent the patient’s principle payer. Principle payer was then subsequently mapped to a standardized variable according to the AHRQ HCUP data standards for the National Inpatient Sample, including Medicare, Medicaid, Private Insurance, Self-Pay and Other (see Chapter III for further discussion on mapping methods). Due to small cell size issues with the use of multivariate logistic regression, Medicare, Medicaid, Self-Pay, and No Charge were combined into the “Other” category resulting in a “Private Pay” or “Other” categorical variable. (details of the mapping are discussion in Chapter III Collection and Treatment of Data section). The “other” category consists predominantly of low income and indigent, and findings were analyzed and interpreted in that context.

Measurement Terms

Measurement terms utilized to examine the relationship of induction of labor on the odds of a primary cesarean delivery were confounding and effect modification, operationalized as follows:

1. *Confounding*: Confounding is present when an independent variable is associated with both the outcome variable (primary cesarean delivery) and the variable of interest (induction of labor), thereby confounding the effect. This influence alters the separate effects of the independent variables upon the dependent variable creating an obscured effect (Portney & Watkins, 2000).

2. *Effect modification*: Effect modification also is referred to as interaction between two variables. Interaction is present when the effect of one variable is not constant across different levels of another variable, and is also referred to as effect modification (Portney & Watkins, 2000). Effect modification was examined by creating interaction terms for induction of labor and other covariates determined to be important confounders. The interaction terms were introduced into the logistic regression model to determine if the interaction terms were significant. An interaction term was considered significant if the p value was .01. or less (Hosmer & Lemeshow, 2000).

Hypotheses

The hypotheses tested in this study population of women 37 to 42 weeks gestation excluding known risk factors for cesarean delivery (including a history of previous cesarean delivery) were as follows:

1. Client characteristics (including parity, gestation, race/ethnicity, maternal age, medical indication for induction, dystocia, fetal distress, and baby weight) confound the effect of labor induction on odds of primary cesarean delivery.
2. Induction of labor for nulliparous women increase the odds of a primary cesarean delivery after controlling for client and system characteristics.
3. Induction of labor for women 40 weeks gestation or less increase the odds of a primary cesarean delivery after controlling for system and client characteristics that influence the relationship.
4. System characteristics (including hospital bed size, urban versus rural status, ownership type, teaching status, and payer type) confound the effect of labor induction on odds of primary cesarean delivery.

Assumptions

The researcher identified the following theoretical assumptions:

1. Interventions affect and are affected by both system and client characteristics in producing desired patient outcomes (Mitchell et al., 1998).
2. Interventions are impacted by dynamic relationships between both the system and client characteristics (Mitchell et al., 1998).
3. The linear technique of logistic regression approximated the dynamic effects of labor induction on the odds of primary cesarean delivery controlling for confounding and effect modifying variables that influence the dynamic relationship.
4. No single intervention acts directly through either system or client alone, and therefore has no direct effect on the outcome (Mitchell et al., 1998).
5. Effects of provider interventions are mediated (confounding) or moderated (interaction) by client and system characteristics (Mitchell et al., 1998).

The researcher identified the following methodological assumptions:

1. A woman induced at 40 weeks or less is more likely to have an undilated cervix than women who are allowed to advance to post term (41-42 weeks gestation) and then induced (Alexander et al., 2001).
2. Payer type is an adequate proxy for socioeconomics.
3. The most pertinent confounders and effect modifiers were identified and controlled for with modeling techniques methods.
4. Gestational age is an adequate proxy to readiness of the cervix for delivery.
5. Data documented by the birth certificate data collectors, the medical record coders, and business office personnel are accurately recorded for the variables of interest for this study (Keeler, Park, Bell, Gifford, & Keeseey, 1997).

Limitations

Limitations and threats to validity for this study fell into two categories: threats to internal validity and threats to external validity. Internal validity is the degree to which it can be inferred that the independent variables under study rather than other extraneous variables are responsible for the results (Polit, Beck, & Hungler, 2001). Controlling for threats to internal validity involves controlling for those variables that might influence the variable of interest and the effect of that variable on the outcome variable. For example, in this study parity was shown to influence the effect of labor induction on the odds of primary cesarean delivery, indicating induced nulliparous women have higher odds of cesarean delivery than do nulliparous women that were not induced (Alexander et al., 2001; Dublin et al., 2000). If a researcher were to examine the effect of labor induction on the odds of primary cesarean delivery without controlling for parity, internal validity would be compromised given that parity has been identified as influencing the effect of labor induction on the odds of primary cesarean delivery. A significant threat to internal validity in this study was the threat of extraneous variables such as parity, gestational age, and comorbidities that affect the relationship of labor induction and primary cesarean delivery. As other studies have indicated, there are multiple factors that influence the cesarean delivery rate that can confound and modify the effect of labor induction on the odds of primary cesarean delivery (Alexander et al., 2001; Dublin et al., 2000; Seyb et al., 1999). This study sought to control for those factors using exclusion criteria and multivariable logistic regression modeling methods to adjust for the effect.

The exclusion criteria included risk of cesarean delivery, including a woman who has already had a cesarean delivery. Elimination of women with prior cesarean deliveries introduced a potential bias to the study that warrants consideration. Eliminating women with a history of prior cesarean delivery excluded those women who failed to deliver a prior pregnancy vaginally.

Subsequently, including multiparous women that were not repeat cesarean deliveries increases the likelihood that multiparous women in the study delivered vaginally, because studies have shown that women with a history of a vaginal delivery have increased odds of successfully delivering by vaginal delivery with subsequent deliveries (Adams, 2001). Additionally, the multiparous women in the study may have had more than one pregnancy represented in the dataset given that this study spans 4 years. The dataset did not match women with more than one delivery represented in the study. The researcher could have used fields within the birth certificate that indicated prior delivery and the date of the prior delivery to determine if a multiparous woman had a prior delivery within the study period; however, the researcher could not be assured that the prior delivery was within the study population given the women could have delivered at hospitals outside of the study population. This limitation was acknowledged and would be difficult to address accurately without matching prior pregnancies in the dataset and inclusion of only one of the multiparous deliveries. This matching criteria was not used by the DFVHC and not available for this study. Recommendations for subsequent studies in Chapter V addressed this issue.

A threat to both internal and external validity was practice variation across hospitals. Practice variation may differ based on such things as the induction protocol within the hospitals, or the lack of 24-hour availability of anesthesia in rural and small hospitals. Studies have indicated that hospital characteristics and payer mix confound the examination of cesarean delivery (Dublin et al., 2001; McCloskey et al., 1992). Beebe et al. (1999) compared the rates of labor induction and the indications for labor induction between a university hospital and two community hospitals. The researchers concluded that induction of labor was more frequent in community hospitals than in a university hospital, and was more likely to be medically indicated at the university hospital. Practice variation was addressed by controlling for hospital characteristics, including bed size, rural versus urban, teaching status, and ownership. It is likely

that controlling for these variables may partially mitigate this threat to internal validity given that the study database contains a diverse mix of hospitals.

Validity of the data was the most significant issue with limitations to this study. The issue of how accurately the data sources measure and record the independent and dependent variables under examination was fundamental to this study. An important issue identified with this study was that the birth certificate and the hospital discharge data disagree significantly (Kappa of .456) with regards to identifying induction of labor. Keeler et al. (1997) addressed this issue by using both data sources to identify induction of labor. DiGiuseppe, Aron, Payne, Snow, Dierker and Rosenthal (2001) tested various models for predicting cesarean delivery and recommended using common variables within the hospital discharge data and the birth certificate data rather than birth certificate data alone. Their research indicated that the predictive model with variables that agree correlated with results from the model using the abstracted medical record.

The researcher did extensive analysis on the agreement of the two data sources for the induction of labor intervention and the mode of delivery outcomes considering various methods for addressing the disagreement of the two data sets on induction of labor. The methodology is reported in Chapter III and findings reported in Chapter IV. The researcher elected to follow the recommendations of DiGiuseppe et al. (2001) and used the data from both data sources that were in agreement as the final dataset for the analysis examining the effect of labor induction on primary cesarean delivery. There is noted limitation with this election given that the hospitals within the dataset demonstrate variation with regards to agreement when examining differences in the Kappa scores by hospital (see Chapter IV, Table 29). These differences may indicate a selection bias inherent with this election with some hospitals appearing to report more frequently in one data source than the other for the induction of labor variable. However, when the data that were in disagreement were analyzed (for example, hospital discharge data indicated an induction

and birth certificate did not), this election introduced cases that were in question as to whether or not the case was an induction of labor or not. The disagreement analysis is discussed extensively in Chapter IV.

The DFWHC's Data Quality Analyst software assists the hospitals with identifying and correcting data errors in the hospital's discharge data. Errors identified by the software are corrected by hospital staff prior to submission to the DFWHC. Because of the availability and use of this software, the Dallas-Fort Worth region is likely to have more accurate hospital discharge data than other hospitals in the nation. The Data Quality Analyst software may improve the internal validity of the study and is unique to this group of hospitals. Therefore, this may impact the generalizability of the study to national data samples, given that all hospitals do not necessarily maintain the same level of rigor with hospital discharge data reporting.

There are numerous studies analyzing the limitations of secondary data analysis. However, Iezzoni has made significant contributions to examining the validity and reliability of using administrative hospital discharge data to examine healthcare outcomes (Iezzoni, 1990, 1997; Iezzoni et al., 1995). Iezzoni's research indicated that the limitations of hospital discharge data were primarily issues relating to physicians' failure to document adequately. A coder cannot code what is not documented by the physician. For example, a nurse may note in the nursing notes the presence of a comorbidity, such as diabetes, but if the physician does not document in the medical record the presence of diabetes, the condition cannot be coded (Iezzoni, 1997). An additional limitation evaluated by Iezzoni was that the ICD-9-CM codes fail to capture pre-existing conditions on admission. For example, anemia may be present on admission, or it may be the result of blood loss during the hospitalization. Additionally, Iezzoni discussed the bias of hospital discharge coding data, given the fact that the coding process is inextricably tied to hospital reimbursement. The very nature of this process introduces a potential for bias.

Another noted limitation to ICD-9-CM data is the lack of adequate operational definitions for clinical factors coded as comorbidities, such as diabetes, hypertension and eclampsia. (Iezzoni, 1997). For example, the coding manuals do not designate the degree of hypertension or define what constitutes “severe” eclampsia. If the physician documented in the medical record that the woman was hypertensive or had severe eclampsia, then the coder is obligated to code the conditions. However, several studies have examined the efficacy of using administrative data sources, including birth certificate data and hospital discharge data, for secondary outcome analysis of obstetrical care (DiGiuseppe et al., 2001; Henry, Gregory, Hobel, & Platt, 1995; Keeler et al., 1997). Most of these studies concluded the data were limited and should be evaluated prior to use and that certain data elements, such as the comorbidities and complications of pregnancy on the birth certificate data, should be used with caution (DiGiuseppe et al., 2001).

Another data limitation to the study is the lack of key clinical information in the data that may relate to the effect of labor induction on primary cesarean delivery. Epidural anesthesia in some studies has been associated with an increase in the odds of cesarean delivery particularly when the woman is induced (Alexander et al., 2001; Seyb et al., 1999), while others found that epidural did not impact cesarean delivery (Jun, Klebanoff, & DerSimonian, 1999). Neither data source (birth certificate or hospital discharge data) has information adequate to identify mothers that received epidural analgesia. Therefore, the inability to control for epidural anesthesia was a recognized limitation of the study. Another key factor that studies have controlled when examining the effect of labor induction on primary cesarean delivery is the cervical status measured by the Bishop Score (Bishop, 1964). The two aforementioned data sources do not contain Bishop scoring information. Therefore, another limitation was the use of gestational age as a proxy to the cervical dilatation.

External threats to validity are those factors that impact the generalizability of the study to the larger population beyond the study population (Portney & Watkins, 2000). The use of a convenience sample from 41 hospitals in the north-central region of Texas restricts the generalizability of the study findings. This study was limited by the number of hospitals represented in the sample population and the geographic distribution which could present practice and outcome biases due to the concentration of hospitals in the north-central Texas region. The population in this study also was limited to women who have not had a prior cesarean delivery. Therefore, this study was only be generalizable to childbearing women in the north-central Texas region of the U.S. who are at low risk for cesarean delivery.

Summary

This study was needed to further clarify the effect of labor induction on the odds of primary cesarean delivery. Rates of cesarean delivery and induction of labor are increasing in the U.S., and the relationship between the two continues to be unclear despite existing research on the topic. The examination of labor induction and the relationship to cesarean birth has been a difficult investigation due to the co-morbidities of both the mother and baby, multiple factors that influence the birthing process, and sample size issues. The effect of labor induction on the odds of primary cesarean delivery is complicated by multiple system and client characteristics. The escalating primary cesarean delivery rates and the increasing induction rates across gestational ages may be related. If the increase in earlier induction of labor (particularly for the induction of labor that appears to be elective) is precipitating primary cesarean deliveries, then interventions to address the issue can be developed. Using a modified versions of the Mitchell et al. (1998) Quality Health Outcomes Model as a conceptual framework, this study seeks to fill a gap in the scientific literature surrounding the effect of labor induction on the odds of primary cesarean delivery for deliveries 40 weeks gestation and less. Additionally, this study contributes to

clarifying the effect of labor induction on the odds of primary cesarean delivery, while controlling for system and client characteristics that confound or modify the effect using a database with scope and size to examine and report the effect.

CHAPTER II

REVIEW OF LITERATURE

There is lack of consensus on the effect of labor induction on primary cesarean delivery. The three reasons for the lack of consensus are: (a). the studies done thus far have focused primarily on induction of labor for gestational ages 41 weeks and greater; (b). studies often lack sufficient sample size to adequately control for the multiple variables that confound and modify the effect., and (c) studies often fail to use appropriate techniques to adequately control for the effect modifiers and confounding variables.

The literature review begins with a discussion of studies pertaining to cesarean delivery, including information on the trends and potential explanations for the increase in cesarean rates. Client characteristics and system characteristics controlled for in the various studies also are discussed. Discussion of client characteristics examines the risk factors for cesarean delivery including patient demographics, complications, and comorbidities. Different modeling techniques are addressed, as well as other methods used by researchers to control for the confounding effects of system and client characteristics. The literature review continues with an overview of the physiology of labor induction with a review of the literature regarding the physiologic onset of labor versus the artificially induced response to gain a better understanding of why induction of labor may relate to an increased rate of primary cesarean, particularly for women 40 weeks gestation and less. Additionally, literature was reviewed that specifically addressed the effect of labor induction on cesarean delivery. This study used secondary data analysis for gaining an adequate sample for statistical power to control for the multiple variables thought to influence the

relationship of labor induction on primary cesarean delivery. The literature review concludes with a general discussion of the use of readily available electronic data sources for outcome studies and then focuses more specifically on data sources used in obstetrical outcome studies, including both clinical data sources and readily available electronic data and the importance of decisions of agreement on the validity of studies.

Cesarean Delivery

The cesarean delivery rates in the United States (U.S.) quadrupled from 1970 to 1990 (Martin, Hamilton, & Ventura, 2001), with a rise from 5.5% to 22%, with virtually no evidence that the maternal or neonatal outcomes improved (Flamm, Berwick, & Kabcenell, 1998). After a review of international and national literature, the U.S. Department of Health and Human Services established a goal in line with the World Health Organizations goal of 15% by 2000 with the initiative *Healthy People 2000*. This goal was not met, and has been re-established for 2010 at a rate of 15.5% (U.S. Department of Health & Human Services, 1991, 2000).

Hospitals continue to seek better ways to manage clinical outcomes for obstetrical patients, many focusing significant efforts on attempting to reduce cesarean delivery rates. The reduction of cesarean delivery rates is a controversial and complicated issue, particularly in the area of vaginal birth after previous cesarean delivery (VBAC). The industry had seen a decline of the cesarean delivery rates from 1989 to 1996, with a drop from 22.8% to 20.7%. However, the cesarean delivery rate reached a high of 22.9% for 2000 (Martin et al., 2002). Recent literature reports increased frequency of uterine ruptures due to VBAC as the reason for the reversal in cesarean rates (Shipp, Zelop, Repke, Cohen, & Lieberman, 2001). According to a report on 2000 birth statistics from the Center for Disease Control's Vital Statistics Report (Martin et al., 2001), the reported uterine ruptures associated with VBACs appear to have resulted in a significant

increase in repeat cesarean delivery rates and, subsequently, an increase in the total cesarean delivery rate.

The total cesarean delivery rate is comprised of all primary cesarean deliveries and all repeat cesarean deliveries. According to the American College of Obstetrics and Gynecology (ACOG), cesarean deliveries are indicated for the following reasons: (a) cord prolapsed; (b) bleeding from the placenta; (c) abnormal pelvic structure; (d) shoulder presentation of the baby; (e) serious maternal health problems such as infection, diabetes, heart disease, high blood pressure, or any circumstance when labor would not be safe for either mother or baby; (f) dystocia, which includes labor that fails to progress, prolonged labor, and CPD (cephalopelvic disproportion); (g) breech presentation; and (h) fetal distress (American College of Obstetrics & Gynecology [ACOG], 2000).

The Increase in Cesarean Rate Trends Examined

Porreco and Thorp (1996) examined trends and causes for the increase in cesarean births, using the National Center for Health Statistics National Hospital Survey. Their study referred to the increase in the cesarean delivery rates as “an epidemic.” The researchers noted differences in regions, with the South reporting the highest cesarean delivery rates and the West reporting the lowest, although no specific rates were reported by region. The researchers noted that older mothers and smaller hospitals tended to have higher rates of cesarean. Addressing hospital characteristics, Porreca and Thorp (1996) reported proprietary hospitals as having the highest rates, with state and local government-owned facilities reporting the lowest rates.

Porreco and Thorp (1996) also focused significant attention on the discussion regarding dystocia, identifying it as one of the major contributors to escalating cesarean rates. The initial focus of the discussion was the differences between nulliparous and parous labor, and the researchers recommended that these factors be taken into account when examining cesarean

delivery rates. They noted that nulliparous women had a much greater propensity for abnormal labor and that oxytocin was used for these women more frequently. They suggested that the use of analgesia may be contributing to the dystocia among nulliparous women. The researchers recommended the following for solutions to the high cesarean birth rates: keep accurate statistics, allow patients with history of previous cesarean delivery to labor, attend to poor progress of labor, modify use of conduction anesthesia, induce labor for specific indications after cervical preparation, be certain of the diagnosis of fetal distress, consider “alternative” management strategies, organize in-house attending obstetrical coverage, and, finally, participate in community educational efforts. They concluded with the following statement: “We should anticipate a continued slow fall in cesarean birth rates over time as initiatives for health care improvement help us focus on strategies to avoid interference in the normal process of labor and vaginal birth”(Porreco & Thorp, 1996, p. 205). Unfortunately, their conclusion did not materialize, and we continue to see increased rates across the U.S. and in other nations (Centers for Disease Control [CDC], 2003).

Canada also is seeing a similar trend in increasing cesarean delivery rates. Soliman and Burrows (1993) conducted a study to determine the effect of the National Consensus Conference on Aspects of Cesarean Birth (a 1986 conference on obstetrical practices) and to identify factors contributing to the increasing cesarean delivery rates in Canada. The researchers compared two years of data, 1982 pre-conference (4,121 cases) and 1990 post-conference (4,431 cases), for two hospitals’ cesarean delivery rates and the indications and predictors of cesarean delivery with these two populations. When comparing the pre- and post-conference data, the researchers found that the cesarean rates for these two hospitals in Canada had decreased.

A clinical labor and delivery database was used for the Canadian study. The researchers used a chart audit to determine validity of the database. They identified an error in only 1 of 1,200

sampled charts reviewed. The researchers used frequency counts to calculate rates, two-by-two tables and the chi-square test for univariate analysis of predictors, and multivariate logistic regression to determine the predictors of cesarean delivery. Characteristics of the patients for both years were reported to be consistent with similar gestational age at delivery. They noted that the age of women was slightly higher in 1990 (28 compared to 26.6 in 1982), with a higher proportion of nulliparous women in 1982 (46% compared to 43.2% in 1990).

The Solimon and Burrows (1993) study results reported a significant decrease in the overall cesarean delivery rates from 1982 to 1990, with a reduction of 8.7% in the overall rate (from 23.1 to 21.1). The rate of primary cesarean delivery was noted to be unchanged. The repeat cesarean rate decreased by 15%. Indicators for cesarean delivery for both years revealed the most common indicator was a history of a prior cesarean delivery. In 1982, dystocia was the second most common indicator, followed by breech delivery and fetal distress. In 1990, the most common cause for cesarean was maternal and fetal indications, dystocia, breech presentation, and fetal distress. Soliman and Burrows followed this analysis with an examination of predictors, using only 1990 data with the following client characteristics identified as independent predictors of cesarean delivery: nulliparity, previous cesarean delivery, labor induction, and non-vertex presentation. The researchers initially created a logistic regression model for all women and followed this with a stratified approach. Two additional models were done for low-risk cesarean groups, one for nulliparous women with vertex presentation and the other for multiparous women with vertex presentation and no previous cesarean delivery. The results of their logistic regression model with final variables and adjusted odds ratios are presented in Table 2.

Table 2

Soliman and Burrows' (1993) Study to Examine the Effect of the Canadian National Consensus Conference on Aspects of Cesarean Birth in 1986 Logistic Regression Results

Variables	All women		Variables included as risk factors for nulliparous vertex presentation		Variables included as risk factors for multiparous vertex presentation and no prior CS	
	Odds ratios	p values	Odds ratios	p values	**Odds ratios	p values
Nulliparity	3.4	<.0001				
Diabetes Mellitus	1.2	0.72	1.6	0.42	0	0.7
Previous CS*	20	<.0001				
Labor Induction	7.1	<.0001	4.5	<.0001	12.5	<.0001
age > 30 years	1.2	0.27	1.5	0.05	1	0.92
nonvertex presentation	12.5	<.0001				
continuous EFM**	1.3	0.17	1.3	0.13	0.8	0.62
Fetus large for gestational age	3	0.1	3.3	0.02	2.9	0.19
Fetus small for gestational age	1.9	0.01	2.4	0.01	2.4	0.01
Hypertension	4	0.07	1000	0.52	6.2	0.44
Toxemia	0.9	0.91	1.3	0.48	1.5	0.44
Antepartum hemorrhage	1.9	0.05	1.3	0.65	7.7	0.0007

Table 2 (continued)

Variables	All women		Variables included as risk factors for nulliparous vertex presentation		Variables included as risk factors for multiparous vertex presentation and no prior CS	
	Odds ratios	p values	Odds ratios	p values	**Odds ratios	p values
Epidural anesthesia	1.4	0.04	1.5	0.04	2	0.05

Note. Soliman, S., & Burrows, R. (1993). Cesarean section: analysis of the experience before and after the national consensus conference on aspects of cesarean birth. *Canadian Medical Association Journal* 148(8), 1315-1993. CS is the acronym for Cesarean Section EFM is the acronym for Electronic Fetal Monitoring. All odds ratios reported were adjusted odds ratios using logistic regression.

Cesarean Risk Models

Hospitals and health plans often report cesarean delivery in “report cards” and rank the rates according to best performance with the assumption that lower rates reflect more appropriate, more efficient care (Aron, Harper, Shepardson, & Rosenthal, 1998). Aron et al. (1998) reported that rankings did not always account for the patient characteristics that may affect the likelihood of a cesarean delivery. Aron et al. conducted a retrospective cohort study to compare hospital cesarean delivery rates before and after adjusting for clinical risk factors that may increase the likelihood of cesarean delivery.

The Aron et al. (1998) study involved 21 hospitals in northeast Ohio. The study population was 26,127 women without prior cesarean deliveries who were admitted for labor and delivery from January 1993 through June 1995. The primary focus of the study involved hospital rankings based on observed and risk-adjusted cesarean delivery rates. The study reported an overall cesarean delivery rate of 15.9% and varied from 6.3% to 26.5% by hospitals. The risk-

adjusted rates varied from 8.4% to 22%, and the correlation between unadjusted and adjusted hospital rankings was not significant with $r = 0.35$, $p = .12$.

The risk factors that Aron et al.'s (1998) research team included in their study were based on prior studies and on the basis of the empirical association with cesarean delivery in the current population. The data used for the study were abstracted from medical records based on the study protocol. This study elected to include the clinical risk factors and did not include race and payer information. The researchers noted that the model discrimination based on the C statistic was no better with race and payer information factors than without them, but did not report the differences in the C statistics with either payer or race included. Aron et al.'s team elected not to include non-clinical factors because of the lack of evidence to suggest their importance as risk factors and because such factors may be associated with differences in healthcare delivery. The C statistic was reported as .84, indicating an excellent discrimination. The authors noted that interaction terms did not improve model performance and that the final model included 44 independent variables, representing 39 distinct risk factors. Aron et al.'s risk factors for cesarean delivery are included in Table 3 with the reported odds ratios and the 95% confidence intervals for each factor.

Table 3

Cesarean Risk Factors Identified by Aron, Harper, Shepardson, and Rosenthal

Variables included as risk factors	Adjusted Odds Ratios (95% CI)
Age:	Referent
18-20	1.08 (0.87-1.33)
21-24	1.51 (1.24-1.85)
25-28	1.94 (1.60-2.36)
29-33	1.89 (1.55-2.30)
34-38	2.43 (1.95-3.02)
>=39	3.20 (2.35-4.35)

Table 3 (continued)

Variables included as risk factors	Adjusted Odds Ratios (95% CI)
Nulliparity	5.39 (4.91-5.93)
Pre-existing comorbid condition:	
Diabetes Mellitus	2.70 (1.62-4.88)
Hypertension	2.06 (1.43-2.97)
Severe comorbid illness	1.81 (1.19-2.75)
Anemia	1.35 (1.12-1.62)
Thyroid disease	1.37 (0.94-2.00)
Lung disease	1.14 (0.92-1.42)
Tobacco use	0.99 (0.90-1.09)
Genital Herpes	3.93 (2.99-5.17)
Other sexually transmitted diseases	0.98 (0.78-1.23)
Gestational diabetes	1.70 (1.41-2.04)
Pregnancy related hypertension	1.64 (1.37-1.95)
Gestation > 42 weeks	3.00 (2.54-3.54)
Preterm delivery (<= 37 weeks)	0.92 (0.77-1.11)
Multiple gestation	1.21 (0.86-1.72)
Infant body weight > 4000 grams	2.08 (1.86-2.33)
Conditions arising during pregnancy:	
Genital Herpes	3.93 (2.99-5.17)
Other sexually transmitted diseases	0.98 (0.78-1.23)
Gestational diabetes	1.70 (1.41-2.04)
Pregnancy related hypertension	1.64 (1.37-1.95)
Gestation > 42 weeks	3.00 (2.54-3.54)
Preterm delivery (<= 37 weeks)	0.92 (0.77-1.11)
Multiple gestation	1.21 (0.86-1.72)
Infant body weight > 4000 grams	2.08 (1.86-2.33)
Obstetrical conditions:	
Breech presentation	58.23 (48.10-70.49)
Face & transverse presentation	21.61 (15.51-30.11)
Placenta previa	14.84 (10.14-21.71)
Umbilical cord prolapse	12.59 (7.34-21.60)
Abruptio placentae	8.11 (6.03-10.90)

Table 3 (continued)

Variables included as risk factors	Adjusted Odds Ratios (95% CI)
Eclampsia or preeclampsia	3.07 (2.50-3.77)
Third trimester bleeding	2.81 (2.31-3.71)
Oligohydramnios	2.35 (1.85-2.98)
Chorioamnionitis	2.31 (2.00-2.67)
Polyhydramnios	2.21 (1.40-2.04)
Intrauterine growth retardation	1.92 (1.41-2.62)
Fetal abnormalities	1.73 (1.03-2.92)
Premature rupture of membranes	1.78 (1.43-2.21)
Meconium staining or aspiration	1.55 (1.40-1.72)
Cervical incompetence	1.39 (0.86-2.34)
Premature labor	0.77 (0.64-0.93)
Admission findings:	
Maternal systolic blood pressure:	
> = 160 mm Hg	1.73 (1.35-2.23)
140-159 mm Hg	1.07 (0.96-1.19)
Maternal heart rate > = 100 beats/min	1.20 (1.09-1.33)
Fetal heart rate:	
> = 160 beats/min	1.24 (1.01-1.52)
< 120 beats/min	1.09 (0.91-1.30)
Hemoglobin < 90 g/L	1.47 (1.02-2.12)

Note. From "Impact of risk-adjusting cesarean delivery rates when reporting hospital performance," by D. Aron, D. Harper, L. Shepardson, and G. Rosenthal, 1998, *JAMA*, 279(24).

Additionally, the Aron et al. (1998) study examined non-clinical characteristics, reporting an overall rate of cesarean delivery that was similar in white and non-white patients (15.8% and 16.1%, respectively), but rates varied by payer, with insured patients experiencing higher rates of cesarean (17.0%) and uninsured patients experiencing lower rates (10.7%). However, after the researchers adjusted for clinical factors, the adjusted odds ratios of cesarean delivery was higher

in non-white patients (OR = 1.34; 95% CI: 1.14-1.57; $p < .001$) and lower for uninsured patients (OR = .65; 95% CI: 0.41-1.03); $p = .067$).

The study concluded that cesarean delivery rates varied across hospitals in a single metropolitan region and that controlling for risk factors is critical when examining differences in provider performance. The major finding of the study was that rankings which fail to account for clinical factors that increase the risk of cesarean delivery may be methodologically biased and misleading to the public.

Keeler et al. (1997) conducted a study to describe the issues of developing a predictive model for adjusting cesarean delivery rates for the purpose of reporting cesarean rates by risk adjusted case mix and to compare the model's performance to other simpler predictors using clinical and statistical criteria. The researchers used a database comprised of Washington state hospital discharge data merged with the birth certificate records. The study population included singleton births greater than 2,500 grams in 80 hospitals in Washington state during 1989 and 1990 for whom mother's and infant's hospital discharge records could be matched to birth certificate data. The researchers stratified the sample population into four groups for modeling risk of cesarean delivery: (a) prior cesarean delivery, (b) malpresentation without prior cesarean delivery, (c) first birth without malpresentation, and (d) all other deliveries. They subsequently developed separate multivariable models for each group based on clinical variables documented in both the birth certificate and the hospital discharge data. Keeler et al. (1997) concluded that differences between adjusted and unadjusted rates were "small," but did not provide the detailed statistical results of what constitutes "small."

One of the principal findings of the study was that the merged data (birth certificate and hospital discharge data) led to better predictor variables than models based on one source. Keeler's study included a four-category classification including: births with prior cesarean,

breech but no prior cesarean, first birth, and other. Keeler reported that the variables explained 30% of the variance in individual cesarean rates. The full clinical model based on abstracted medical records fit the data well and explained 37% of the variance. Multiparas without serious complications comprised 35% of the mothers and averaged less than 2% of the cesareans.

This study is pertinent to the reported study for several reasons. First, the Keeler data source used a database of merged hospital discharge data and birth certificate data, as was done in the reported study. Additionally, the researchers performed data validity checks prior to embarking on the study, using cross checks to examine agreement for key variables of interest in both data sets. Kappa scores were reported for total cesarean at .96. The researchers also noted that they elected to use either source if one source indicated the case was a cesarean delivery, stating that most errors were errors of omission. The reported Kappa score for prior cesarean delivery was 0.83. The agreement score on both sources for breech delivery was .52. As with cesarean delivery, if either source indicated a breech delivery, the researchers coded it as breech.

The second interesting element of this study was the researchers' decision to omit race and ethnicity and other non-clinical factors such as hospital characteristics and payer. This was similar to the Aron et al. (1998) study. The researchers indicated they wanted to examine the effect of race *after* they adjusted for clinical risk. Similar to the Aron et al. (1998) study, Keeler's team also elected not to use the procedure information such as tocolysis, induction of labor, and electronic fetal monitoring because they believed the procedures involved practice management decisions. They did not want to report risk-adjusted rates for cesarean, adjusting for physician practice management decisions. The study also did not adjust for hospital characteristics. One might assume this omission was due to the same reason (e.g., hospital characteristics might reflect provider's management style rather than clinical risk). The models reported in this study

appeared to clearly focus on *clinical* risk adjustment for cesarean delivery and prediction (Keeler et al., 1997).

Again, comparison of the Keeler et al. (1997) study to the reported study is warranted. This inquiry adjusted for hospital characteristics, and the key focus area was induction of labor and the effect on cesarean delivery. Or, precisely, the focus of the reported study was to examine the practice decision to induce a woman's labor compared to those not induced in order to determine the impact of that practice decision on a woman's delivery outcome. Clinical factors that were clearly a risk for cesarean were excluded to separate the effect of the clinical risk factors from the decision to induce. The Keeler et al. (1997) and Aron et al. (1998) research teams created predictive models, whereas the reported study is a risk modeling study isolating the effect of labor induction on the odds of a primary cesarean delivery.

The Keeler et al. study also reported strong interactions between the categories (births with prior cesarean, breech but no prior cesarean, first birth, and all other) and the independent risk factors reported in Table 4. Unfortunately, they did not report details on the specific variables that interacted. This was interesting because Aron et al. (1998) reported not having found any significant interaction terms. The researchers elected to fit separate models for each of the four clinical categories, and they reported that logistic regression models fit poorly but that probit regression models led to "satisfactory" models. They also reported having fit a quadratic function for birth weight and age as a linear spline with hinge points at 16 and 39 years of age (Keeler et al., 1997).

Table 4

Keeler et al. (1997) Risk Factors for Adjusting Cesarean Rates

Variables included as risk factors

Age:

Linear spline with hinge points at ages 16 and 39

Any medical or obstetrical risk created one dichotomous variable:

Anemia
cardiac disease
acute or chronic lung disease
diabetes (Pregnancy or gestational)
genital herpes
Polyhydramnios
Oligohydramnios
Hemoglobinopathy
hypertension (chronic or pregnancy associated)
Eclampsia
incompetent cervix
previous infant 4,000+ grams
Preterm
small for gestational age

Fetal conditions:

Polyhydramnios
oligohydramnios
Rh-sensitizations

Placenta or cord problems:

abruptio placenta
placenta previa
cord prolapse
Breech
first birth
2nd, 3rd, & 4th birth (as opposed to 5+)
interval between births < 1.5 or > 4 years
baby birth weight (quadratic function)
male infant

missing risk
hypertension

Table 4 (continued)

Variables included as risk factors
pre-pregnancy diabetes
gestational diabetes
active herpes
amnionitis
serious congenital anomalies
weeks gestation (entered as a linear term)
post dates (≥ 42 weeks)
admission year

Note. From “Adjusting for cesarean delivery rates for case mix,” by E. Keeler, R. Part, D. Gifford, & J. Keeseey, 1997, *Health Services Research*, 32(4), 511-528.

Keeler et al. also grouped risk factors into two dichotomous variables: one for maternal risk, and the other for fetal conditions. Keeler et al. reported that the research team elected to place a risk factor in the model if there was evidence in the scientific literature that the factor “clinically” contributed to cesarean delivery or if the rate of cesarean was high for that particular factor within their Washington deliveries for the 2-year period. Keeler et al. noted that he controlled for practice changes over the 2-year period by creating a year variable from the admission date. The final set of variables that Keeler et al. used is listed in Table 4. Note that Keeler apparently accounted for risk factors more than once. For example, the study appeared to place hypertension in the “any medical or obstetrical risk” aggregated variable, which is defined as a dichotomous variable created with the presence of one or more of the numerous risk factors identified as a “1” for *yes*, otherwise “0” (indicating the risk factors were not present). Similarly, diabetes and gestational diabetes appeared to be in both the aggregated risk factor and as individual factors (Keeler et al., 1997).

The Keeler et al. study (1997) is similar to another more recent study. Keeler et al.'s stratification methods were similar to a Pennsylvania study done by the Pennsylvania Healthcare Cost Containment Council (PHC4), where the high-, moderate-, and low- risk cesarean categories were stratified and cesarean rates reported by the stratified risk categories. There also were notable differences in the two studies.

The PHC4 study (2002) was done using 1999 Pennsylvania hospital discharge data and a similar stratification method to that used by Keeler et al. (1997). The study involved 142 acute care hospitals in the state of Pennsylvania. The research created six categories for reporting on cesarean delivery, including: (a) total cesarean rate, (b) high risk for cesarean rate, (c) low risk for cesarean rate, (d) repeat cesarean delivery rate, (e) repeat cesarean delivery rate in low risk deliveries, and (f) VBAC.

The report indicated that after a review of the literature on cesarean delivery and input from hospitals in Pennsylvania, PHC4 selected this alternative method for reporting on cesarean deliveries for their state's "report card." Historically, the Council had reported cesarean delivery rates collectively and without any apparent control for risk.

The methods used were to identify cases that were at high risk for cesarean delivery and to create risk categories. The risk factors selected for the high risk category are listed in Table 5 and include malpresentation, obstructed labor, premature separation of the placenta, severe pre-eclampsia, placenta previa, and prolapsed cord. The low risk for cesarean delivery category excluded all of the diagnoses listed as high risk. VBAC rate was defined by a vaginal delivery after having had a previous cesarean delivery divided by the total number of obstetrical deliveries that had a prior cesarean delivery. The low risk category was identified and then reported by two rates, the first by a low risk for cesarean delivery category, excluding prior cesarean delivery, and the second by low risk delivery category for repeat cesarean.

The PHC4 report indicated that the five conditions of breech, prolapsed cord, placenta previa, pre-eclampsia, and premature separation of placenta also were used in a Maine Medical Assessment Foundation (MMAF) analysis. PHC4 assessed the data for Pennsylvania births and noted the high rate of cesarean delivery for the five conditions identified by MMAF. It was noted that Pennsylvania deliveries showed high rates of cesarean for four additional conditions which included malpositions of transverse or oblique presentation, face or brow presentation, high head at term, and unspecified malposition. The decision was made to include those additional factors as high-risk diagnoses. Therefore, the high-risk category had the 10 high-risk conditions listed in Table 5, with statistics and operational definitions using ICD-9-CM codes.

This method is interesting in light of the reported study for four reasons. First, the creation of the low risk category was an important concept, given the intent of the study to identify those cases that have a low risk of cesarean delivery and examine the effect of labor induction on those deliveries. Second, it is interesting that the PHC4 methods did not control for any other factors such as demographic client characteristics. Third, the researchers selected a simple stratification approach rather than multivariable logistic regression. Fourth, the report broke the various rates into regions of Pennsylvania and also reported by payer. Again, stratification methods were employed. So, the researchers controlled for regional bias and payer effect, but not other client characteristics such as race, ethnicity, or system characteristics such as hospital characteristics (ownership, bed size, rural versus urban, or teaching status). Findings of the study were also interesting, indicating that once the patients were separated into high and low categories (within the 6 categories above), Medicaid recipients had the lowest cesarean rates and the highest vaginal birth after cesarean delivery among major payer groups. Additionally, the report indicated that there was significant variation in the cesarean rates among hospitals, even after separating the deliveries into the risk groups.

Table 5

Risk Factors Used by the State of Pennsylvania to Report Cesarean Deliveries

Variables included as risk factors	ICD.9.CM Codes	# of Cases	% of Cases	Cesarean Rate
Malpositions:				
Obstruction from malpositioned fetus at onset of labor	660.01	1,041	0.70%	92.90%
Malposition, high head at term	652.51	1,527	1.10%	88.70%
Malposition, breech	652.21	4,875	3.50%	88.10%
Malposition, transverse or oblique presentation	652.31	969	0.70%	77.20%
Malposition, face or brow presentation	652.41	222	0.20%	65.80%
Malposition, unspecified malposition	652.91	93	0.10%	62.40%
Placenta previa	641.01 or 641.11	624	0.40%	81.30%
Prolapsed cord	663.01	536	0.40%	63.80%
Pre-eclampsia (severe)	642.51	1,083	0.80%	62.30%
Premature separation of placenta	641.21	1,664	1.20%	50.40%

Note. From "C-Section Deliveries in Pennsylvania," by Pennsylvania Healthcare Cost Containment Council, 2001, Technical Notes retrieved September 21, 2003 from www.phc4.org.

The contrast between the Keeler and the PHC4 studies was interesting to examine. The Keeler et al. study employed a sophisticated study design that involved both stratification methods and control for risk using modeling techniques. The analysis required some complex and

time-consuming statistical modeling techniques, including tests for interaction, data transformations, and examination of different models to determine the final probit approach that best fit the data. The PHC4 study, on the other hand, utilized a straightforward approach that made it easy for most individuals to understand precisely what was done to control for the various factors impacting the cesarean delivery rates. The PHC4 study was much less time consuming for the analysts and more than likely did a fair job of controlling for risk. The stratification methods were traditional epidemiologic methods often used to control for the effect modification seen with interaction between variables. Both Keeler et al. (1997) and the PHC4 (2001) methods merit consideration.

Yet another study in contrast to the PHC4 findings was a study done by Dobie, Hart, Fordyce, Andrilla, and Rosenblatt (1998) examining whether Medicaid-insured women in Washington state with low-risk obstetrical care received less adequate obstetrical care than privately insured. Dobie et al. (1998) defined low risk as being from 18 through 34 years of age at entry into care and having private insurance or Medicaid coverage, a first prenatal visit during the first trimester, no more than three previous live births, no prior still births, not more than four previous spontaneous abortions before 14 weeks gestation, no previous births of less than 36 weeks gestation, no prior obstetrical complications (e.g., gestational diabetes, preterm labor, etc.,) or cesarean delivery, no history of alcohol or drug abuse, and no history of concurrent major medical conditions (e.g., hypertension).

The Dobie et al. (1998) team used a complex sampling methodology (not reported in the study overview) and utilized Sudaan for the random effects model. The total study sample was 2,054 births occurring in Washington state from September 1988 through August 1989. After controlling for patient, practice, and provider characteristics, the researchers did not show significant differences for low-risk Medicaid women with the relative risks being 1.04, 1.09, and

1.03 for total, prenatal and intrapartum resources respectively, with none of the findings being significant ($p > .05$). The intrapartum resources included evaluation of labor induction compared to spontaneous labor. The researchers reported weighted estimates for the Medicaid compared to privately insured groups with induction rates for Medicaid being 14.7 and privately insured being 18.4 and the total 19.9 (CI: 14.9-20.9). The researchers reported that vaginal delivery rates did not differ between the groups with 71.9% of Medicaid women delivering vaginally, and 68.9% of the insured women delivering vaginally. It is interesting to note that the researchers indicated the study was limited by power with an $n = 363$ for the low-risk Medicaid population, researchers pointed out that a high proportion of the Medicaid population were high risk obstetrical cases, which may account for differences that other studies such as the PHC4 study demonstrated. The PHC4 was limited by controlling for the six categories of risk upon which they stratified and it was likely that the populations had additional risk factors which they did not account for but which may have been accounted for in the Washington state study done by Dobie et al. (1998).

Koroukian, Trisel, and Rimm (1998) conducted a study utilizing Ohio birth certificate and Medicaid data. This study sought to investigate the proportion of cesareans that might have been done unnecessarily. One of the key objectives of the study was to present a method that estimates the proportion of unnecessary cesarean deliveries using birth certificate data. The study was a population-based cross-sectional study using two databases, Ohio birth certificates and Medicaid eligibility files. The study cohort was singleton deliveries born during the period of July 1991 through June 1993. The total sample size was 262,013.

There were 57 independent variables reported that might be indicative of adverse events, including maternal medical risk factors, complications of labor and delivery, and congenital anomalies that are available on the birth certificate. Each independent variable was examined to estimate the rate of “unnecessary” cesarean deliveries. The study reports that approximately 40%

of the repeat cesareans had no documented abnormalities on the birth certificate to justify cesarean delivery. The researchers conclude that other studies utilizing medical records have yielded similar results, and therefore they believe that this justifies the use of birth certificate data as a reliable method to measure and monitor the rate of unnecessary cesarean deliveries.

The Koroukian team's study examined both repeat and primary cesarean delivery, but elected to focus significant attention on repeat cesareans. The author's defined "unnecessary cesarean deliveries" as "repeat cesarean deliveries with no reported or documented complications justifying a decision to deliver by cesarean" (p. 1327). This definition has become controversial due to reported complications with vaginal birth after previous cesarean delivery.

VBAC deliveries have also become a controversial issue due to two recent reports of uterine ruptures (Rageth, Juzi, & Grossenbacher, 1999; Shipp, Zelop, Repke, Cohen, & Lieberman, 2001). The Koroukian group recommended abandoning a policy of routine repeat cesarean deliveries. Given this issue has become controversial in the last few years, the reported study did not address the repeat cesarean delivery and eliminated all women with prior history of cesarean delivery.

The Koroukian group also utilized an algorithm linking mother and baby records using the mother's and the infant's last name, first name, date of birth, and county of residence. The linkage criteria also were similar to the criteria for the reported research data file of birth certificate and hospital discharge data. The Koroukian team reported a match rate of mother to baby record of 83%.

One other feature of note is that the study design controlled for hospital characteristics, identifying teaching and non-teaching facilities, as did the reported study. Teaching facilities were defined as a hospital approved to participate in residency training by the Accreditation Council for Graduate Medical Education and reported within the American Hospital Association

Guide to Healthcare in 1993. Additionally, geographic regions of Ohio were differentiated as to urban and non-urban. The reported study utilized similar criteria for controlling for hospital characteristics. Finally, using logistic regression to analyze medical and non-medical factors to predict a primary or repeat cesarean delivery is also the major analytic statistical method in the researcher's reported study. Because this study explains rather than predicts the researcher, used a different approach to logistic model building than that used in the Koroukian et al. study. The reported study uses risk modeling techniques rather than predictive modeling techniques.

The Koroukian et al. study stratified primary and repeat cesareans with separate models to address each of the outcome variables. The researchers identified all factors with more than a 2.5% prevalence rate in the entire population, meaning that the factor was present in 2.5% of the sample in order to be included as a risk factor. The authors reported the use of the C statistic (a measure of concordance) to measure the ability of the model to discriminate, explaining that they elected not to use any variables with less than a 2.5% prevalence rate in the total study population because (according to the researchers) including variables with lower prevalence did not improve the model's predictive ability. The medical factors included in the model were (a) pregnancy-associated hypertension, (b) "other" medical risk factors for the mother, (c) meconium, (d) premature rupture of membranes, (e) breech or fetal malpresentation, (f) cephalopelvic disproportion, (g) fetal distress, (h) "other" complications of labor and delivery, (i) prematurity, and (j) birth weight greater than 4,000 grams.

The non-medical variables introduced into the model were (a) the hospitals' teaching status, (b) eligibility for Medicaid at the time of delivery, and (c) maternal age. Other factors included were race, education and residence in urban counties. The odds ratios for primary cesarean delivery were most notable in this study, with teaching hospital and Medicaid eligibility lowering the likelihood of a cesarean delivery with odds ratios reported as .92 (95% CI: 0.89,

0.95) and .79 (95% CI: 0.76, 0.81), respectively. Additionally, this study also demonstrated that maternal age greater than 35 years increased the likelihood of a cesarean delivery with an odds ratio of 1.24 (95% CI: 1.18, 1.31) reported. All other variables in the model were significant predictors and increased the odds of a cesarean delivery. The most notable odds ratios were reported with breech or other malpresentation with an odds ratio of 127.55 (95% CI: 118.02, 137.84) cephalopelvic disproportion with an odds ratio of 541.09 (95% CI: 459.32, 637.44). Fetal distress also had a high odds of cesarean delivery reported with an odds ratio of 14.54 (95% CI: 13.89, 15.23) (Koroukian et al., 1998).

Induction of Labor

Physiologic Onset of Labor

The onset of labor is not well understood, but is thought to involve three key physiologic processes. The first is hormonal factors that cause an increased uterine contractility that is believed to be a result of a ratio of estrogen to progesterone. Progesterone inhibits contractions of the uterus during pregnancy. Estrogen increases the degree of uterine contractility. Progesterone and estrogen are secreted in progressively increasing amounts throughout pregnancy. From approximately the 7th month on, estrogen secretion continues to increase, while progesterone remains constant, or may even decrease. It has been proposed that the estrogen to progesterone ratios increase sufficiently toward the end of pregnancy to be partially responsible for the increased contractility of the uterus (Guyton, 1986).

The second factor believed to be responsible for the spontaneous onset of labor is the effect of oxytocin on the uterus. The neurohypophysis secretes oxytocin, a hormone that specifically causes uterine contractility (Guyton, 1986). The uterine myometrium and decidua contain receptor sites for oxytocin. Oxytocin works to stimulate the physiologic smooth muscle contractile response by increasing myometrial cell membrane permeability to the sodium ion,

thus increasing the number of contracting myofibrils. Although oxytocin occupies myometrial and decidual receptor sites during labor, for some unknown reason, the uterus is not in a constant state of contraction but ebbs and flows with rhythmic and coordinated contractions (Clayton, 2000). There are four reasons that oxytocin is believed to be responsible for uterine contractility. First, the uterus increases responsiveness to oxytocin in the later parts of pregnancy. Second, the rate of neurohypophysis secretion of oxytocin is considerably increased at the time of labor. Third, a redelivery of the hypophysis in humans increases the length of labor for humans. Fourth, clinical research on animals has indicated that the stretching of the cervix, which occurs during labor, increases the neurogenic reflex that creates an increased release of oxytocin.

The third factor that may account for spontaneous onset of labor is the effect of fetal hormones on the uterus. The pituitary gland of the fetus secretes increasing amounts of oxytocin that might be responsible for exciting the uterine contractility. The fetal adrenal gland plays a role with the secretion of large quantities of cortisol that also may create uterine stimulation. The fetal membranes release prostaglandins in high concentration at the onset of labor that also may increase the uterine contractility (Guyton, 1986).

In addition to the physiologic factors believed to be responsible for the spontaneous onset of labor, there also are mechanical factors that may play a role. The stretching of the smooth muscle organs physiologically excites contractility. The intermittent stretch, as with the ebb and flow of the uterus in response to fetal movement, elicits smooth muscle contraction.

An additional mechanical factor believed to be particularly responsible for the onset of spontaneous labor is the natural process that occurs in the later stages of pregnancy preparing the cervix for delivery. The stretching of the cervix and irritation as the infant descends may create a natural response increasing uterine contractility. The actual physiologic reason for this is unknown. This response is often demonstrated when obstetricians artificially rupture the

membranes so that the head of the baby stretches and irritates the cervix more forcefully. It has been purported that when irritated, the cervical nerves stimulate the body of the uterus creating a stimulant effect that initiates or increases the uterine contractility (Guyton, 1986). This response is seen with the artificial rupture of membranes by obstetricians as a means of stimulating the onset of the natural laboring process.

The actual onset of labor is theorized to be the response of physiologic positive feedback loops. During most of the months of pregnancy the uterus contracts with Braxton-Hicks contractions, which are slow rhythmic contractions of the uterus. These contractions become progressively stronger toward the end of pregnancy. The Braxton-Hicks contractions change rather suddenly, usually within hours, to become stronger contractions that start stretching the birth canal. The physiologic mechanism that creates this sudden change is largely unknown. However, one theory is that the stretch of the cervix by the fetal head finally becomes great enough to elicit strong reflexes that increase the contraction of the body of the uterus. This pushes the baby forward eliciting more stretch of the cervix, initiating more stimulation and stronger contractions of the uterus. This phenomenon is believed to be a positive feedback loop because labor contractions follow all the principles of positive feedback; that is, once the uterus begins to stretch, the uterine contractions become greater than some critical value, each contraction leads to subsequent contractions that become increasingly stronger until they reach their maximum.

The actual feedback loop is considered to be two stage. The first stage is the stretch of the cervix increasing uterine contractility that propels the fetus forward, creating more excitement and continuing until the baby is delivered. The second stage to the feedback loop is the cervical stretch stimulating oxytocin release, thereby further increasing uterine contractility (Guyton, 1986).

The pain of childbirth is a result of the contractions of the uterus and the birth canal. The pain response is believed to elicit a neurogenic reflex from the spinal cord to the abdominal muscles creating intense contractions of the abdominal muscles. The result of abdominal contractions is further force that causes expulsion of the baby. Additional mechanical responses involve the location of the uterine contractions. The uterus contracts during labor at the top or fundal segment, spreading downward. The strength of the contraction is greater at the top and body of the uterus and weaker in the lower portions of the uterus closer to the cervix. The contractions in the top of the uterus force the infant down into the weaker segments of the body of the uterus, forcing the baby towards the cervix and into the birth canal.

Early stages of labor contractions occur approximately 30 minutes apart, and towards the later stages as close as 1 to 2 minutes apart. The combined uterine and abdominal muscle contractions create approximately 25 pounds of pressure or force during each strong working contraction. The natural birthing process creates an intermittent contractile response. This is important to the birthing process because during strong contractions the blood flow may be impeded through the placenta and can create problems with over-stimulation of the uterus (Guyton, 1986). In fact, using oxytocin intravenous drips to artificially induce labor can over-stimulate the uterus and create blood flow problems to the fetus, resulting in fetal heart rate decelerations (Schellpfeffer, Hoyle, & Johnson, 1985).

One additional physiologic change supporting the birthing process that occurs toward the end of the pregnancy is the softening and dilatation of the cervix. The cervix begins to soften, allowing for the stretch of the cervix and descent of the head as labor contractions become more efficient in later stages of labor (Guyton, 1986). The result is that the contractions moving the baby's head forward act on the cervix to dilate the cervix such that the baby can pass through the birth canal.

In 1964, Edward H. Bishop, M.D. proposed a method for evaluating the woman's "readiness" for labor and proposed a scoring mechanism for determining if the woman is a good candidate for an induced labor (Bishop, 1964). The Bishop score is comprised of many of the factors believed to be physiologically and mechanically in support of the birthing process. Developed by Bishop in the 1960s, the Bishop score is frequently used as a quantifiable measure in assessing feasibility and predicting success of labor induction (Leveno et al., 2003).

There are five components of the Bishop score: dilatation of the cervix, effacement, station of the fetus, consistency of the cervix, and position of the fetal head. Each of the five components is scored with a rating of 0 through 3 for dilatation, effacement, and station, and a score of 0 through 2 for consistency and position. The total combined score of the five components constitutes a guide for determining the proximity of spontaneous onset of labor. Bishop concluded that a score of 9 or better, represented appropriate criteria for successful induction of labor (Bishop, 1964).

Oxytocin occurs naturally (the endogenous form of oxytocin) and is secreted by the woman and fetus during labor. Oxytocin also is available in synthetic form (the exogenous form of oxytocin) and is used to artificially stimulate labor with artificial induction of labor. Both the endogenous and exogenous form of oxytocin work according to the same mechanism. During the first stage of spontaneous labor, the maternal circulating concentrations of endogenous oxytocin are approximately what would be achieved with a continuous infusion of exogenous oxytocin at 2-4 mu/min. The additional oxytocin, believed to be the response of the fetal secretions during labor, is considered to be similar to an infusion of oxytocin at approximately 3 mu/min. The result of the combined effects of maternal-fetal contribution to maternal plasma oxytocin concentration is the equivalent of an infused range of approximately 4 to 6 mu/min (Clayton, 2000).

With artificial labor induction the synthetic or exogenous oxytocin is administered intravenously at an ordered starting dose determined by the obstetrician and then, at predetermined intervals (by order and/or hospital policy), the dose is increased until an adequate contraction pattern is achieved (Clayton, 2000; Guyton, 1986). The protocols and policies of institutions are based on the theoretical foundation of the physiologic and anatomical changes that occur towards the later stages of pregnancy. Artificial induction of labor is a means of creating the same physiologic and anatomical response by medical intervention. Unfortunately, this process is not always successful with failed induction of labor resulting in a cesarean delivery.

The model in Figure 4 was developed based on the physiologic phenomenon of labor onset presented above, from consideration of the Health Outcomes Model and from consideration of the influences of the client and system characteristics present, namely effect modifiers and confounders that may impact the effect of labor induction on the odds of primary cesarean delivery such as parity, gestation, the weight of the baby, and failure to progress (Dublin et al., 2000). The model in Figure 4 proposes controlling for factors, which potentially modify the effect or confound the relationship of labor induction and primary cesarean delivery.

As with cesarean delivery rates, induction of labor in the United States also is rising steadily. The trend was first identified when birth certificate data became available in Martin et al., 2002). There is consensus in the healthcare industry that induction of labor are often done for non-medical reasons related to issues of convenience (McCloskey et al., 1992). The “Breakthrough Series” on reducing cesarean delivery rates initiated by the Institute on Healthcare Improvement in 1997 identified failed induction of labor as a key area for improvement in reducing cesarean delivery rates (Flamm et al., 1998). Yet the literature surrounding the relationship between induction of labor and cesarean delivery can be misleading due to the multiple factors that influence a decision to perform a cesarean delivery.

Background Information on Induction of Labor

Theobald and colleagues first described the use of oxytocin administered intravenously for induction of labor in 1948. This use was followed five years later by Du Vigneaud and associates synthesizing the first oxytocin, a polypeptide hormone (ACOG, 1999). Oxytocin is the one of the most commonly used drugs in the United States. Induction of labor is similar physiologically to the process of spontaneous labor; however, individual women vary with response and sensitivity (Satin, Leveno, Sherman, Brewster, & Cunningham, 1992; Satin, Leveno, Sherman, & McIntire, 1991). In a study examining the plasma oxytocin levels during infusion of oxytocin, Seitchik, Amico, Robinson, and Castillo (1984) demonstrated that uterine contractions usually begin after 3 to 5 minutes of infusion of oxytocin with a steady state of plasma levels reached by 40 minutes. Additionally, the actual response of the uterus increases with duration of pregnancy, with a gradual increase at 20 to 30 weeks of gestation. At approximately 34 weeks gestation and until term, there is a plateau with sensitivity of response to oxytocin rapidly increasing at term (Cunningham et al., 1997).

Research on augmentation of labor and induction of labor is often inconclusive with regards to how much oxytocin to use and what protocol is best (Satin, Leveno, Sherman, & McIntire, 1992; Xenakis et al., 1997). These issues further complicate the understanding of the relationship between induction of labor and failure to progress. Findings from a study examining oxytocin and the predictability of response done by Satin et al. (1992) demonstrated that the mechanism of action for oxytocin are not fully understood, and therefore unpredictable. The Satin et al. study (1992) was a retrospective study using clinical data collected for a previous study examining 1,773 pregnancies delivered at Parkland Memorial Hospital in Dallas, Texas from 1990 to 1991. Satin et al.'s research team (1992) focused their research on developing a predictive model that would provide information to obstetricians for the maximum therapeutic dose of

oxytocin to successfully deliver a non-complicated birth vaginally. Independent variables examined as predictors included cervical dilatation, parity, and gestational age. The findings indicated that these independent variables are predictive of successful induction of labor but could not be used to adequately create a predictive model that would serve as a guide for maximum oxytocin dosage for successful induction of labor due to the wide confidence interval around the maximum dosages predicting successful delivery.

The Satin team's study (1992) found that statistically significant predictors of dose response of oxytocin were three factors. Satin and colleagues studied 1,773 pregnancies and oxytocin dosage necessary for adequate labor stimulation and found that predictors of dose response to oxytocin for labor stimulation were: (a). gestational age, (b). parity, and (c). cervical dilation. Maternal body surface area and higher oxytocin usage was found to be associated *only* with women undergoing induction of labor in contrast to women that were augmented (Satin et al., 1992). Of the three predictive factors, cervical dilation is not within the data for the reported study; however, gestational age and parity are controlled for within the reported study.

The team further concluded that until the pharmacokinetics of oxytocin are better understood, each woman and her response to oxytocin will have to be set based on the woman's individual response, rather than a prescribed approach. This study provided supporting evidence that the mechanism for onset of labor and the effect of oxytocin, either naturally occurring or artificially induced are not entirely understood. It is important to better understand factors that either positively or negatively influence a successful induction of labor. A clearer understanding of those factors may contribute to an improved ability to manage obstetrical outcomes.

The ACOG (1999) issued a clinical guideline for induction of labor. Methods for labor induction listed in the ACOG guidelines are membrane stripping, amniotomy, and administering

prostaglandin E (PGE) analogues. Maternal and fetal indications for induction of labor also are outlined in the ACOG guidelines and are listed in Table 6.

Table 6

Maternal and Fetal Conditions for Induction of Labor

Conditions for Induction of Labor

Abruption placentae

Chorioamnionitis

Fetal demise

Pregnancy-induced hypertension

Premature rupture of membranes

Postterm pregnancy

Maternal medical conditions (e.g., diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension)

Fetal compromise (e.g., severe fetal growth restrictions, isoimmunization)

Preeclampsia, eclampsia

Note. Indications for induction of labor noted in the *Clinical Guidelines for Induction of Labor* (ACOG, 1999).

Gabbe, Niebyl, and Simpson (2002) listed “absolute indications” and “relative indications” for induction of labor. The absolute and relative indications for induction of labor are listed in Table 7. Gabbe et al. (2002) also defined elective induction of labor as termination of pregnancy without an acceptable medical indication, and cautioned against elective induction of labor being done for convenience to the patient and practitioner. Reasons for caution include potential complications such as iatrogenic prematurity and the possible increase in the risk of cesarean delivery. However, this obstetrics text also states that delivery after 41 weeks gestation may not be associated with an increased risk of cesarean delivery emphasizing that the success rate will depend on the status of the cervix, which is more likely to be ready for labor beyond 41

weeks gestation (Gabbe et al., 2002). The ACOG (1999) also indicated that labor may be induced for logistic or anticipatory reasons including such things as history of rapid labor, distance from the hospital, or psychosocial indications. With these indications ACOG advises that confirmation of gestational age be established.

Table 7

Indications for Absolute and Relative Indication

Absolute Indication	Relative Indication
Maternal indication	Chronic hypertension
Preeclampsia/eclampsia	Gestational diabetes
Pregnancy-induced hypertension	Logistic factors
Maternal medical problems	Risk of rapid labor
Diabetes mellitus	Distance from hospital
Chronic pulmonary disease	Psychosocial indications
Chronic renal disease	Premature rupture of membranes
Fetal indications	Fetal macrosomia
Chorioamnionitis	Fetal demise
Abnormal fetal testing	Previous stillborn
Intrauterine growth restriction	Fetus with a major congenital anomaly
Postdate pregnancies (> 42 weeks)	Unexplained oligohydramnios
Uteroplacental indications	
Placenta abruption	

Note. From *Obstetrics: Normal and problem pregnancies* (4th ed.) by S. Gabbe, J. Niebyl, & J. Simpson, 2002, New York: Churchill Livingstone.

The ACOG (1999) outlines clinical contraindications for induction of labor, which are listed in Table 8. Should any of these clinical conditions be present, ACOG recommends careful consideration prior to induction of labor. Contraindications for induction of labor will be

identified using ICD-9-CM diagnosis codes and excluded from the study within the high risk for cesarean delivery risk factor, because these factors also are associated with high risk for cesarean delivery. The indications for induction of labor also will be identified by ICD-9-CM codes and included as a risk factor aggregated into the “medical indication for induction” variable (see Appendix C for detail definitions of this factor).

Table 8

Contraindications for Induction of Labor

Contraindications
One or more previous low-transverse cesarean
Breech presentation
Maternal heart disease
Multifetal pregnancy
Polyhydramnios
Presenting part above the pelvic inlet
Severe hypertension
Abnormal fetal heart rate patterns necessitating emergent delivery

Note. From “Clinical Management Guidelines for Obstetrical-Gynecologists: Induction of Labor,” by ACOG, November 1999, *ACOG Practice Bulletin* No. 10.

Studies Examining the Effects of Labor Induction on the Risk of Cesarean Delivery

Seyb et al. (1999) conducted a study to quantify the risk of cesarean delivery associated with elective induction of labor in nulliparous women at term. The study focused on a very specific patient population in a major urban hospital serving predominantly private obstetric practices. The study cohort was all term, nulliparous women with vertex, singleton pregnancies that delivered during an 8-month period. The study population was 1,561 women, divided into three groups: (a). spontaneous labor, (b). elective induction of labor, and (c). medical induction of labor. The research team conducted a pilot over a 1-month period with 224 nulliparous women to perform a power calculation. The ratio of spontaneous labor to elective induction of labor for cesarean delivery rates was 9% and 18%, respectively. The power analysis (α was set at .05 and power at 80%) estimated a sample size of 1,220 would be needed to detect a two-fold difference (9% versus 18%) in cesarean rates. Stepwise logistic regression was used to create a final model of risk factors with a $p < .05$ for entry of a variable into the model.

The Seyb et al. (1999) study results indicated that women experiencing spontaneous labor had a 7.8% cesarean delivery rate, whereas women undergoing elective labor induction had a 17.5% cesarean delivery rate (adjusted odds ratio of 1.89; 95% CI: 1.12, 3.18) and women undergoing medically indicated labor induction had a 17.7% cesarean delivery rate (adjusted odds ratio of 1.69; 95% CI: 1.13, 2.54). Other independent variables identified as significant ($p \leq .05$) risk contributors to cesarean delivery included epidural placement at less than 4 cm dilatation (adjusted odds ratio of 4.66; 95% CI: 2.25, 9.66), chorioamnionitis (adjusted odds ratio of 4.61; 95% CI: 2.89, 7.35), birth weight greater than 4000 g (adjusted odds ratio of 2.59; 95% CI: 1.69, 3.97), maternal body mass index greater than 26 kg/m² (adjusted odds ratio of 2.36; 95% CI: 1.61, 3.47), Asian race (adjusted odds ratio of 2.35; 95% CI: 1.04, 5.34), and magnesium sulfate

use (adjusted odds ratio of 2.18; 95% CI: 1.04, 4.55). The researchers concluded that elective induction of labor is associated with a significantly increased risk of cesarean delivery in nulliparous women, and recommended that avoiding labor induction in cases with an unproven benefit to mother or baby may aid efforts to reduce the primary cesarean delivery rate (Seyb et al., 1999).

Alexander et al. (2001), in a prospective observational study of 1,325 women using clinically collected data from 1997 to 2000, concluded that risk factors intrinsic to the patient, rather than labor induction itself, were the cause of excess cesarean deliveries in women with prolonged pregnancies. The group reported that a limitation of the study was inadequate sample size. They estimated by power analysis that they would have needed 5,200 patients for a reliable study and their sample size contained 1,325 cases. The findings in this study are interesting in that nulliparity, undilated cervix prior to labor, and epidural analgesia were the risk factors for cesarean delivery identified in the study. This study was limited in scope, examining women who reached 41 weeks gestation between December 1, 1997, and April 4, 2000 and who were scheduled for induction of labor at 42 weeks. A factor that is often attributed to failed induction of labor is that obstetricians may begin an induction of labor as early as 37 weeks of gestation, perhaps initiating an induction prior to readiness of the cervix for labor (Satin et al., 1992).

In a broader study evaluating the effect of labor induction on cesarean delivery, Maslow and Sweeney (2000) investigated women 38 through 42 weeks gestation. This research team conducted a retrospective study involving 1,135 nulliparous women, using administrative billing data, Washington state birth certificate data, and chart review to verify induction of labor. Women with complications and comorbidities were excluded from the study. The exclusion criteria included: (a) diabetes, (b) fetal problems, (c) anemia, (d) previa or abruption, (e) cord

prolapse, (f) breech or transverse lie, (g) active herpes, (h) prolonged rupture of membranes, and (i) history of classic or vertical incision or more than two previous cesarean deliveries.

The purpose of the Maslow and Sweeney (2000) study was to examine low risk term (38-41 weeks) pregnancies and examine the effect of elective induction of labor on cesarean delivery, with a focus on the cost associated with elective induction of labor. Maslow and Sweeney (2000) compared the cost of health care in women who had elective induction of labor with that of women who did not have elective induction of labor. The study period included all women who delivered and were discharged between June 1, 1997, and January 26, 1998. Labor was electively induced in 263 (23.2%) of the women in the study population. This study found that nulliparous women who had been induced were 3 times more likely, at the 95% confidence interval, to deliver by cesarean delivery than those who were not induced. After controlling for variables including gestational age, birth weight, and maternal age in the nulliparous population, the odds ratio for cesarean delivery after elective induction of labor was 2.4 (95% CI: 1.2, 4.9). When all nulliparas women with infant birth weights over 4,000 grams were excluded, gestational age and elective induction of labor were the only variables significantly associated with cesarean delivery.

When elective induction of labor resulted in vaginal delivery, it increased the cost by \$273, with a mean induced labor cost of \$1,351 and a mean non-induced labor cost of \$1,078. These costs were significantly higher than those women who delivered vaginally who were not electively induced with a $p < 0.001$. These same labor induced cases also required an average of 4 additional hours in the hospital prior to delivery, compared to women who did not have induced vaginal deliveries ($p < 0.001$). Maslow and Sweeney's (2000) study concluded that elective induction of labor in nulliparas women led to greater costs per patient and higher cesarean rates. With the importance of controlling healthcare costs in the United States, their study provides

evidence that suggests the need to curtail elective induction of labor based on economic, as well as clinical, factors.

Maslow and Sweeney (2000) and the Alexander et al. (2001) study were very similar in design and findings, but differed with regards to the data sources utilized and the study population. The similarities and differences between the two studies are important to note. Both groups investigated similar sized samples, one in the southwest region of the United States primarily serving a large Hispanic population, and the other in Washington state, serving a more diverse population. Both studies were conducted between 1997 and 2000, yet the two studies used different data sources. Both studies excluded complicated and comorbid cases that might predispose a woman to cesarean delivery.

Gestational age was handled differently in both studies. Alexander et al. (2001) focused on 41 weeks gestation and greater, while Maslow and Sweeney (2000) included the 37 weeks gestation and greater. Both studies indicated that gestation and parity were key factors for successful induction of labor. These two studies demonstrate the need to further clarify the relationship between induction of labor and cesarean delivery, particularly for women delivering at less than 40 weeks gestation.

Sanchez-Ramos et al. (2003) provided a different research approach. Sanchez-Ramos and team conducted a meta-analysis on the effect of labor induction on the odds of cesarean delivery. The Sanchez-Ramos team identified randomized controlled trials that compared induction of labor and spontaneous onset of labor (expectant management) for uncomplicated, singleton, births of at least 41 weeks gestation and evaluated at least one outcome of interest including: perinatal mortality, mode of delivery, meconium-stained fluid, meconium aspiration syndrome, meconium below the cords, fetal heart rate abnormalities, abnormal APGAR scores, and neonatal intensive care unit admissions. The study's primary focus was neonatal mortality and cesarean

delivery rates, with a total of 16 studies that met the inclusion criteria. The researchers reported testing for homogeneity across the studies using a Breslow-Day test and qualitative visual inspection of L'Abbe plots. Additionally, they looked at the sensitivity by analyzing change upon the main effect when study results from one study at a time were omitted. Their findings indicated that induced women had lower cesarean delivery rates (20.1% versus 22.0%) than women allocated to expectant management of labor. Their systematic review of clinical trials indicated that induction of labor decreases the risk of cesarean delivery by 12% (OR .88; 95% CI: 0.78, 0.99).

The Alexander et al. (2001) study and the Sanchez-Ramos et al. (2003) studies demonstrate the confusion over the relationship between induction of labor and cesarean delivery. Both studies focused on postterm deliveries, yet the two studies reported significant differences with the effect of labor induction on cesarean delivery rates. However, one important point to note is that Alexander and team (2001) reported that once patient characteristics, including cervical dilatation, epidural analgesia, and nulliparity were controlled for, the significant effect of labor induction on cesarean delivery diminished, and the patient characteristics were more important contributors to cesarean delivery than induction of labor per se.

McCloskey et al. (1992) investigated rates of cesarean delivery for dystocia across three practice organizations: private, health maintenance organization and clinic practices. McCloskey et al. (1992) identified dystocia as a key risk factor for cesarean delivery that warrants special attention. According to these researchers, dystocia is a risk factor for cesarean often related to failed induction of labor, with failed induction of labor frequently resulting in a cesarean delivery. Dystocia is an all-inclusive diagnosis often used for "failure to progress," "cephalopelvic disproportion," and "prolonged labor." McCloskey et al. (1992) indicated that dystocia was the primary indication for primary cesarean delivery.

McCloskey et al.'s (1992) study used aggregate data from a perinatal database maintained at Cedars-Sinai Medical Center in California. Cedars-Sinai was selected for the study because the medical center has three distinct practice organizations that deliver in a single hospital. The study found variations in cesarean delivery according to the source of care, which this group believed may be contributing to the rising cesarean rates. In the research presented, the likelihood of cesarean delivery was examined for low-risk, primiparous women with physicians who practice in a single hospital, but practice in one of three practice organizations: a health maintenance organization (HMO), private practice, or a hospital clinic. The study controlled for a wide spectrum of clinical factors and focused on the diagnosis of dystocia. The researchers defined dystocia as "abnormal labor" and a "catch-all" diagnostic category. The study focused on the dystocia diagnosis because it is the largest contributor to the primary cesarean delivery rate and it was considered critical to addressing increasing cesarean delivery rates. The sample size included 3,522 primiparous women who had spontaneous onset of labor and delivered a live full-term infant from 1984 to 1985. It is important to note that this study did not include induction of labor, and focused solely on spontaneous onset of labor. The reported study also examined dystocia and its impact on induction of labor as it related to cesarean delivery.

McClosky et al. (1992) utilized a mix of techniques to control for factors impacting cesarean delivery, including exclusion criteria, stratification, and multivariate analysis. The researchers first addressed the question of which demographic or biologic risk factors were significant predictors of cesarean delivery. The factors examined were age of the mother, height of the mother, weight of the infant, gestational age, antepartum risk (defined as greater than one risk factor), intrapartum risk (defined as greater than one risk factor), and use of epidural anesthesia. Use of epidural and age greater than 35 years compared to less than 25 years (as the reference group) demonstrated the highest odds ratios at 2.51 and 2.9, respectively. Weight of the

infant greater than or equal to 4,000 grams compared to less than 4,000 grams also demonstrated an increased odds at 2.27. All variables within the model were significantly associated with cesarean delivery.

The researchers also compared models from private practice versus HMOs. The study compared the practice of HMO physicians to private practice physicians and reported a decreased odds ratio of .66 (95% CI: 0.55, .83). When all demographic and biologic factors were controlled for, the odds increased to .78 (95% CI: 0.60, 1.00), and when maternal age (only) was controlled for, the odds of a cesarean delivery was reported to be .84 (95% CI: 0.66, 1.08). Maternal age was the only variable that altered the statistical significance of the difference between the private and the HMO groups of women. In order to better understand the impact of age on source of care as it relates to cesarean delivery, this group of researchers elected to stratify by age and then compared the odds ratios by HMO versus private practice. Women in the greater than 35 years of age category had an odds ratio of 1.18 (95% CI: 0.48, 2.88), compared to the delivery of a less than 25 year old mother as the reference category. Only among women in the age range of 25 to 29 years who had an HMO physician was there an association with a lower likelihood of cesarean delivery ratio of .57 (95% CI: 0.35, .94) (McCloskey et al., 1992).

There are several important features of this study that are noteworthy. The first relevancy to the reported study is the finding that maternal age was a significant factor in determining the decision for a cesarean delivery independent of clinical risk and physicians' practice organization. The stratification method used once this relationship was identified to further investigate the relationship also is interesting. One additional method that could have been employed is to create interaction terms. These researchers did not report whether or not they analyzed age in the logit to determine if logistic regression assumptions were met requiring continuous variables to be linear in the logit, which is advised by Hosmer and Lemeshow (2002). The researchers may have

elected to stratify by age because maternal age was not linear in the logit or anticipated effect modification. However, because the researchers failed to report a preliminary analysis of age, maternal height, weight, baby weight, and gestational age examining linearity in the logit, it appears these researchers elected to break the continuous variables into categories or dichotomous variables for the purpose of stratifying and introducing categorical and dichotomous variables into the model, creating more easily interpretable odds ratios, more than likely due to effect modification. This also is a straight-forward method for addressing non-linear logit terms, as well as explaining effect modification.

MacDorman, Mathews, Martin, and Malloy (2002) conducted an informative study examining the increasing rates of induced labor in the United States from 1989 to 1998 using birth certificate data for all U.S. births during that time period. MacDorman and team reported that 17% of the induction of labor in 1998 were delivered by cesarean delivery. Additionally, they reported an increase in postterm induction of labor, from 9% in 1989 to 19.2% in 1998. The researchers also reported a significant increase in preterm induction of labor with the rate doubling from 1989 to 1998 from 6.7% to 13.4%. The study noted that the marked increase in preterm induction of labor was a shift in obstetrical practice that warranted further investigation, particularly for analyzing physician decision-making protocols and the impact of these practice changes on patient outcomes. The reported study evaluated both preterm and postterm induction of labor, and the impact of labor induction on the outcome of cesarean delivery.

One important study design criteria with implications for the reported study is MacDorman et al.'s (2002) definition of preterm births, "moderately" preterm births, term births, and postterm births. The researchers defined preterm births as less than 32 weeks gestation, moderately preterm births as 32 to 36 weeks gestation, term births as 37 to 41 weeks gestation, and postterm births as 42 weeks and greater. Additionally, this study used logistic regression to

examine the risk of having an induction of labor in relation to several socio-demographic factors, including maternal age, race/ethnicity, educational attainment, marital status, live birth order and nativity (mother's born out of the U.S. compared to those born in the U.S.).

The study also examined client characteristics, including prenatal care utilization, plurality (multifetal), birth weight, small-for-gestational age, and birth attendant. Indications and contraindications according to ACOG also were evaluated and adjusted odds ratios reported. The highest incidence of labor induction was reported with maternal hypertension disorders, including pregnancy-induced hypertension (45% induced), chronic hypertension (37% induced), and eclampsia (37% induced). This study indicated that overall induction rates varied by race and ethnicity, with white, non-Hispanic women having the highest induction rate at 22.7% of all births in 1998 followed by American Indian (19.7%); black, non-Hispanic (15.1%); Asian and Pacific Islander (13%); and Hispanic (12.9%). This is interesting because the Alexander team's study (2001) had a patient population that had a high proportion of Hispanic births. Therefore, it is important to substantiate if race and ethnicity impact the effect of labor induction on cesarean delivery with a more diverse population.

Dublin et al. (2000) conducted a study on maternal and neonatal outcomes after induction of labor without an identified indication on 2,886 women with induced labor and 9,648 women with spontaneous labor. This study used a merged database of Washington birth certificate and hospital discharge data. The study cohort was a 14% randomly selected sample from all births in Washington from 1989 through 1993. This study was limited by the number of ICD-9-CM diagnoses and procedure codes available in the database (e.g., five diagnoses codes and three procedure codes). The researchers were seeking to isolate the effect of labor induction in healthy, low-risk women limiting the study to singleton fetuses in vertex presentation, and 37 and 41 weeks gestational ages. Using ACOG criteria, the researchers excluded all high-risk for cesarean

delivery cases and all women with medical indications for induction. This is similar to the reported inquiry, in that the researcher isolated the effect of labor induction on a group of low risk for cesarean delivery women, and controlled for medical indications for induction, utilizing the same criteria as was used in the Dublin et al. (2000) study.

The Dublin et al. (2000) study also was interesting because the researchers elected to control for differences in race and ethnicity (Black, Non-Hispanic White, Hispanic, Asian-Pacific Islander, and American Indian), insurance coverage (Medicaid/Medicare or uninsured), hospital level of nursery care and number of births (combined variable), maternal age, parity, marital status, urban residence, year of delivery, gestational age, and birth weight. The independent variables in this study are similar to the variables in the reported study.

The researchers concluded that elective induction of labor was associated with a significantly increased risk of cesarean delivery in nulliparous women, but found no significant difference in cesarean delivery risk for multiparous women. This is very similar to Alexander et al.'s study reported in 2001 and Seyb et al.'s study reported in 1999. As with the MacDorman et al. (2002) study, the Dublin et al. (2000) study found that women with induced labor were more likely to be white, non-Hispanic women, and covered by commercial insurance. The hospital levels were similar in the induced compared to the spontaneously laboring group. Women who were induced were more likely to be 41 weeks gestation. The study also found that nulliparous women had a 19% cesarean delivery rate, compared to 10% in the group that was not induced. They also noted that adjustment for risk did not significantly alter the risk estimate.

Important to note in the Dublin et al. (2000) study is the analysis of payer. The research team grouped payer (as was done in the reported study) into two categories: "Insured" and "Medicaid and Uninsured." In the category for "Medicaid and uninsured", Medicare, Medicaid, self-pay, and charity care were included. In the Insured category, commercial insurer, health

maintenance organizations, and Blue Cross/Blue Shield were included. The Dublin et al. (2000) study findings indicated that induced women were more likely to be non-Hispanic, white, and covered by commercial insurance.

Additionally, the Dublin research team used the Mantel-Haenszel pooled estimator of relative risks to calculate adjusted relative risks and 95% confidence intervals. If the adjustment for a covariate altered the relative risk for an outcome by greater than or equal to 10%, the covariate was considered to be a confounder. The Breslow-Day test for homogeneity was used to identify possible interactions.

A prospective study done by Xenakis et al. (1997) investigated 597 women with maternal or fetal indications for induction of labor assessing the success rates and labor characteristics associated with induced labor using an integrative protocol for labor induction including: prostaglandin use, amniotomy, and oxytocin. Success was defined as a successful vaginal delivery compared to a failed induction of labor resulting in a cesarean delivery.

In this study, patients were categorized into three groups at admission, according to the woman's cervical findings on pelvic exam using the Bishop scores (Xenakis et al., 1997). Bishop Scores are calculated based on criteria for dilatation of the cervix, effacement, station of the fetus, consistency of the cervix, and position of the fetal head. These factors determine a score that indicate how ready the woman is for spontaneous onset of labor (Bishop, 1964). In the Xenakis et al. study (1997), the Bishop score groupings were 0-3, 4-6, and ≥ 7 . Cervical priming with prostaglandin 2 (PGE₂) was done when Bishop scores were under 7; oxytocin was begun with a Bishop score of 7, and amniotomy done as soon as feasible. The study outcomes examined included: prostaglandin priming duration, time from oxytocin to 4 cm dilatation, time from 4 cm dilatation to active labor, and from complete dilatation to delivery.

The neonatal outcomes also were evaluated. Patients were compared to a concurrent cohort of spontaneous labor patients that served as the control group. The findings in this study indicated significantly higher failed induction rates in women with Bishop entry scores of 0-3 than for those women with Bishop scores over 3. Women in the 0-3 Bishop score group demonstrated a 13 times higher risk of failed induction of labor and a 23 times higher risk in low-score primiparas. The 0-3 Bishop score category women had a higher risk of cesarean delivery overall than did those with scores of ≥ 4 . The women with 0-3 Bishop scores who were induced had the highest risk of cesarean delivery compared to spontaneous-labor women. Women with over 3 scores also were at greater risk for cesarean delivery than were spontaneous labor patients. Maternal complications with induced labor and delivery were not frequent; 93% of the study population had no complications, regardless of Bishop scores.

The study findings concluded that there were no significant differences in cesarean delivery or failed induction rates between women who were given PGE₂ (Prostaglandin E₂, a cervical ripening agent) with Bishop scores 4-6 and those who began induction of labor with scores of ≥ 7 ; and that scores of ≥ 4 are favorable for labor induction if prostaglandin cervical priming is used. The study further concluded that since the rate of cesarean delivery is significantly higher in induced women, and there is a particularly high induction failure rate in women with an unfavorable cervix, the authors advocate that the indications for delivery be carefully analyzed, with examination of risks and benefits of labor induction weighed with consideration of other management strategies (Xenakis et al., 1997). This study further supported the need to examine the relationship of labor induction to cesarean delivery, particularly for women that might be earlier in gestation and have unfavorable cervix for delivery.

Beebe et al. (1999) compared the rates of labor induction and the indications for labor induction between a university hospital and two community hospitals. The study design included

all cases of labor induction over a 6-month period from October 1, 1997, to March 31, 1998.

Medical records were retrospectively reviewed by a trained abstractor using a standardized form at the university teaching hospital and at two community hospitals for 574 deliveries. Data on the maternal characteristics, reasons for labor induction, and perinatal outcomes were abstracted.

Using a chi-square analysis methodology, the researchers found that rates of labor induction rates were significantly ($p < .001$) different between the three hospitals with the University Hospital having a 18.2% rate; Community Hospital A having a 21.4% rate; and Community Hospital B having a 33.7% rate. Findings on the indications were interesting in that the community hospitals frequently had no cited indication for induction of labor or were for reasons other than those suggested by the ACOG guidelines. Community Hospital A failed to report a cited ACOG indication in 45% of the cases, and Community Hospital B in 56% of the cases, with the University Hospital failing to do so in only 5% of the cases. The presence of a favorable cervix at term was the most common reason for labor induction at Community Hospital B (26%).

Cesarean delivery rates among women being induced were not significantly different between the hospitals (University Hospital 18%; Community Hospital A, 15%; Community Hospital B, 11%). The conclusion of Beebe et al.'s study (1999) was that induction of labor was more frequent in community hospitals than in a university hospital and was more likely to be medically indicated at the university hospital. However, the more frequent induction of labor at the community hospitals did not result in higher cesarean delivery rates among cases with induction of labor. One clear limitation of this study was the failure to report any risk adjustment methodology.

In a study reported in 2000, Alexander et al. examined pregnancy outcomes at 40, 41, and 42 weeks gestation and the effect of labor induction on neonatal outcome and operative delivery comparing gestational weeks of delivery. The study population was 56,317 women who gave birth at Parkland Memorial Hospital in Dallas, Texas between 1988 and 1998. A total of 29,136)

of the women were delivered at 40 weeks gestation; 16,386 were delivered at 41 weeks, and 10,795 at 42 weeks. All births were singleton pregnancies. Exclusion criteria for the study were women with hypertension, prior cesarean, diabetes, malformations, breech presentation, and placenta previa. Alexander et al. (2000) examined differences for labor characteristics and neonatal outcomes of pregnancies at 41 and 42 weeks gestation, compared with women delivered at 40 weeks. Women with certain criteria had induction of labor at 42 weeks with gestational age confirmed by three methods: calculated from the last menstrual period (LMP), sonography when available, and clinical examination. Demographic differences were analyzed for extreme age pregnancies, defined as mother's age less than or equal to 15, mother's age greater than or equal to 35 years.

Labor characteristic differences also were evaluated, including oxytocin induction, chorioamnionitis admission to delivery greater than 10 hours, second stage greater than 2 hours, forceps delivery, and cesarean delivery. Cesarean delivery was examined by total cesarean deliveries, cesarean for dystocia, and non-reassuring fetal heart rate. Statistical analysis consisted of chi square and analysis of variance. Alexander et al. (2000) found that labor induction increased significantly between 40 and 42 weeks gestation. They also found that cesarean and vaginal operative delivery increased significantly at 41 and 42 weeks gestation, noting that the increased rates might be attributed to dystocia and nonreassuring fetal heart rates. Neonatal outcomes were reported to be no different by gestational age. The study findings have implication for this study in that the researchers indicated that the increased rates of cesarean delivery might be attributed to dystocia and nonreassuring fetal heart rates. The reported study also controlled for both of these patient characteristics within the logistic regression analysis to determine the effect of these variables on the relationship of labor induction and primary cesarean delivery.

One particular research design issue that this study addressed should be noted because it will be a limitation of the reported study. The Alexander team included one randomly selected delivery from the multiparous women. The issue that the team addressed was that multiparous women were in the study more than once, introducing a bias for women who had previously delivered by potentially counting the women in the study more than once. The reported study had the same issue, where multiparous women were potentially introduced into the study more than once. Given that the dataset covers a 4-year period, it is highly likely that an unknown percentage of the multiparous women delivered more than once in the dataset. Since the data were protected for confidentiality prior to release to the researcher, addressing this bias was not possible and is a recognized limitation of the study.

Alexander et al. followed their 2000 study with a 2001 study examining pregnancy outcomes, comparing 40 weeks gestational births with those that delivered at 41 and 42 weeks gestation (Alexander et al., 2001). The study population was 56,317 singleton births pregnancies including 29,136 at 40 weeks gestation, 16,386 at 41 weeks gestation, and 10,795 at 42 weeks gestation. The study excluded factors that might confound the outcomes. The exclusion criteria were women with hypertension, prior cesarean delivery, diabetes, malformations, breech presentation, and placenta previa. Labor characteristics and neonatal outcomes were compared for women delivering at 41 and 42 weeks gestation compared to those delivering at 40 weeks gestation. The study findings indicated that routine induction of labor at 41 weeks may increase the complications and the cesarean delivery rate without improving the neonatal outcomes. Their study supports the need to better understand the relationship of labor induction to cesarean delivery, given that there is a steady increase in induction of labor for all gestational ages (Martin et al., 2003).

Synopsis of Labor Induction and Cesarean Delivery Literature

A synopsis of key studies impacting the presented study are presented in Appendix D. Articles are reported from 1997 to as current as 2003. The synopsis in Appendix D highlights the issues inherent in the review of the literature surrounding the effect of labor induction on cesarean delivery. First, the sample size is often inadequate (Alexander, Bloom, McIntire, & Leveno, 1999; Alexander et al., 2001; Maslow & Sweeney, 2000; Rogers et al., 1997; Seyb et al., 1999). Second, the risk modeling is often handled with different approaches with some using logistic regression methods to adjust for risk (Alexander et al., 1999; 2001; Coonrad, Bay, & Kishi, 2000; Johnson, Davis, & Brown, 2003; Seyb et al., 1999; Yeast & Poskin, 1999), while others used traditional epidemiologic methods with stratification to adjust for risk and the Mantel-Haenszel pooled estimator of relative risk to statistically adjust (Dublin et al., 2000; Heffner, Elkin, & Fretts, 2003). Yet another approach was a meta-analysis of 16 randomized clinical trials which contained 14 relatively old studies (1969 through 1997). All of the current studies reviewed were conducted from 1997 to 2003. The present researcher believed that the older research might not be relevant to current labor management practices and therefore restricted review to 1997 and more recent.

The synopsis shows the studies produced markedly different conclusions. Seven studies found that there is an increased odds or risk of primary cesarean delivery with induction of labor. One study found that several confounders accounted for the increased primary cesarean delivery often thought to be associated with induction of labor (Alexander et al., 2001). Several other studies found that under certain circumstances (primarily nulliparity), induction of labor increased the odds of a primary cesarean delivery with induction of labor (Alexander et al., 2001; Dublin et al., 2000; Johnson et al., 2003). Yet, Heinberg et al. (2003) conducted a matched-pair case control study and found that elective induction of labor does not increase the odds of a primary cesarean

delivery. The Sanchez-Ramos et al. (2003) meta-analysis findings also were interesting in that they found that induction of labor for 41 weeks or greater *decreased* the odds of cesarean delivery by 12% (OR 0.88; 95% CI: 0.78, 0.99).

An important methodological defining factor was identified in the synopsis. The consolidated findings indicated two studies (Coonrad et al., 2000; Dublin et al., 2000) defined a confounder as any variable that changed the coefficient of labor induction greater than 10%. These two studies and the findings of the current study (discussed further in Chapter IV) encouraged the researcher to lower the threshold of defined confounder from the 15-20% recommended by Lemeshow to a 10% or greater threshold.

Outcomes Research Using Readily Available

Electronic Data Sources

The Agency for Healthcare Quality and Research (AHRQ) has done research and development using hospital discharge data to investigate quality and patient safety. Recent development involves standardized quality indicators for hospitals. The AHRQ Quality Indicators are measures of health care quality that make use of readily available hospital inpatient administrative data. AHRQ (2003) states, "Health care decision makers need user-friendly data and tools that will help them: 1) assess the effects of health care program and policy choices; 2) guide future health care policy making and; 3) accurately measure outcomes, community access to care, utilization, and costs" (http://www.qualityindicators.ahrq.gov/general_faq.htm#1). AHRQ has further developed an array of health care decision-making and research tools that can be used by program managers, researchers, and others at the federal, state and local levels (AHRQ, 2003).

Although AHRQ has focused significant efforts into developing standardized measures using hospital discharge data, AHRQ has *not* developed a standardized approach to examining birth outcomes using linked birth certificate and hospital discharge data. Over 40 states

throughout the United States mandate that hospitals submit hospital discharge data on all inpatient admissions, and some states link these data to the birth certificate data for examining birth outcomes. Washington state is an excellent example of a state that has utilized administrative billing data and birth certificate data to examine birth outcomes, policy development and public reporting on outcomes (Keeler et al., 1997).

The cost of acquiring clinical databases has stimulated many researchers to use hospital discharge data as a source of readily available data for health outcomes research (Iezzoni, 1997). Administrative databases are advantageous for use because they are often available in public domain, are relatively inexpensive, and encompass large populations (Schilp & Gilbreath, 2000). However, Schilp and Gilbreath (2000) pointed out the limitations of administrative data as follows:

Gaps in clinical information in administrative data due to coding nuances, inaccuracies, or incomplete information, may produce misleading results when measuring clinical care processes and outcomes. . . . The first imperative for those involved in the measurement of care and performance improvement is to understand the limitations of administrative data and use it accordingly. (pp.145-146)

This study used the delivering mother's hospital discharge data including demographic information, ICD-9-CM diagnosis and procedure codes, and discharge and admission information linked to the baby's birth certificate record for client characteristics, interventions, and outcomes variables. Hospitals are required to submit bills to governmental and private payers in a standard electronic bill format, which includes demographic and clinical information for all hospital discharges, and to provide a standardized format in which data are collected and maintained by hospitals. The demographic data include such things as age, sex, place of residence, payer information, date of admission, and discharge. The clinical information is derived from the ICD-

9-CM diagnosis and procedure codes. Researchers have used both the hospital discharge administrative data and the birth certificate data to examine obstetrical outcomes (Dublin et al., 2000; Keeler et al., 1997).

Lisa Iezzoni has done research on the use of hospital discharge data to examine outcomes of care and the validity and reliability of the data for outcomes research (Iezzoni, 1990; Iezzoni, Ash et al., 1995; Iezzoni, Foley et al., 1992). She discussed this research in a comprehensive discussion in the text, *Risk Adjustment for Measuring Outcomes* (Iezzoni, 1997). Key points that Iezzoni addressed are data limitations, background, and the evolution of the dataset as it relates to methods for examining outcomes, clinical content of ICD-9-CM codes, context, sources and types of error, guidelines and steps in coding that impact its reliability.

Iezzoni discussed administrative hospital discharge data with caution as to the limited ability of the codes to capture patient's risk factors adequately. Iezzoni (1997) does this in the context of exploring potential pitfalls and not to advise against the use of the data. In fact, she stated the following regarding use of administrative data: "...the data clearly offer important advantages. They are relatively inexpensive and readily available; they generally cover either populations or large groups of persons whose numbers are known; and from creative and clinically informed use of ICD-9-CM codes, one can get a sense---albeit preliminary---of the clinical status of the patient." (p. 234). Iezzoni also pointed out the importance of using the 5th digit to gain a better understanding of the clinical conditions. The reported study took into account all digits maintained by the ICD-9-CM (see Appendix C for details). She recommended creative combinations of ICD-9-CM codes to create clinical pictures of disease staging, such as the work done by Elixhauser and McCarthy (1996) on the Clinical Classifications for Health Policy Research, which creates clinical hierarchical groupings of numeric ICD-9-CM codes.

Iezzoni addressed key limitations to coding data in her discussion on the lack of clinical operational definitions for some codes. She pointed out that there are over 39 fourth and fifth digit codes for different anemias, but ICD-9-CM coding fails to address what constitutes a level of hematocrit justifying an anemia diagnosis. She expressed concern over the introduction of variation across coders and hospitals when operational definitions (such as hematocrit limits with anemia) are lacking. Iezzoni also pointed out that charting by individual physicians was a problem. A coder is dependent on accurate and specific physician documentation to code the conditions present. Therefore, the data are only as good as the documentation of the physician, which often varies by individual practitioner. Iezzoni also discussed the bias of ICD-9-CM data, given the coding process is inextricably tied to hospital reimbursement. The very nature of this process introduces a potential for bias.

A final point addressed in Iezzoni's text is the issue of coding sequence, with the principal diagnosis being the highest priority from a clinical or resource use standpoint and the secondary diagnoses following in order of importance. She addressed the importance of these sequencing decisions by medical record coders and their interpretation of physician documentation. The reported study did not address the sequencing of principal and secondary diagnosis codes, but instead checked all nine fields for the presence of the ICD-9-CM diagnosis codes and all six fields for the procedure codes. This, however, will not address errors that might be introduced by a physician failing to document findings accurately, or coding personnel errors. According to Iezzoni, errors introduced by coders include such things as incorrect application of the codes, selection of inappropriate or vague codes, and clerical mistakes. Iezzoni further indicated that only a small fraction of the coding errors were due to clerical mistakes. The most significant problem was that the physicians' documentation failed to capture enough information for the coder to accurately code the conditions (Iezzoni, 1997). These issues have also been

recognized as limitations in studies using hospital discharge data to examine obstetrical outcomes (Aron et al., 1998; DiGiuseppe et al., 2001). Three researchers addressed the issues emphasized by Iezzoni through use of a second set of data to validate the hospital discharge data (DiGiuseppe et al., 2001; Henry et al., 1995; Keeler et al., 1997). Birth certificate data are one of the data sources often used to evaluate obstetrical outcomes, either merged with hospital discharge data or as a single data source. Hospital discharge data and birth certificate data were used in this study. It is important to validate these data sources prior to using such data sources in a study examining outcomes (discussed in Chapter III).

Use of Vital Statistics Data

Birth certificate records and other vital statistics data sources, such as death certificate and census bureau data, are increasingly important resources for evaluating perinatal and obstetrical outcomes (Gould et al., 2004). In the United States, epidemiologists rely heavily on birth certificate data to examine perinatal outcomes because it is the sole source of uniformly collected data on birth outcomes, demographics, and associated risk factors (Adams, 2001). There are six specific procedures collected on the birth certificate record and reported nationally for the purpose of tracking birth statistics for the Centers for Disease Control and Prevention. The six procedures reported are:

- Amniocentesis
- Electronic Fetal Monitoring (EFM)
- Induction of Labor
- Augmentation of Labor
- Tocolysis
- Ultrasound (Martin et al., 2003)

In the most recent report of the CDC's National Vital Statistics (Martin et al., 2002), electronic fetal monitoring (EFM), followed by ultrasound was the most prevalent procedure reported of the six. Eighty-four percent of the approximately 4 million births reported the use of EFM, followed by ultrasound for 66% of the births.

Induction of labor was reported in 20% of the births. Induction of labor was first reported on the birth certificate record in 1989 under the procedure information. Since that time, there has been a steady increase of labor induction reported in the U.S. The demographic information in relation to induction of labor is notable. White women are more likely to have an induction of labor in the U.S. with a 21% induction rate, in contrast with black women who have a 16% induction rate (Martin et al., 2002).

Vital statistics data sources can be linked using probabilistic matching criteria such as birth and death certificate data or birth certificate and census data (Jaro, 1995). When these sources are linked, they provide added clinical data, such as birth weight in grams and history on the number of previous pregnancies providing information on gravida. Additionally, matched birth certificate and hospital discharge data are frequently used to validate the use of these data by comparing the information from both sources (Keeler et al., 1997). Three states, including Washington State (Keeler et al., 1997), Minnesota (Gyllstrom, Jensen, Vaughan, Castellano, & Oswald, 2002), and Pennsylvania (Webb, Culhane, Synder, & Greenspan, 2001) have examined the efficacy of using birth certificate and hospital discharge data to examine birth outcomes and policy issues.

A 2002 study by Mostello, Catlin, Roman, Holcomb, and Leet supported the use of birth certificate data for population based outcome analysis concluding that this data source provided valuable information when large numbers of cases need to be evaluated. The researchers indicate that without the large number of cases that the Missouri state data provided, their study would

have been cost prohibitive. The study was a case control design examining all births in Missouri from 1989 to 1997, examining the risk of preeclampsia in a second pregnancy and to determine if gestational age at delivery in first pregnancies increases the risk of preeclampsia in subsequent pregnancies. The larger sample size is reported as a strength of their study particularly because the data provide a wide distribution of hospitals that eliminate selection bias inherent with other hospital-based studies. The researchers acknowledge the issues inherent in birth certificate data, including the variability with physician documentation and birth certificate clerks collecting the data. They did not report any evaluation of the data to determine the validity of using the data. Mostello and team (2002) also state that these benefits are countered by the nature of birth certificate data that depends heavily on the nurse, physician, and vital statistics personnel at the hospital reporting the information accurately. It follows, then, that this dependency was a limitation of the reported study, just as the size of the database was a strength.

A study using birth certificate data for all births in the U.S. from 1997 to 1998 was done by Honein, Paulozzi, and Watkins (2001). This study sought to assess the validity of birth certificate data for estimating the association between maternal smoking and birth defects. The U.S. public-use natality data from the CDC's National Vital Statistics Department were used to calculate the prevalence ratio for the association between maternal smoking and 13 birth defects. The researchers adjusted for maternal age, education, race, and ethnicity. The analysis was restricted to 45 states, New York City, and the District of Columbia because these states collect both maternal smoking and birth defect data.

The results of the Honein et al. (2001) research team's study have implications for the reported study because the researchers substantiated the use of birth certificate data for examining the association between an outcome of interest (e.g., birth defects) with smoking, their key independent variable of interest. Honein et al. (2001) found that maternal smoking was associated

with an increased prevalence for the following conditions: hydrocephaly with the adjusted prevalence ratio of 1.24 (95% confidence interval of 1.08 to 1.42), microcephaly with the adjusted prevalence ratio 1.47 (95% confidence interval of 1.15 to 1.88), omphalocele and gastroschisis with the adjusted prevalence ratio of 1.37 (95% confidence interval of 1.22 to 1.53), cleft lip/palate with the adjusted prevalence ratio of 1.5 (95% confidence interval of 1.25 to 1.45), clubfoot with the adjusted prevalence ratio of 1.62 (95% confidence interval of 1.49 to 1.75), and polydactyly/syndactyly/adactyly with the adjusted prevalence ratio of 1.33 (95% confidence interval of 1.23 to 1.42). The prevalence ratio is used to report the disease status and prevalence is defined as the proportion of a population that has the disease or outcome at a specific given time (Rothman & Greenland, 1998).

The researchers concluded that their findings suggest that birth certificate data may be useful for exploratory or corroborative studies estimating the association between birth defects and some risk factors reported on the birth certificate records. The authors point out that their study reports similar findings to previous studies which have demonstrated an association between maternal smoking and gastroschisis, oral clefts, and clubfoot with effect estimates of similar magnitude as their study. They cite the corroboration of their study with previous studies as support for using the birth certificate data source for evaluation of obstetrical and birth outcomes.

New York state has developed a birth registry that includes the birth certificate data and special quality improvement questions asked of all women delivering a live birth in the state (Dye, Wojtowycz, Applegate, & Aubry, 2002). New York state researchers Dye et al. (2002) stated the following regarding the importance and expanding role of readily available electronic healthcare information: "The sharing of data for multiple purposes reduces redundancy and potentially increases accuracy by consolidating the data functions into a few systems and

increasing the utility of these systems” (p. 286). Dye et al.’s research team also pointed out that the use of birth registry data for research purposes is appealing because the databases often contain information on large populations, providing opportunity to research rare events and to perform research that might otherwise not get done because the primary data collection might prove expensive or impossible.

Birth Certificate Procedure Data is Likely to be Under Reported

The procedural data on the birth certificate is likely to be under-reported according to Dobie, Rosenblatt, Fordyce, Andrilla, and Hart (1998). This conclusion was the result of a study conducted by Dobie et al. (1998) to evaluate Washington state birth certificate data. Their study compared abstracted and coded medical records to the birth certificate record and examined agreement using the Kappa Score. Dobie’s team (1998) reported a Kappa score of 86% with a 95% confidence interval of 83.1% to 88.9%. The study also evaluated sensitivity, reporting that 71.7% of the conditions were accurately reported on the birth certificate record. The investigators determined the sensitivity by using the abstracted and ICD-9-CM coded information as “the gold standard.” Dobie et al.’s study (1998) indicated that birth certificate data are likely to under-report induction of labor. Therefore, the reported study used both the birth certificate and the ICD-9-CM data to identify induction of labor. If both databases indicated the woman was induced the case was identified as an induced labor with both cases providing evidence that the case was indeed an induction of labor.

Mostello et al. (2002) conducted a population based case control study using birth certificate data and a maternally linked cohort. The purpose of this study was to identify risk factors for preeclampsia in second pregnancies and to determine whether gestational age at delivery in the first pregnancy increases the risk of recurrent preeclampsia. It is important to note that these researchers considered the clinically estimated gestational age a valid field on the birth

certificate data, improved over previous methods of calculating the gestational age from the date of the last menstrual period and the date of birth.

Mostello et al. (2002) used birth certificate data from the Missouri maternally linked cohort and included women that delivered their first two singleton pregnancies between 1989 and 1997. Analysis included controlling for differences in age, race, cigarette smoking, pre-pregnancy BMI, and whether or not the woman was enrolled in Medicaid using multivariate logistic regression. The study reported that a history of preeclampsia confers with the highest risk for preeclampsia in the second pregnancy. Additionally, the researchers found the risk of preeclampsia is inversely proportional to gestational age at delivery of the first pregnancy. The adjusted odds ratio were 15.0; 95% CI, 6.3-35.4 for 20 to 33 weeks; adjusted odds ratio, 10.2; 95% CI, 6.2-17.0 for 33 to 36 weeks; and adjusted odds ration, 7.9; 95% CI, 6.3-10.0 for 37 to 45 weeks. These findings indicate that the relative risk of recurrent preeclampsia increases with earlier gestational age at delivery of the first pregnancy that was complicated by preeclampsia. This may be an issue in the reported study given that some second pregnancies, the physician and patient may elect to induce early due to a history of preeclampsia (or other comorbidities) with previous pregnancies. A history of preeclampsia was not documented in either data source; however, follow-up studies performed in databases of birth certificate and hospital discharge data with protected healthcare information available could link previous pregnancies and address whether the history of a comorbidity may have precipitated the decision to induce early. One additional component of the study with implications for the reported study is the use of logistic regression to adjust for patient and system characteristics (age, race, cigarette smoking, pre-pregnancy BMI, and whether or not the woman was enrolled in Medicaid). Many of the demographics controlled for as confounders were addressed in this study, such as age, race, and

payer status. It is interesting to note that the researchers did not elect to adjust for any hospital characteristics in the study.

Matched Birth Certificate and Hospital Discharge Data

Gyllstrom et al. (2002) conducted a study of linked birth certificates with Minnesota Medicaid claims data in order to identify Medicaid births. This study described the linkage methodology used and the results of the study. Medicaid claims data from 1997 were used to identify women with a delivery code using ICD-9-CM codes 72.0 through 74.4, which are cesarean delivery and vaginal delivery procedure codes. Identifiers used for the match of birth certificate and hospitals' discharge Medicaid claims included mother's name, mother's date of birth, service date, and father's last name. The match rate for this study was reported at 93.2%. Match status was not different for maternal age, yet some women in border counties matched at much lower rates than the remainder of the population. The authors inferred that this finding may relate to immigration issues and illegals failing to provide accurate information.

DiGiuseppe et al. (2001) conducted a study combining birth certificate data and hospital discharge data to compare the discrimination of risk-adjustment models for primary cesarean delivery and to determine if the two types of models yield similar hospital profiles of risk-adjusted cesarean delivery rates. The study population was 29,234 women, without prior cesarean delivery, admitted for labor and delivery between 1993 and 1995 into one of 20 hospitals in northeast Ohio for whom hospital data and birth certificate data could be linked. The study design involved the creation of matched pairs for three multivariate models for examining risk of cesarean delivery. The three models were (a) the full complement of variables in both the medical records database or birth certificates; (b) variables that were common to the two sources; and (c) variables for which agreement between the two data sources demonstrated high reliability (defined as $> .60$ Kappa). The result was six models that predicted rates of cesarean delivery for

each hospital. Outliers were identified as hospitals with observed and predicted rates of cesarean delivery differing significantly ($p < .05$).

DiGiuseppe and team (2001) found that discrimination of the full medical record and birth certificate models were higher ($p < .001$) than the discrimination of the more limited common and reliable variable models. Discrimination for the models were measured using the C statistic. The full medical record model identified six hospitals as statistical ($p < .01$) outliers (three high and three low). Yet, the full birth certificate model identified five low and four high outliers, with classifications differing for 7 of the 20 hospitals. A z score was used to calculate statistically significant outliers comparing observed and risk adjusted rates with each of the six models classified as outliers if the z score was greater than 1.96 or less than -1.96. Even though the models derived somewhat different results, the correlations of the z scores between hospitals adjusted hospital rates was impressive ($r = .71$). It is interesting to note that correlations between the full hospital discharge data model and the more limited common ($r = .84$) and reliable ($r = .88$) variable birth certificate models were higher and differences in classification of hospital outlier status were fewer.

The conclusion of this research group was that birth certificates can be used to develop cesarean delivery risk adjustment models that have excellent discrimination and that a limitation may be that the full complement of birth certificate variables may lead to biased hospital comparisons. Their findings indicated that the model using a full birth certificate complement of data did not perform well compared to the “gold standard” of the abstracted medical record. Whereas, when they limited their model to the variables with a Kappa of .6 or better the model performance correlated well with that of the medical record model. The group proposed that limiting models to data elements with known reliability (Kappa of .6 or better) may yield better models for performance comparison (DiGiuseppe et al., 2001). This study supported the

researcher's decision to use both data sources for the present study to substantiate and identify common variables for induction of labor and primary cesarean. This study would indicate that total agreement between the two sources would yield a better model aligning with the abstracted medical record.

Summary

In summary, the literature on cesarean delivery and induction of labor is extensive, yet there continues to be a question as to precisely how the increases in induction of labor may relate to the increases in primary cesarean delivery. The relationships between system characteristics, client characteristics, and interventions as they relate to obstetrical outcomes are very complex. The literature suggests that differences may exist in the clinical evaluation and treatment between hospitals and individual practitioners. Induction of labor protocols also vary across hospitals and physicians (system characteristics), creating complexity in analyzing induction of labor and the relationship to cesarean delivery. A better understanding of labor induction and the relationship to cesarean delivery, particularly primary cesarean delivery, may help address the rise in cesarean rates. Additionally, it is important to better understand the client and system characteristics that influence a successful vaginal delivery in order to effectively design interventions to address the issues.

It appears there may be differences in occurrences of cesarean delivery among various races and ethnic groups, as well as differences in who might be paying for the care (e.g., Medicaid versus private insured). In spite of the differences identified, it continues to be unclear precisely how the differences in outcomes among these subgroups relate to induction of labor and the specific impact on primary cesarean delivery. Outcome research is difficult to accomplish due to the complexity of measuring outcomes with various client and system characteristics confounding and modifying the effect of labor induction on cesarean delivery.

The literature continues to be unclear on whether induction of labor increases or decreases the odds of primary cesarean delivery, particularly for women 40 weeks gestation and less. Additionally, many of the studies had a sample size that could not accommodate the number of variables that appear to be involved with the relationship of labor induction and cesarean delivery. In conclusion, cesarean delivery has been studied extensively, with various methods and study design approaches utilized to examine client and system characteristics that predict and explain cesarean delivery, including exclusion criteria and stratification methods, complicated regression modeling techniques (logit and probit), meta-analysis and randomized control trials. This study sought to further clarify the effect of labor induction on the odds of primary cesarean delivery after controlling for client and system characteristics that often confound and modify the relationship with a database of sufficient size to measure the effect.

CHAPTER III

METHODS

With the increasing cesarean delivery rates, and the shifting emphasis in obstetrical practices to intervene with induction of labor, it is important to examine the effect of labor induction on the odds of primary cesarean delivery. This study examined the effect of labor induction on the odds of primary cesarean delivery, while controlling for client and system characteristics that confound and modify the effect.

Study Design

The study design was a retrospective, explanatory study design, using secondary data analysis with a database comprised of hospital discharge data, birth certificate data, variables from the AHA Annual Hospital Survey data, and the DFWHC NICU Survey (2002). The study was explanatory in nature because it sought to explain the effect of labor induction on the odds of primary cesarean delivery after controlling for multiple extraneous variables that confound or modify the effect. It was a retrospective study because it used readily available electronic data for births from 1999 through 2002. The study utilized a risk modeling logistic regression analysis method recommended by Hosmer and Lemeshow (2000) in their text, *Applied Logistic Regression* (2nd ed.) rather than a predictive modeling approach.

Setting

The setting for the study was a collaborative network of 41 hospitals in the north central Texas area, covering an approximate 220 mile radius surrounding the metropolitan area of Dallas/Fort Worth. The Dallas/Fort Worth Hospital Council Data Initiative supports 61 hospitals

in the north-central Texas area with 41 of the hospitals with obstetrics units that were included in the study. The 41 hospitals are located in a 12-county area. Hospitals include both urban and rural facilities with the largest proportion of births (93%) occurring in the urban hospitals. Births in the 41 hospitals total 327,512 for the 4-year period. Approximately 23% of Texas births occur in this 12-county region. The 41 hospitals represented in the data set account for 88% of the total births for the 12-county region; therefore, this sample of births represented approximately 20% of the total Texas births (see Table 9 for details regarding the percentages of births represented in this setting). The column on the far right indicates that approximately 88% of the region's births occur in the 41 hospitals in the study population.

Table 9

Breakdown of Births Represented in the Study Population

Year	Frequency for Study Population	Texas	Region	% Texas	% of Region
1999	77,001	349,157	88,478	22.05%	87.03%
2000	81,376	363,325	93,042	22.40%	87.46%
2001	84,235	365,092	95,746	23.07%	87.98%
2002	84,900		not available		

Note. Birth statistics for Texas retrieved from the *Texas Department of Health Vital Statistics* (2004).

Hospitals range in bed size from 20 to 982 beds, and ownership includes non-profit, for-profit, and public hospitals with percentage of total births by hospital types being 53.5, 22.6, and 23.8, respectively. The consumers served by the Dallas/Ft. Worth Hospital Council member hospitals (including all 364,594 births for the 4-year period in 47 hospitals) consist of a racial mix in ascending order as follows: 0.2% American Indian/Eskimo/Aleut, 3.2% Asian, 12.9% Black,

24.9% Other, and 58.7% White according to the hospital discharge data. This racial analysis is reflected in Table 10. This compares to the 2000 U.S. Census in ascending order as follows: .9% American Indian/Eskimo/Aleut, 3.6% Asian, 12.3% Black, 8% Other, and 75.1% White (U.S. Census, 2003). Hispanic origin for the regional population is 30.7% which is significantly higher than the 2000 Census reported for the U.S. with 12.5% of the U.S. population reported as being of Hispanic origin (U.S. Census, 2003). The service area for the Dallas/Fort Worth Hospital Council member hospitals based on the births per county is derived from over 114 urban and rural counties.

Table 10

Race and Ethnicity of 41 Hospitals in Dallas/Fort Worth Area

Race	Percentage	Hispanic Origin	Percentage
American Indian/ Eskimo/Aleut	0.20%	Hispanic Origin	30.70%
Asian	3.20%	Non-Hispanic Origin	69.30%
Black	12.90%		
White	75.10%		
Other	8%		

Note. This reflects the total birth population for the 47 hospitals in the DFWHC DI. The data source used to identify race and ethnicity was the hospital discharge data.

Instrumentation

The birth certificate record (see Appendix E) was the data capture tool used to collect data from the state's Department of Health. Additionally, the UB92 (see Appendix F) is the electronic file format used to collect the administrative billing data for an inpatient stay. A small subset of the American Hospital Association's Annual Survey data collected and used by the

DFWHC also was used in the study to represent hospital characteristics of bed size, ownership, rural versus urban, and teaching status. The validity of the data in these sources was dependent on the process used by the organizations to collect and report this information and was addressed as a limitation of the study.

Population and Sample

The sampling method was a convenience sample involving 4 years of births taking place in 41 hospitals in the north-central Texas area that participate in the DFWHC DI. The study population was term and near term (37 to 42 weeks gestation) childbearing age women that gave birth over a 4-year period from 1999 through 2002, in one of the 41 hospitals located in the north-central Texas area. The study population was isolated from the 364,594 total births in the 47 hospitals participating in the DFWHC DI. Of those 47 hospitals, 6 do have birth certificate data. The total births for the 41 hospitals that submit birth certificate data were $n = 353,426$. The match rate of the mother's hospital discharge data record to the baby's birth certificate data record was 92.7% representing, 327,512 deliveries with matched data.

Exclusion Criteria

The study population excluded women with a high risk of cesarean delivery, including women with a history of prior cesarean delivery, isolating a study population that was considered to be low risk for primary cesarean delivery. The vaginal birth after previous cesarean delivery (VBAC) has become a controversial issue due to recent reports of uterine ruptures (Shipp et al., 2001). Alexander's research team (2001) excluded women that had a prior cesarean delivery from their study. Therefore, all women that delivered previously by cesarean delivery were identified using ICD-9-CM codes (654.20-654.23) and excluded from the study.

The hospital discharge data had a small number of cases ($n = 274$) coded as vaginal deliveries that also had a code indicating the woman had a possible abortive pregnancy (ICD-9-

CM procedure codes of 69.01, 69.51) or an unspecified complication following an abortion, ectopic and molar pregnancies (ICD-9-CM diagnoses codes 630 & 639.9). These cases were questionably coded as vaginal deliveries. It is important to identify these cases, and exclude the abortive, ectopic or molar pregnancies from the study population. Therefore, women with an ICD-9-CM procedure code of 69.01 or 69.51, indicating the woman had a dilation and curettage of the uterus for termination of pregnancy, or a diagnosis code of 630 and 639.9 indicating the woman had an ectopic, molar pregnancy or other pregnancy with an abortive outcome were excluded.

Additional exclusion criteria were women with a high risk for cesarean delivery. The records indicating that women had predisposing risk factors for cesarean delivery were identified and excluded from the study. Factors identified as risk for cesarean delivery are listed in Appendix C and are discussed in more detail in the Collection and Treatment of Data section. Alexander et al. (2001) excluded all medical and obstetrical risk factors considered at risk for cesarean delivery to isolate a patient population at low risk for cesarean. This exclusion also was supported by other studies examining the effect of labor induction on cesarean delivery (Maslow & Sweeney, 2000; Seyb et al., 1999).

Women with ACOG contraindication criteria for induction of labor, including history of one or more previous low-transverse cesarean, breech presentation, maternal heart disease, multifetal pregnancy, polyhydramnios, and severe hypertension, were identified using ICD-9-CM diagnoses. Since many of these conditions are also highly associated with cesarean delivery, these comorbidities also were identified using ICD-9-CM diagnoses codes, and included in the high risk for cesarean delivery variable and used as exclusion criteria (see Appendix C for detailed classification). After excluding high risk for cesarean delivery cases, the study population was at low risk for primary cesarean delivery, including women with singleton pregnancies and cephalic

presentations. The birth certificate data also had $n = 1,480$ cases recorded as a repeat cesarean or VBAC delivery. Those cases were also identified as a prior cesarean delivery and excluded. After applying the high risk for cesarean and contraindications for labor induction exclusion criteria, the potential study population was reduced to $n = 223,574$ deliveries.

Gestational ages less than 37 weeks and no greater than 42 weeks (term or near term deliveries) were identified using the birth certificate data element listed as “estimated gestation,” and all other gestational ages were excluded due to special consideration for preterm birth and postterm gestational ages. The treatment of the gestation independent variable is addressed in greater length in the discussion of *Collection and Treatment of Data*. The estimated gestation variable in the birth certificate record (single source for gestational age was the birth certificate data) had 7,901 cases missing estimated gestation. Once less than 37 weeks and greater than 42 weeks gestational ages and missing estimated gestational age data were excluded the remaining potential study population was $n = 208,172$.

Extremely low birth weight neonates. The potential study population of $n = 208,172$ had 24 cases with extremely low birth weights. *Williams Obstetrics* (Cunningham et al., 2001) defines extremely low birth weight as less than 1,000 grams recorded as the first newborn birth weight (Cunningham et al., 2001). These cases are also considered high risk obstetrical deliveries and were excluded from the final study population, leaving a potential study population of $n = 208,148$.

Missing data. The potential study population including 37 to 42 weeks gestation, low risk for primary cesarean deliveries also had a number of cases with missing data for parity (derived from the birth certificate data), race and ethnicity (derived from the hospital discharge data) and payer (derived from the hospital discharge data). The total number of cases with missing data represented $n = 8,847$. Parity was missing in a total of 8,649 cases, of those one case also was

missing private payer. The cases missing payer information included 156 cases, of those 126 were also missing race and ethnicity, with one of the 156 also missing parity. Once the cases with missing information involving any of the client and system characteristics identified as important potential confounders or effect modifiers were accounted for the potential study population was reduced to $n = 199,434$.

Cases with disagreement on induction of labor and mode of delivery. The cases with disagreement on induction of labor and primary cesarean delivery in the hospital discharge data and the birth certificate data were also excluded. This exclusion represented 38,810 cases (discussed in Chapter IV). After all study exclusions were taken into account, the study population was a total of 160,533 deliveries. Table 11 lists the breakdown of the exclusion criteria and the effect of the exclusion criteria on the sample size. Figure 5 reflects a flow chart of all exclusion criteria and the final study population.

Table 11

Total Birth Population in DFWHC Member Hospitals and Exclusion Criteria

Exclusion Criteria	Population
47 hospitals birth hospitals in DFWHC	364,594
41 hospitals submit BC data to DFWHC	353,426
Hospitals with a match to BC Data	327,512
Exclusion of CS risk factor & abortion codes	223,574
Exclude < 37 weeks & > 42 weeks or cases missing gestation	208,172
Exclude cases with extremely low birth weight (< 1,000 grams)	208,148
Exclude cases with missing data (parity, race/ethnicity and payer)	199,343
Exclude cases with disagreement on primary CS and induction of labor	160,533
Final study cohort	160,533

Note: Final Study population was 160,533 for final model.

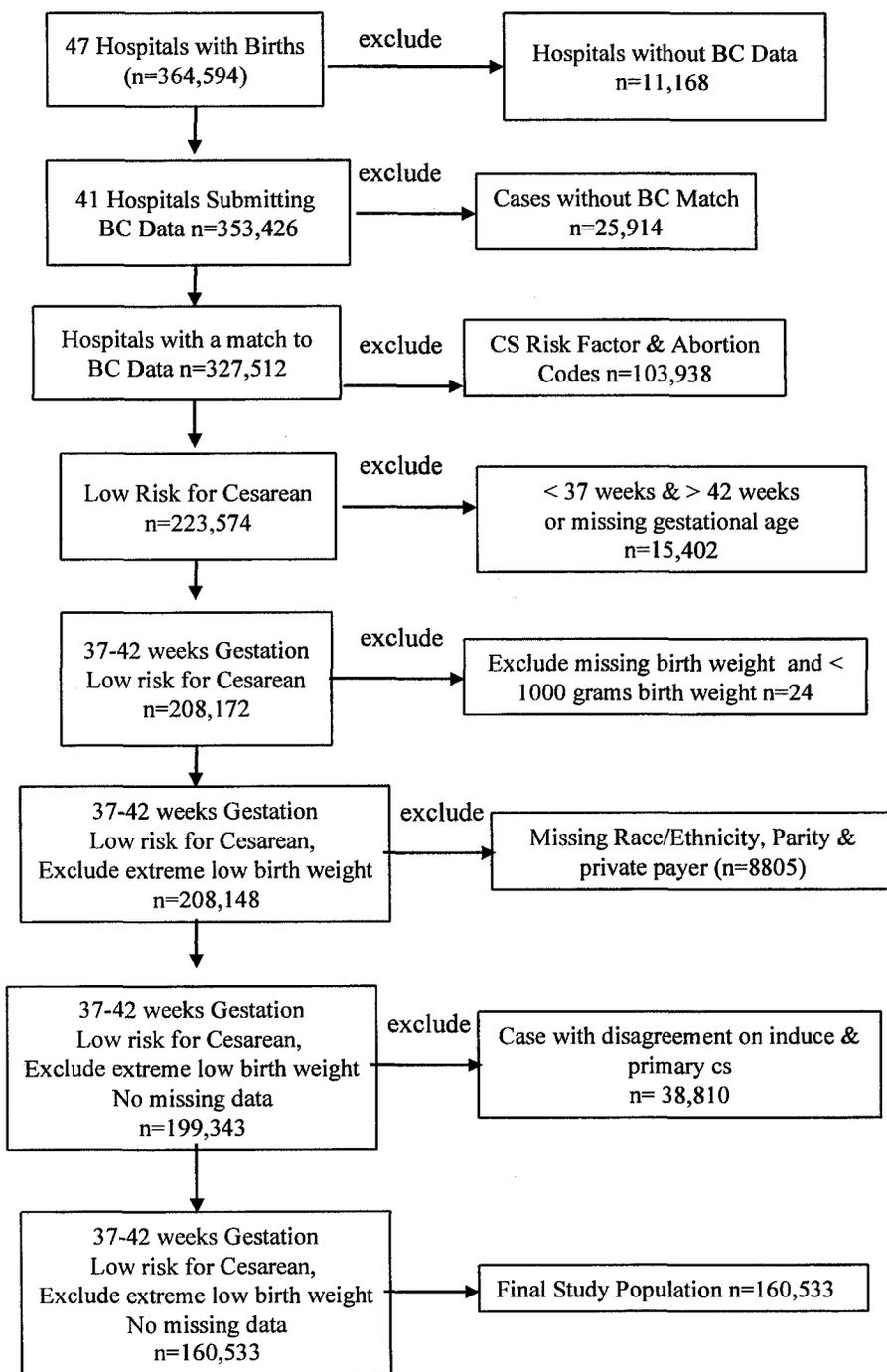


Figure 5. Exclusion criteria and final study population flow chart

Note. n = 160,533 reflects the final study population used for logistic regression modeling.

Sample Size

The sample was comprised of 160,533 births that occurred in the 41 hospitals in the north-central Texas area participating in the DFWHC DI. These births represent all births meeting the study population criteria. The number of cases needed to evaluate the effects of the independent variables on the outcome of interest would be too expensive to abstract clinical data on births totaling over 150,000. Therefore, the researcher identified an alternative data source for maternal and neonatal data in the hospital discharge, birth certificate, AHA Annual Survey data, and the DFWHC NICU Survey (2002). There was a total of 22 independent variables that were used in this study to examine the effect of labor induction on the odds of primary cesarean delivery, including those factors that were considered confounding and effect modifying variables in previous studies examining induction of labor and primary cesarean delivery.

Protection of Human Subjects

The human subjects to which these data refer, and physicians and hospitals were protected by strict adherence to procedures to assure confidentiality. The researcher obtained an institutional review board (IRB) approval from the Texas Woman's University and a written authorization from the DFWHC to utilize the data for the reported study. A special request was made to the organization's Executive Committee and Board for acquisition of the data (see Appendix G for request letter and letter providing permission). The organization required a previous review and approval of the Texas Woman's University Institutional Research Review Board. The DFWHC staff merge the birth certificate data and administrative billing data annually for use of the data by the hospitals. Prior to release of the data to the researcher, the DFWHC staff removed all identifying personal healthcare information including name, address, and Social Security number of the patient. The data were assigned a unique identification number to the case so that data can be mapped back to the patient's identifiable information by the Council staff

should the Council staff choose to do so, once the analysis was complete and the data were returned to the Council. The name of the attending and operating physicians was also removed from the data. The name of the hospital remained in the file in order to examine and validate hospital characteristics and patterns in the data integrity for such things as bed size, public, private and rural versus urban and teaching status of the hospitals. The hospital names will not be reported or published with any findings of the study. The administrative inpatient billing data and birth certificate data were merged and matched by the DFWHC staff during their quarterly processing of the data. The DFWHC staff imported the research data file into SPSS and the physician names were eliminated from the data file. The staff removed all identifying patient information. The DFWHC have requested results of the analysis be provided back to the Council for use with the Council hospitals should the Council decide the study results provide value to individual hospitals. The unique patient number provides the Council with the ability to link the cases back to the specific patient for use of the analysis results by hospitals. The staff provided the research data file to the researcher on a disk.

Collection and Treatment of Data

This study used readily available data to examine the effect of labor induction on primary cesarean delivery. The first data source is the Birth Certificate record (see Appendix C for a sample birth certificate form). The birth certificate is used throughout the United States, the U.S. Islands, and the Commonwealths to capture data on birth with some variation state by state on precisely what is collected, for example, some state's collect APGAR scores, whereas, Texas does not. This information is used to track vital statistics for perinatal, maternal health, and birth data. Hospitals and medical care facilities primarily rely upon healthcare professionals, medical records personnel or birth certificate clerks, to collect the birth information and to enter the data that will be submitted to the state.

The birth certificate is a key source of vital statistics information for maternal-child health research. Researchers, epidemiologists, and health policy professionals rely on the birth certificate data as sources of information on birth in the United States. Federal, state, and local officials rely on birth certificate data for funding and policy decisions. Despite the frequent use of the birth certificate data by policy makers and researchers, some researchers have pointed out that the data is subject to data collection variability (Northam, Polancich, & Restrepo, 2003) while others have examined the validity of the birth certificate data for use with obstetrical outcome analysis and found it to be valid (DiGiuseppe et al., 2001; Keeler et al., 1997). A unique component of this study was the use of birth certificate data provided by the hospitals to the DFWHC rather than birth certificate data provided by the state.

The second data source used in this study is the hospital discharge billing data. The hospital discharge data file is a standardized data set established by the National Uniform Billing Committee ([NUBC], 2003). The NUBC was first organized in 1975 for the primary goal of developing, promoting, and maintaining a uniform standard data set and format(s) which can be used by the institutional health care community to transmit related charge and claim information to all third-party payers (NUBC, 2003). A sample of the 1,450 electronic billing form used to capture the electronic information is shown in Appendix D. Examples of data that are available in the hospital discharge record are patient demographics, diagnoses codes, procedure codes, payer information, charges, admission and discharge information. The data provide an expansive source of data that has been extensively used for healthcare research and for evaluating quality in healthcare organizations. (Iezzoni, 1997). The data within the study were audited for content and format errors by the DFWHC hospitals using software created by the DFWHC, Data Quality Analyst. Hospitals can elect to correct errors in their data prior to submission to the DFWHC.

A third data source was the AHA Annual Survey data for the hospital characteristics including bedsize, ownership, teaching status, and rural versus urban variables. This information is available through a self-reported survey process conducted annually by the AHA. These data do not require an audit process prior to submission by the hospitals.

The fourth data set was a NICU survey done by Dallas Fort Worth Hospital Council and distributed to member hospitals. NICU levels are reported to the DFWHC annually through a survey process (DFWHC, 2002). The levels were selected by the DFWHC because they were the identified method in the Guidelines created by the Committee on Perinatal Health (1993). The DFWHC modeled their annual survey process according to this committee's recommendations on what classifies the three levels of nursery care. Level I provides basic obstetrical and neonatal services excluding assisted ventilation, Level II Special Care Nursery provides up to, but not necessarily all inclusive of intravenous therapy, supplemental oxygen, continuous positive airway pressure and short-term (≤ 7 days) assisted mandatory ventilation. Level III and IV include those NICU facilities capable of providing the same services as those listed under Level II, and provide assisted ventilation for greater than 7 days.

Source of the Data

The four data sets were merged for 41 hospitals in the north-central area of Texas. The database was obtained from the Dallas/Fort Worth Hospital Council (DFWHC) which maintains the hospitals' data for purposes supporting quality and performance improvement, and the Texas mandate to submit hospital discharge data to the state of Texas. The data that were used for this study were obtained through a special request to the DFWHC's Executive Committee and Board. This study met the requirements for an exempt Institutional Review Board (IRB) study since the study used secondary data analysis of data sources that are in the public domain. All patient and physician identifiers were eliminated from the database prior to the researcher receiving the file

and the DFWHC staff assigned a randomly assigned unique identification number to each case. The DFWHC required the review and approval of the Texas Woman's University IRB for an exempt study prior to approving the use of the file.

Reliability and validity of data sources. The internal and external validity of this study was dependent on the reliability and validity of the data sources and the generalizability of the findings. The DFWHC maintains a data integrity software tool (Data Quality Analyst [DQA]) that is used by all member hospitals for the discharge data to improve data accuracy. The DQA software tool edits for specific content errors such as a female child with a circumcision procedure code, or records with invalid patient diagnoses codes (such as expired codes), or inaccurate payer codes within the hospital discharge data. This is important to a researcher seeking to use the hospital discharge data because it assists with substantiating the accuracy of the data. However, the birth certificate data is dependent on the methods for collection within the institution. The researcher identified discrepancy within institutions with the way in which the hospitals capture information on induction of labor. Some hospitals appeared to capture induction of labor more consistently in hospital discharge data within ICD-9-CM codes and some utilized the birth certificate. Table 29 in Chapter IV contains the Kappa scores on agreement within the institutions and the frequency of notation of labor induction in each data source. The disagreement on induction of labor was recognized as a limitation of the study. Given the disagreement on this variable and the importance of the variable to the study, the researcher elected to identify induction of labor and primary cesarean delivery when both data sources indicated that an induction of labor was done to overcome this limitation. To address this limitation the researcher excluded 38,810 cases that did not agree on induction of labor and primary cesarean delivery. This is discussed further in the Agreement Analysis section.

Use of ICD-9-CM in the Reported Study

The DFWHC's staff prepares and merges the birth certificate and the discharge data set annually for evaluation of obstetrical and neonatal outcomes, and returns the data to the individual hospitals for use in their obstetrical performance improvement initiatives. In the preparation process, key risk factors in the ICD-9-CM data are identified and variables created to designate that the woman had a comorbidity. This information is important data preparation for this study given the number of diagnoses codes involved with identifying comorbidities and the number of diagnoses fields that might identify the presence of a comorbidity (nine total diagnoses fields in the hospital discharge record).

The ICD-9-CM is a fundamental component of the reported study. The diagnostic and procedure codes recorded on the medical record, and subsequently collected as hospital discharge data for billing purposes, provide clinical information for examining comorbidities and complications of care provided in hospitals. Each hospital discharge record typically reports up to nine diagnostic codes, one E code and six procedural codes. "E" codes, which reflect external cause of injury, and "V" codes which provide additional information on health status and contact with health services (PMIC, 2002) also are often included in the ICD-9-CM nine fields.

A key first step for the study was to identify exclusion criteria to eliminate women that were predisposed to cesarean delivery. The ICD-9-CM codes are modified and updated every year. This is different from a full revision which changes the revision number following the ICD acronym (the next full revision is the ICD10). The updates are available approximately September 15th of each year. The codes were checked for any modifications made to the ICD-9-CM during the 4-year period under study to determine if any additional codes or revisions to the noted codes had been added or codes modified. ICD-9-CM codes indicating there were complications or comorbidities present predisposing a woman to a cesarean delivery were

identified using the *ICD-9-CM Millennium Edition International Classification of Diseases 9th Revision Clinical Modifications* (6th ed.), 2003 (2002, pp.369-387; 630-677).

Risk Factor Exclusion Criteria

Careful considerations of the scientific literature, expert clinical opinion, and the data were used to identify high risk for cesarean deliveries that were excluded from the study. The ACOG criteria for cesarean delivery were primarily used to identify the exclusion criteria, ACOG indication for cesarean delivery are: (a) cord prolapsed; (b) bleeding from the placenta; (c) abnormal pelvic structure; (d) shoulder presentation of the baby; (e) serious maternal health problems such as: infection, diabetes, heart disease, high blood pressure, or any circumstance when labor would not be safe for either mother or baby; (f) dystocia, which includes labor that fails to progress, prolonged labor, and cephalopelvic disproportion (CPD); (g) breech presentation; (h) multifetal gestation; and (i) fetal distress (ACOG, 2000). Special consideration was given to dystocia, failure to progress, and fetal distress because the aforementioned may actually be precipitated by induction of labor. The data were also used to empirically determine high risk of cesarean delivery (Keeler et al., 1997). Table 12 lists the frequency distribution for all factors identified as high risk for cesarean delivery and cases with any of the listed criteria were excluded from the study.

Alexander and team (2001) isolated dystocia and fetal distress and reported cesarean delivery statistics, treating these diagnostic categories differently than other risk factors for cesarean delivery by using stratification methods to examine the different cesarean rates for these factors. The researcher elected to include dystocia and fetal distress as independent variables to adjust for any confounding effects that may be present between either dystocia or fetal distress and induction of labor, and the combined effects on cesarean delivery.

Other researchers have indicated that a key issue with induction of labor and cesarean delivery is that induced woman often fail to progress resulting in a decision to perform a cesarean delivery. This may be due to unfavorable conditions of the cervix (Maslow & Sweeney, 2000; Seyb et al., 1999). In order to further investigate whether cervical conditions may impact the effect of labor induction on the odds of primary cesarean delivery, particularly as it relates to dystocia and failure to progress diagnoses, gestational age and its effect were evaluated. The assumption was that if a woman is 40 weeks gestation or earlier her cervix is less likely to be favorable to delivery than a woman delivering at greater than 40 weeks gestation (Alexander et al., 1999). Gestational age was initially introduced into a logistic regression model as a categorical variable 37 weeks, 38 weeks, 39 weeks, 40 weeks, 41 weeks, and 42 weeks to determine the effect of the various gestational ages on the labor induction coefficient.

Table 12

Risk Factors for Primary Cesarean Rates

Risk Factor	Presence of Factor	Primary CS Admin Data (Outcome)		
		No	Yes	Rate
Uterus-Cervix Abn	Yes	3,696	1,337	27%
Placenta Abruption	Yes	1,407	1,452	51%
Placental Hemorrhage	Yes	426	240	36%
Breech	Yes	2,037	7,512	79%
CHF	Yes	46	51	53%
CPD from Abn-Obs of Bony Pelvis	Yes	591	2,598	81%
Cong Abn-Uterus	Yes	451	472	51%
Delayed Deliv 2nd twin	Yes	2	7	78%
Large Fetus-Hydrdocephalus	Yes	25	49	66%
Deliv before 37 weeks	Yes	17,096	6,648	28%
Face-Brow Presentation	Yes	134	292	69%
Fetal-Intrauterine Death	Yes	160	28	15%
Obstruction r/t Malposition	Yes	244	1,658	87%
Fetal-Mat Hemorrhage	Yes	4	7	64%
Unstable lie	Yes	63	103	62%
Cervical Incompetence	Yes	985	381	28%
Locked Twins	Yes	0	2	100%
Prolapsed Arm	Yes	1,776	2,260	56%
MultiGest w Malpresentation	Yes	582	1,690	74%

Table 12 (continued)

Risk Factor	Primary CS Admin Data (Outcome)			
	Presence of Factor	No	Yes	Rate
Multigestation	Yes	1,514	1,545	51%
Myomectomy	Yes	76	233	75%
Abnormalities of organs & tissue of pelvis	Yes	451	472	51%
Oligohydramnious	Yes	6,191	2,619	30%
Placenta Previa	Yes	1,189	1,430	55%
Rupture of Uterus	Yes	566	612	52%
Transverse Lie	Yes	881	1,478	63%
Prolapsed Cord	Yes	8,008	2,026	20%
Tumors of Uterus	Yes	1,288	1,679	57%
Valvular Dx	Yes	27	12	31%
Genital Herpes	Yes	377	571	60%
HPV	Yes	98	19	16%

Note. Rate indicates the rate of presence of the factor.

Risk Factor Identification Process

The ICD-9-CM codes on a hospital discharge data record contain nine diagnoses and six procedure codes and an E code field. There are multiple opportunities for a certain diagnosis to be recorded on a hospital discharge record. The DFWHC staff have created a software program (Remus & Lee, 1998) that efficiently queries each diagnosis or procedure field to locate a set of pre-identified ICD-9-CM codes and then creates categorical or dichotomous variables. For example, the Risk Factor program creates a dichotomous variable coding 1 for “yes” the factor was present in the hospital discharge record. To further illustrate the example, in this study the series of codes that identify a woman as having abnormalities of the uterus and cervix are as follows: 654.31-654.32, 654.41-654.42, 654.61-654.62, 654.71-654.72, 654.81-654.82, and 654.91-654.92 (all risk factors including the risk factor for abnormalities of the uterus and cervix are in table format in Appendix C.) These codes can appear in any one of the nine diagnoses fields on the record. The DFWHC custom software package queries all nine fields for the list of codes and creates a variable “AbnUtCer” and indicates “1” for the condition of “abnormalities of the uterus and cervix” being present, otherwise the field is left blank. This routine is followed with each of the risk factors and procedures that are in the obstetrical record for the conditions that might place the woman at risk for a cesarean delivery. Most of the variables needed for the study were created by the DFWHC staff with this process prior to the researcher receiving the data. However, the researcher created variables to check the validity of this instrument for all risk factors and validated the ICD-9-CM codes for the factors by the updated ICD-9-CM codes. The DFWHC risk factor software and the SPSS code created by the researcher allowed for validation of accurately identifying all risk factors. The isolation of these factors is very tedious code syntax and has potential for human factors error in development, this added validation was considered necessary by the researcher. Once the DFWHC staff ran the program that prepared the hospital

discharge data with the risk factors identified, the risk factor data file was held until the matched data were prepared. The process designed at the DFWHC was created such that the matching process and the risk factor process are *different* files and separate processes, requiring that both files be merged once both processes have been completed.

Data Preparation and Matching Process

The DFWHC staff matched the data prior to the researcher receiving the data, because the match process must be done using protected healthcare information to match the mother's record to the baby's record. Additionally, the additional risk factor file must be merged using the patient's protected healthcare information. The Council staff used probabilistic matching software, Autostan 4.7 and Automatch 4.2 (MatchWare Technologies, Inc., 1998). The data matching process was a very important aspect of the study because a process that inefficiently matches the mother and the baby record, results in missing cases; and a matching process that inadvertently matches the wrong mother to the wrong birth certificate, results in error. Therefore, it is important to outline the rigor involved in this process.

A file containing the mother's hospital discharge data is extracted from the DFWHC data warehouse containing the date range of the latest year (all other years have been merged). A baby file is also exported from the data warehouse containing the birth certificate data on all births for the given year. A file is created that is standardized on the fields that the staff use to merge the data (the standardization process is defined and described below). Like variables are selected from both files to uniquely identify the mother to baby match. The fields used to match are birth hospital identification number, Social Security number of the mother, mother's date of birth, first and last name of the mother, street address, city, and zip code (see Table 13). The fields are then standardized so that an electronic match can occur. This process is depicted in Figure 6.

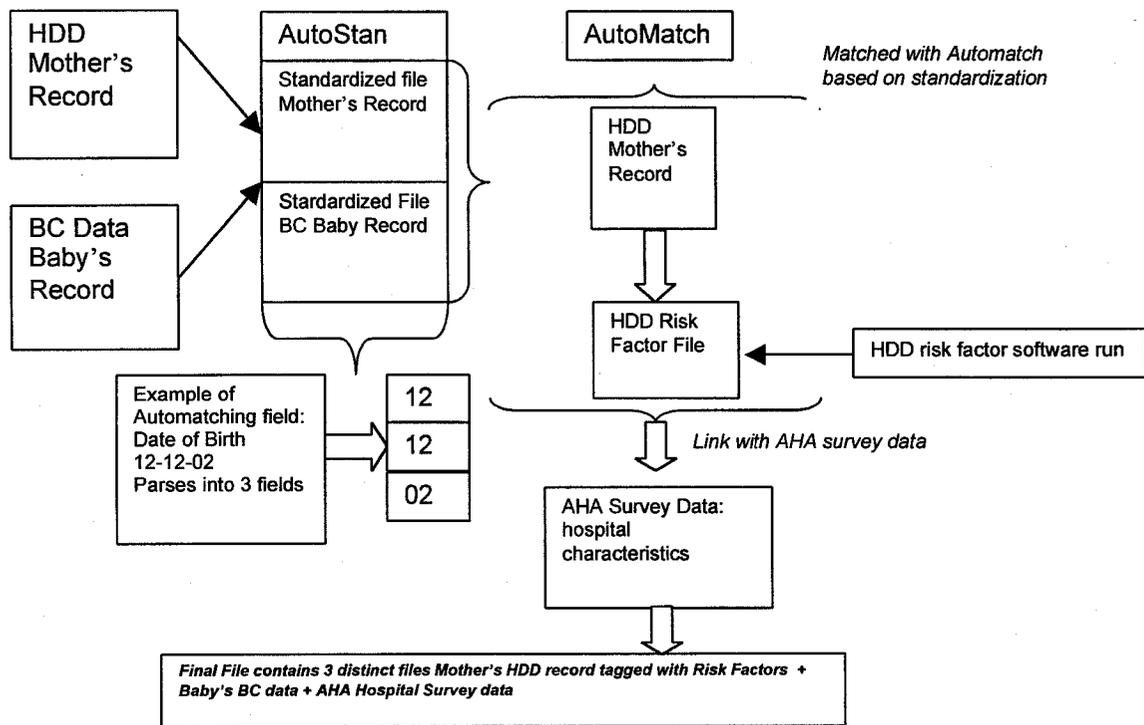


Figure 6. Matching process utilized by DFWHC.

Note: Autostan matches based on several standardized data elements listed in Table 13. Autostan 4.7 and Automatch 4.2 (MatchWare Technologies, Inc., 1998). The HDD Risk Factor table is merged after the matching process.

Standardization process. The first step is to parse the data into fields that can be standardized and matched. The parsing function is essentially a function that the Autostan software used by the Council runs, separating the data into individual fields so that more specific information can be obtained from each data component. The staff must “tell” the computer precisely where the field begins and where it ends so that the data can be separated into fields for easier match. For example, date of birth is parsed into three fields containing year, month, and day. Free text fields are particularly difficult to address when attempting to match data. The Autostan software takes the large text field (which may contain data such as full street address)

and separates that data into smaller homogenous text fields. For example, “487 North McKinney Avenue” in one text field, would become several fields of street #: 487; direction: North; street name: McKinney; and modifier: Avenue. Another aspect of standardization is that the name is examined for differences that might prevent a match, such as a “St” in one file and “Street” in the other. The program standardizes these descriptive text values such that the program can map them into one standard term. Both files are prepared in this manner so that all of the fields to be matched are in like formats. Once this standardization occurs the file is ready to be matched. Figure 7 is a simplistic version of the text standardization process described.

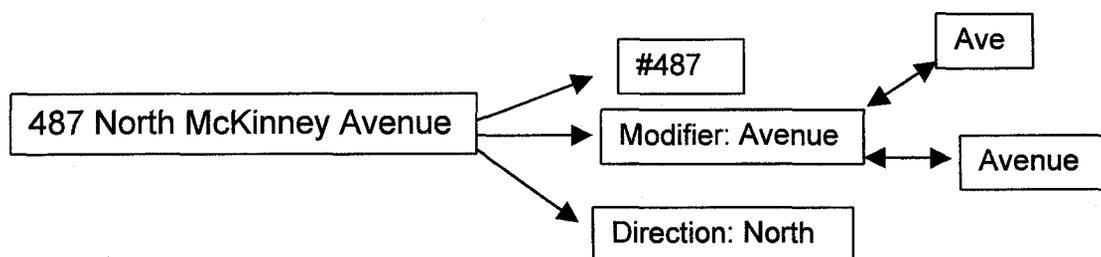


Figure 7. Example of text standardization process.

Note. Example of an address broken into standardized components.

Matching process. The matching process occurs in blocks with established probabilities set at desired levels allowing for as much error as the researcher might tolerate (level of error tolerated). The initial block of criteria require an exact match, followed by probabilistic match criteria. The DFWHC staff uses a .99 probability match rate on the key identifying numeric and date fields, such as Social Security number, hospital identification number, and date of birth. This drops slightly for last name (.97), first name (.95), and mother’s city of residence (.95), where one might expect to see more mismatch in a text field. This match process is run in iterative blocks

until a final match is obtained, and all factors must correspond to be considered a matched case. A list of the fields and the probability that the Council staff sets on the matched fields are highlighted in Table 13.

Table 13

Matching Criteria for Birth Certificate and Hospital Discharge Data Match

Birth Certificate Data	Hospital Discharge Data	Probability Assigned
Block 1:		Exact Match
Hospital ID from BC Data	Hospital ID HDD	
Date of Birth Year	Date of Birth Year	
Date of Birth Month	Date of Birth Month	
Date of Birth Day	Date of Birth Day	
Mother's Social Security #	Mother's Social Security #	0.99
Last Name Mother	Last Name Mother	0.97
First Name Mother	First Name Mother	0.95
Mom's City of Residence	Mom's City of Residence	0.95
Mom's Street of Residence	Mom's Street of Residence	0.90
Mom's Street #	Mom's Street #	0.90
Block 2:		Exact Match
Mother's Social Security #	Mother's Social Security #	
Last Name Mother	Last Name Mother	
First Name Mother	First Name Mother	
Hospital ID from BC Data	Hospital ID HDD	0.9
Date of Birth Year	Date of Birth Year	0.9

Table 13 (continued)

Birth Certificate Data	Hospital Discharge Data	Probability Assigned
Date of Birth Month	Date of Birth Month	0.9
Date of Birth Day	Date of Birth Day	0.9

Note: Dates refer to mother's birth date year, month, day. BC is an acronym for Birth Certificate Data. HDD is an acronym for Hospital Discharge Data.

Once the matching process is complete the Council staff merges the risk factor data with the mother's hospital discharge data and the baby's birth certificate data using mother's account number and the medical record number to merge the data. Historically, the match process for the DFWHC has produced a 90% or greater match of the mother to the baby's birth certificate record. The research data file for this study contained a 92.7% match of mother to baby records for those hospitals that submit birth certificate data. All cases that did not have a match of mother's record to baby's record were excluded from the study, but were examined for factors that might introduce bias. The unmatched discharge data were examined to determine if there was a pattern within the data that might introduce bias regarding the population of interest and key variables of interest.

Gyllstrom et al.'s (2002) study linked birth certificates with Minnesota Medicaid claims data identifying Medicaid births. It is interesting to note that the births reported in this study in the entire state of Minnesota were 64,491 births for 1997. The sample size for the entire state of Minnesota is comparable to the size of the reported study population. The data set for this study has 84,902 births in 1999 increasing to 90,493 in 2001. The match rate for this study was similar at 92.7% compared to 93.2% in the Minnesota 1997 study. Similar matching criteria were used by the Hospital Council to match mother's hospital discharge record to the birth certificate record.

The Minnesota study has further implications as to match statistics with no difference demonstrated for match rates by maternal age, but differences demonstrated by race and ethnicity (e.g., Hispanic women matched at consistently lower rates).

Hospital Characteristics Data Source

The DFWHC staff also maintain a database that contains the AHA Survey information reported by their member hospitals. The AHA survey information was obtained from the DFWHC staff, and merged according to hospital identification number, resulting in a file that contains the birth certificate data, hospital discharge data, risk factor hospital discharge data file, and the AHA hospital characteristics. The AHA variables used in this study are bed size, ownership, and teaching compared to non-teaching hospital. Although the validity and reliability of the AHA data have been questioned by researchers; the bedsize, ownership, and teaching status are variables that are used by researchers to control for hospital characteristics believed to influence outcomes (Aiken, Clarke, Sloan, Sochalski, & Silber, 2002). The major problem reported with the AHA survey data is that the information is self reported with no validity checks by AHA. However, the data are available to most researchers and provides better generalizability. "Rural area" was determined by a county that had a population in the most recent decennial United States census of 150,000 or less, or if part of a county with a population of greater than 150,000 that is not delineated as urbanized by the United States Census Bureau (Ellison, 2002).

Analysis Methods

Initial data analysis included exploration of the data, descriptive statistics, and cross tabs of all independent variables by induction of labor and primary cesarean delivery. T-tests and chi-square analysis were used to evaluate univariate differences by patient and hospital characteristics in the induced population compared to women that were not induced. Cross tabulations and error bar charts were also used to examine the demographic variables in the study. The Alexander et al.

(2001) study first evaluated the demographics of the patient population to determine if there were differences in each variable of interest for women who were induced compared to those who went into spontaneous labor. The variables examined were maternal age, race/ethnicity (Hispanic, Black, White, and Other), and nulliparity. The Alexander et al. (2001) study concluded that there were no significant differences by demographic characteristics in the 1,325 women in the study, except for nulliparity, with nulliparous women having a labor induction rate of 54% compared to multiparous women with a rate of 49%. Missing data were examined and a decision was made to exclude cases with missing data for any one of the variables of interest, as was done with the current study. Logistic regression was the primary mode of analysis to examine the effect of labor induction on odds of primary cesarean delivery.

There was a total of 22 independent variables examined in the current study. Interaction terms were isolated and introduced to determine the impact on the relationship of labor induction to primary cesarean delivery. The key independent variables in this study are listed in Table 14 with the total number of independent variables that were accounted for after dummy coding was done. Dummy coding is required for the independent variables that are categorical level when using a regression method of analysis. Dummy coding is a mechanism for re-categorizing a discrete variable into a series of dichotomous variables by indicating the presence or absence of one of the categories (Tabachnick, 1996). An example of one of the independent variables that were dummy coded in this study is the race/ethnicity variable, with black, white, Hispanic, and other. Once dummy coding is done, the result is a count of $k-1$ independent variables, where k equals the number of discrete categories in the variable (Tabachnick, 1996). In the case of the race/ethnicity variable $k = 4$, where k equals number of race/ethnicity categories. Therefore, after dummy coding, this variable represents three variables.

The number of independent variables that were accounted for are noted by each categorical variable listed in Table 14. Categorical variables are listed as follows with the count of independent variables represented by the category: (a) race/ethnicity of mother (Black, White, Hispanic, & Other as 3 independent variables); (b) gestational age (37 weeks, 38 weeks, 39 weeks, 40 weeks, 41 weeks, 42 weeks as 5 independent variables); (c) payer type (Private Insurance and Other as 1 independent variable); (d) hospital ownership (public, non-profit, for profit, as 2 independent variables); (e) urban versus rural hospital (as 1 independent variable); (f) bedsize (≤ 80 beds, 81 to 260 beds, and ≥ 261 beds as 2 independent variables); and (g) teaching status (teaching versus non-teaching as 1 independent variable). Dichotomous and continuous variables include the following variables representing one independent variable each: (a) nulliparity “yes” or “no,” (b) induction of labor “yes” or “no,” (c) birth weight of the baby in grams (continuous variable), (d) dystocia “yes” or “no,” (e) fetal distress “yes” or “no,” (f) age of mother (continuous variable), and (g) medical indication for induction of labor “yes” or “no.”

Table 14

Independent Variables, Values, and Value Labels

Measure Name	Definition	Source	Value Labels	Values	Number of Variables
			Client Characteristics		
Induction	Dichotomous Variable	BC & HDD	Yes No	1 0	1
Nulliparity	Calculated field from BC data	BC data	Yes No	1 0	1
Gestational Age	Calculated field from the BC data	BC data	37 weeks 38 weeks 39 weeks 40 weeks 41 weeks 42 weeks	1 2 3 4 5 6	5
Fetal Distress	Dichotomous Variable	HDD	Yes No	1 0	1
Dystocia/Failure to Progress	Dichotomous Variable	HDD	Yes No	1 0	1
Medical Indication for Induction	Dichotomous Variable	HDD	Yes No	1 0	1
Baby's Birth Weight	Continuous Variable	BC data			1

Table 14 (Continued)

Measure Name	Definition	Source	Value Labels	Values	Number of Variables
Demographics					
Race/Ethnicity	Categorical Variable	HDD	White	1	3
			Black	2	
			Hispanic	3	
			Other	4	
Maternal Age	Continuous Variable			11-53 years	1
Hospital Characteristics					
Bed Size	Categorical Variable recoded from AHA Survey Data with the use of NICU Survey Data to determine bed size breaks	AHA & NICU Survey Data	< 80 beds	1	2
			81-260 beds	2	
			> 261 beds	3	
Urban versus Rural	Categorical Variable recoded from AHA Survey Data	AHA Survey Data	Rural Urban	0 1	1
Teaching Status	Categorical Variable recoded from AHA Survey Data	AHA Survey Data	Teaching Non-Teaching	1 0	1

Table 14 (continued)

Measure Name	Definition	Source	Value Labels	Values	Number of Variables
Ownership	Categorical Variable recoded from AHA Survey Data	AHA Survey Data	Public	1	2
			Non-Profit	2	
			For Profit	3	
Payer	Categorical Variable	HDD	Private Insurance	1	1
			Other	0	

Note: There are 22 independent variables once categorical variables are considered for dummy coding with k-1 variables with k representing the number of discrete categories.

Outcome of Interest: Primary Cesarean Delivery

The outcome of interest for this study was mode of obstetrical delivery, with a specific focus on examining the effect of labor induction on the odds of primary cesarean delivery. The mode of delivery was identified using a combined data set of birth certificate and hospital discharge data. The combined data set of birth certificate and hospital discharge data has many factors that can be used to examine obstetrical outcomes (see Appendix F for detailed definitions). The data were recoded from both sources to establish like variables for comparisons and final determination of the outcome variable, meaning primary cesarean delivery, repeat cesarean delivery, VBAC delivery or vaginal delivery. For example, the discharge data contain two variables relating to mode of delivery. Cesarean delivery is coded in the hospital discharge data by ICD-9-CM codes 74.0, 74.1, 74.2, 74.4, and 74.99; and the hospital discharge data also indicate if the patient had a prior cesarean delivery as designated by ICD-9-CM codes 654.20-654.23. The combined fields of cesarean delivery and prior history of cesarean delivery can be used to derive repeat cesarean deliveries, vaginal births, and primary cesarean delivery.

The birth certificate also contains birth outcomes. The four variables on the birth certificate indicating mode of delivery are primary cesarean delivery, vaginal birth, repeat cesarean delivery and vaginal birth after cesarean delivery. The birth certificate record is completed by a birth certificate clerk or healthcare professional checking a box for the appropriate mode of delivery. The two sources can be compared to ascertain the agreement between the two sources. The researcher used both sources to identify mode of delivery or induction of labor. Exclusion criteria included women with a prior history of a cesarean delivery; therefore, it was important to identify the mode of delivery accurately using both data sources to

indicate if there was a history of a prior cesarean. If both sources indicated a history was present, the case was excluded in the final study population.

Induction of Labor: The Covariate of Interest

Induction of labor was considered the covariate of interest in the study. The major purpose of the study was to explain the effect of labor induction on the odds of primary cesarean delivery while controlling for other covariates that might influence the relationship. Induction of labor is coded on the medical record by use of the procedure codes and the diagnosis codes. The procedure data captures induction of labor as either a surgical or medical procedure. Artificial rupture of membranes is captured in the ICD-9-CM procedural codes as 73.01. Medical induction of labor is coded as 73.4. Insertion of prostaglandin suppository is coded as 96.49. Failed medical induction of labor is coded with a diagnosis code of 659.10, 659.1, 659.11, or 659.13. Failed mechanical or surgical induction of labor is coded as 659.0, 659.01, 659.02, or 659.03. Induction of labor was identified by the procedure or diagnoses codes and coded as “Induction Hospital Discharge Data,” 1 for “yes” induction of labor was recorded on the hospital discharge data, otherwise 0 for “no” it was not recorded.

Induction of labor is also recorded under the procedural information on the birth certificate data by a check box indicating “yes” the procedure was done; otherwise the birth certificate data collector leaves the check box blank. The birth certificate data were recoded to reflect, 1 for “yes” the induction of labor was indicated on the birth certificate record, otherwise 0 for “no” it was not recorded.

Agreement Analysis on Induction of Labor and Primary Cesarean Delivery

Agreement analysis was done to examine the best approach to address appropriate identification of labor induction and primary cesarean delivery in both data sources that minimized the degree of error that may have been introduced. Four methods were examined to

identify a case as having an induction of labor or primary cesarean delivery. These methods are discussed extensively in Chapter IV.

Several criteria were taken into account in order to determine the best approach for identifying an induction of labor and primary cesarean delivery. First, the researcher examined the literature with regards to the best approach for using both data sources (HDD and birth certificate data) for examining cases that were accurately identified as having an induction of labor or a primary cesarean delivery. Second, the researcher examined the data using a Kappa statistic to determine the amount of agreement between both data sources (analysis also discussed in Chapter I). The agreement analysis was done in a pilot study prior to the main study to examine the feasibility of using the hospital discharge data and the birth certificate data to examine induction of labor and primary cesarean delivery. Third, the researcher examined approximation to specificity and sensitivity with a discussion on potential false positives and false negatives depending on which data set is considered “the gold standard.” Fourth, the researcher created crude and base logistic regression models (described in Logistic Regression Modeling Methods) for the four methods to examine any differences that may have been introduced depending on the method for identifying labor inductions and primary cesarean deliveries.

The agreement between data sources was an important issue. Keeler et al.’s study (1997) addressed the specificity and sensitivity of the two data sources to identify clinical factors in their study testing predictive modeling methods. The Keeler team found that identifying a factor as present in *either* data source created better predictive models for examining cesarean delivery in risk adjusted outcome models than models based on a single source. As done by Keeler et al. (1997) the researcher examined the Kappa scores for the independent variable of interest (induction of labor) and the dependent variable (primary cesarean delivery). Additionally, four modeling methods were used. One of the approaches followed Keeler et al.’s (1997)

recommendation of identifying induction of labor and primary cesarean as present if *either* data source indicated the factor was present. A second method used cases with agreement on primary cesarean delivery. A third method utilized cases with agreement on induction of labor. Finally, the fourth method utilized all cases for induction of labor and primary cesarean delivery with total agreement on both variables. Preliminary logistic regression models were created for each of the methods using several scenarios to determine the effect the different methods might have on the overall modeling process. The researcher examined the variability the different methods introduced to the modeling process to determine the best method for identifying primary cesarean delivery and labor inductions in the administrative data available for the study. This analysis (presented in Chapter IV) focused on three areas: (a) the differences in magnitude of change on the labor induction coefficient as each of the covariates were introduced into the logistic regression model, (b) the consistency of the direction of the effect of the coefficient changes on the labor induction coefficient, and (c) the differences of which covariates entered the model by a 10% or greater change on the labor induction coefficient, with a 10% or greater change defined as a potential confounder.

Once this analysis was done the researcher determined that the appropriate method for identifying labor inductions and primary cesarean delivery was to include the case if both data sources (birth certificate and hospital discharge data) agreed. The researcher recommended follow-up studies to validate the choice of the researcher to substantiate the degree to which this election might have biased the results of the study (see Chapter IV and V for discussion on this topic). The researcher elected to use total agreement because the pool of cases is likely to be “true” induction of labor and “true” primary cesareans if both data sources agreed. However, this election resulted in the loss of cases in disagreement (loss of $n = 38,810$ cases), where one source indicated an induction of labor or primary cesarean was done and the other did not. The

researcher concluded that the sacrifice of sample size in this decision was better than introducing potential error with the cases that did not agree on whether or not the woman was induced or had a primary cesarean delivery. A recognized limitation with this approach was the biased elimination of those hospitals that appeared to under code induction of labor on ICD-9-CM data and appeared to note induction of labor on the birth certificate (see Table 29, Chapter IV).

Other Covariates in the Study

Interpretation of odds in logistic regression was important in understanding the effect of labor induction on primary cesarean deliveries, and the effect of the various covariates and the confounding influence of those variables. The odds ratio is the increase (or decrease if the ratio is less than one) in the odds of being in one outcome category compared to another. In this case, the odds of having a primary cesarean delivery compared to not having a cesarean delivery was the focus of the analysis. The covariates in the study are listed in Table 14, and discussed in the following section.

Medical indication for induction. Women that have a medical indication for induction were included in the study. Some of these comorbidities are likely to increase the odds of cesarean delivery, such as diabetes and eclampsia. Therefore, a variable was created that identifies medical indications for induction, listed in Table 7 in Chapter II. This variable is a dichotomous variable with 1 indicating “yes” there was a medical indication for induction present, otherwise 0 for “no.” These factors were analyzed by frequency of occurrence and their association with cesarean delivery, and were introduced into the model to determine the effect of medical indications for induction on the relationship between induction of labor and primary cesarean delivery as a single aggregated variable.

Dystocia and fetal distress. Alexander and colleagues (2001) identified risk factors that predispose a woman to delivery by cesarean. These factors included anomalous fetus, diabetes, prior cesarean delivery and “other medical and obstetrical indication for delivery” (p. 911). The “other medical and obstetrical indication for delivery” for the reported study were primarily operationalized using the ACOG’s indications for cesarean delivery. The ACOG (2000) has provided a list of conditions for which the physician might “reasonably” make a decision to deliver a woman by cesarean. These conditions are: (a) cord prolapsed; (b) bleeding from the placenta; (c) abnormal pelvic structure; (d) shoulder presentation of the baby; (e) serious maternal health problems such as: infection, diabetes, heart disease, high blood pressure, or any circumstance when labor would not be safe for either mother or baby; (f) dystocia, which includes labor that fails to progress, prolonged labor, and CPD (cephalopelvic disproportion); (g) breech presentation; and (h) fetal distress.

Alexander and team (2000) elected to include dystocia and fetal distress within their study population, as have other researchers seeking to explain the relationship of labor induction and primary cesarean delivery (Seyb et al., 1999). Therefore, these factors although identified as risk factors for cesarean delivery by ACOG were not excluded. Alexander et al. (2000) and Seyb et al. (1999) both opted to stratify and report cesarean delivery rates by three stratified groups: “cesarean all” (total cesarean delivery rate), “failure to progress,” and “fetal distress.” As indicated in the literature review the stratification method to isolate high risk, moderate risk and low risk cesarean delivery cases is a common approach (Alexander et al., 2001; Pennsylvania Healthcare Cost Containment Council, 2001). Alexander and team (2000) stratified for the purpose of analyzing these three groups by cervical dilatation. Stratification methods were used by the Alexander et al. group (2000) to isolate the effect of labor induction on primary cesarean delivery and to examine cesarean birth rates by cervical dilatation in women who entered

spontaneous labor before induction of labor, compared with those who underwent induction of labor at 42 weeks gestation. This preliminary analysis was followed by analysis using logistic regression to control for population differences.

This study did not have cervical dilatation, given none of the available data sources have that clinical information available, but instead the researcher used gestational age as a proxy to cervical readiness, with the assumption that the earlier the delivery the more likely the cervix might not be dilated. Additionally, this study utilized logistic regression modeling techniques rather than stratification to examine the effects of dystocia, failure to progress and gestation by examining the labor induction coefficients and the changes to the coefficient as these variables were introduced.

Cases with one of the failure to progress ICD-9-CM codes were identified as “yes” the woman failed to progress and cases without these codes were coded as “no” the woman did not fail to progress. The list of ICD-9-CM codes indicating one of the clinical conditions defined as the subcategory of dystocia are as follows: cephalopelvic disproportion 653.51, obstruction by soft tissues (lip of the cervix) 660.21, obstruction of labor by shoulder dystocia 660.41, deep transverse arrest and persistent high head at term 652.51, primary uterine inertia 661.01, 661.21, and 661.41; secondary uterine inertia 661.11; other and unspecified uterine inertia 661.21 and 661.41; prolonged first stage of labor 662.01; prolonged secondary stage of labor 662.21; and other unspecified prolonged labor 662.21. These factors were combined into a single variable “Dystocia.” Detail on the ICD-9-CM definitions are located in Appendix C.

Baby weight and maternal age. Maternal age and baby’s birth weight in grams are continuous variables that were considered initially as a continuous variable. The differences between the induced population compared to the spontaneous laboring patient were examined for age differences and by baby weight and the two variables were used to control for any differences

identified. When interpreting the coefficient for a continuous variable in a logistic regression model; as noted above, it is assumed that the logit is linear (Hosmer & Lemeshow, 2000). The assumption of linearity in the logit for age and birth weight was examined at the univariate stage of model building, and the final modeling stages. Once either age or baby weight were determined to be important variables for explaining the effect of labor induction on primary cesarean delivery, the two were handled according to the process outlined in the Special Considerations section under the analysis discussion of the study.

Demographics. Race and ethnicity are reported within the hospital discharge data and are collected by the admitting clerk upon admission to the hospital. Race and ethnicity were operationalized as one variable. The method used to standardized race and ethnicity complies with the data standards for the electronic hospital bill standard in the 1450 6.0 data specifications for Race and Ethnicity adopted by the Texas Health Care Information Council (THCIC) for submitting data to the state of Texas for public reporting (THCIC, 2003). The researcher opted for this method of standardization because the study provides results that can be compared state-wide and are, therefore, generalizable in other Texas regions with similar demographics.

The THCIC reports race based on the following categories and coding scheme: 1 for "American Indian/Eskimo/Aleut," 2 for "Asian or Pacific Islander," 3 for "Black," 4 for "White," and 5 for "Other." An Ethnicity variable is also collected by the hospitals and reported to the THCIC representing 1 for "Hispanic" and 2 for "Non-Hispanic" ethnic origin. The researcher elected to concatenate the Race and Ethnicity variables to create one variable. Hispanic origin appears to be a distinctly different effect for induction of labor on primary cesarean delivery, because studies have shown that Hispanic women are less likely to be induced or have a cesarean delivery (Dublin et al., 2000). Given this difference in Hispanic compared to non-Hispanic women, the researcher opted to identify any concatenated element with Hispanic in the field as

Hispanic origin. The concatenation is listed in Table 15. Note that with the concatenation process represented in Table 15, the final variable for Race/Ethnicity is reduced to “White,” “Black,” “Hispanic,” and “Other.”

Table 15
Concatenated Race & Ethnicity for Hospital Discharge Data

Concatenated Factors	Total Population		Study Population		Concatenated Labels Assigned to Determine Final Coding	Final Coding
	Frequency	Percent	Frequency	Percent		
	275	0.08			Missing	
11	65	0.02	29	0.00	(1 = American Indian / Eskimo / Aleut) + (Hispanic Origin = 1)	3 = Hispanic
12	564	0.15	248	0.20	(1 = American Indian / Eskimo / Aleut) + (Non-Hispanic Origin = 2)	4 = Other
21	272	0.07	144	0.10	(2 = Asian or Pacific Islander) + (Hispanic Origin = 1)	3 = Hispanic
22	11,426	3.13	5,013	3.10	(2 = Asian or Pacific Islander) + (Non-Hispanic Origin = 2)	4 = Other
31	1,049	0.29	481	0.30	(3 = Black) + (Hispanic Origin = 1)	3 = Hispanic
32	46,115	12.64	19,435	12.10	(3 = Black) + (Non-Hispanic Origin = 2)	2 = Black
41	54,516	14.95	27,283	17.00	(4 = White) + (Hispanic Origin = 1)	3 = Hispanic
42	159,405	43.72	67,827	42.30	(4 = White) + (Non-Hispanic Origin = 2)	1 = White
5	9	0.00			(5 = Other)	4 = Other
51	56,177	15.41	24,909	15.50	(5 = Other) + (Hispanic Origin = 1)	3 = Hispanic
52	34,721	9.52	15,164	9.40	(5 = Other) + (Non-Hispanic Origin = 2)	4 = Other
Total	364,594	100.00	160,533	100.00		

Note: Race factor is the first digit of the concatenated field, with 1=American Indian/Eskimo/Aleut, 2=Asian or Pacific Islander, 3=Black, 4=White, and 5=Other. Ethnicity is the second factor of the concatenated field with 1=Hispanic and 2=Non-Hispanic. If Hispanic was indicated the final coding defaults to Hispanic.

Table 16 lists the final concatenated variables with the respective percentages and frequencies for the total data set by the race/ethnicity variable. The missing category has 275 cases that are missing either race or ethnicity. These cases were excluded from the analysis.

Table 16

Recode Concatenated Race and Ethnicity from the Hospital Discharge Data

	Total Population		Study Population	
	Frequency	Percent	Frequency	Percent
Missing	275	0.08%		
Black	46,116	12.65%	19,435	12.11%
White	159,405	43.72%	67,827	42.25%
Hispanic	112,079	30.74%	52,844	32.92%
Other	46,720	12.81%	20,427	12.72%
Totals	364,595	100.00%	160,533	

Note. The results of the recoded concatenation is a four category variable.

Payer type. Payer has historically been identified as a significant contributor to differences in cesarean delivery rates, as well as, labor induction rates (Dubin et al., 2001). Payer type was categorized according to standardized methodology used by the National Inpatient Sample of data maintained by the AHRQ under the Health Care Cost and Utilization Project ([HCUP], 2003). Table 17 lists the nonstandard and standard payer types reported in the hospital discharge data. The principle payer was recoded to reflect the following six categories: 1 for “Medicare,” 2 for “Medicaid,” 3 for “Private Insurance,” 4 for “Self-Pay,” 5 for “No charge,” and 6 for “Other.” Medicare includes both fee-for-service and managed care Medicare patients. Medicaid includes both fee-for-service and managed Medicaid. Private insurance includes Blue

Cross, commercial carriers, private Health Maintenance Organizations (HMO), and Preferred Provider Organizations (PPO).

Table 17

Summary of Primary Payer Categories

Standard Payer Codes	Non-Standard Payer Codes	Primary Payer Categories
A = Self-Pay	T = State or Local Government Programs	C = Medicare
B = Workmen's Compensation	U = Commercial PPO	FU = Commercial PPO
C = Medicare	V = Medicare Managed Care	FY = Commercial HMO
D = Medicaid	X = Medicaid Managed Care	A = Self-Pay
E = Other Federal Program	Y = Commercial HMO	D = Medicaid
F = Commercial	Z = Charity	F = Commercial
G = Blue Cross		CV = Medicare Managed Care
H = Champus		G = Blue Cross
I = Other		I = Other
		DX = Medicaid Managed Care
		IZ = Charity
		B = Worker's Compensation

Table 17 (continued)

Standard Payer Codes	Non-Standard Payer Codes	Primary Payer Categories
		GU = Blue Cross Commercial PPO
		GV = Blue Cross Medicare Managed Care
		H = Champus
		IT = State or Local Government Program
		IU = Commercial PPO
		DT = Medicaid State or Local Program
		E = Other Federal Program
		GY = Blue Cross Commercial HMO

Note: Variable created by combining the standard and non-standard payer codes to represent the patient's primary payer. All other combinations are not valid, but were included as they represent the combination of the two payer codes present in the patient record as submitted.

“Other” includes workers compensation, CHAMPUS, and additional governmental programs. The mapping strategy from principle payer coded to the National Inpatient Sample standards is listed in Table 18.

Table 18

Principle Payer Mapped to National Inpatient Sample's Standard

Field created by combining the standard and non-standard payer codes to represent the patient's primary payer	NIS Standard
C = Medicare	1=Medicare
FU = Commercial PPO	3=Private Insurance
FY = Commercial HMO	3=Private Insurance
A = Self-Pay	4=Self Pay
D = Medicaid	2=Medicaid
F = Commercial	3=Private Insurance
CV = Medicare Managed Care	1=Medicare
G = Blue Cross	3=Private Insurance
I = Other	6=Other
DX = Medicaid Managed Care	2=Medicaid
IZ = Charity	5=No Charge
B = Worker's Compensation	6=Other
GU = Blue Cross Commercial PPO	3=Private Insurance
GV = Blue Cross Medicare Managed Care	1=Medicare
H = Champus	6=Other
IT = State or Local Government Program	6=Other
IU = Commercial PPO	3=Private Insurance
DT = Medicaid State or Local Program	2=Medicaid
E = Other Federal Program	6=Other
GY = Blue Cross Commercial HMO	3=Private Insurance

Note. All other combinations are not valid, but were included as they represent the combination of the two payer codes present in the patient record as submitted. NIS is an acronym for National Inpatient Sample.

Due to small cell size issues “Medicare,” “Medicaid,” “Self-Pay,” “No Charge,” and “Other” were aggregated into one group as “Other” with 49.3% of the population represented. This payer type was primarily the low income and indigent care. Private Insurance was the predominant payer by a small percentage of difference of 50.7%. The mapping for the final payer variable is depicted in Table 19.

Table 19

Principle Payer Standardized to AHRQ NIS Specifications

Payer	Total Population		Study Population		Final Group	
	Frequency	Percent	Frequency	Percent	Group	Percent
Medicare	469	0.13	183	0.10	Other	
Medicaid	128,573	35.26	60,529	37.70	Other	
Private Insurance	195,299	53.57	81,398	50.70	Private Payer	50.70%
Self Pay	25,687	7.05	11,935	7.40	Other	
No Charge	8,897	2.44	4,427	2.80	Other	
Other	5,321	1.46	2,061	1.30	Other	
Missing	348	0.10			Missing	
Total	364,594	100.00	160,533	100.00		

Note. Medicare, Medicaid, Self Pay, No Charge and Other becomes one group designated as "Other," representing 49.3%.

Hospital characteristics. Hospital characteristics are bed size, ownership, rural versus urban, and teaching status. This information is available predominately through a survey process conducted annually by the AHA. Because the data in this study did not have information on epidural anesthesia, it is unclear as to whether the smaller hospitals might have resources such as 24-hour anesthesia coverage. One way to get a proxy to resource availability was to use the different hospital characteristics. The assumption might be that hospitals with small bed numbers and in rural communities lack in-house 24-hour anesthesia coverage. Therefore, some of the cesareans done for fetal distress may be because physicians are more apt to make the decision to call a fetal distress with less indication due to timing of anesthesia availability. The hospital characteristics for the reported study was an important consideration in controlling for differences that hospital types may introduce. The researcher does not relate differences to resource inadequacies; however, it was important to adjust for differences in hospital levels.

The level of neonatal intensive care unit is reported to the DFWHC staff in a survey process. This information is reported regionally by a level I, II, III, and IV designation. The neonatal intensive care unit levels were used to make a decision as to how to break the bed size of the respective hospitals into groups. Leung, Elashof, Rees, Hasan, and Legorreta, (1998) somewhat arbitrarily broke bed size designations according to less than 100 beds, 101 to 499 beds, and greater than 500 beds. The HCUP Inpatient National Sample also establishes a bed size variable; however, the HCUP data breaks bed size by rural versus urban and then specifies by different ranges of small, medium, and large hospital.

Although HCUP establishes a standard for use by researchers, this designation was problematic in that the individual categories would have created small cell size issues in the study. Therefore, the researcher elected to establish bed size breaks with another method. Using the DFWHC NICU (2002) level to identify where the bed numbers tend to break with the specific

levels. This also provides a proxy to resource availability and is similar to the Dubin et al. (2000) study which used NICU level and number of births in a combined variable to adjust for hospital level differences.

NICU levels are reported to the DFWHC annually through a survey process (DFWHC, 2002). The levels were selected by the DFWHC because they were the identified method in the Guidelines created by the Committee on Perinatal Health (1993). The DFWHC modeled their annual survey process according to this committee's recommendations on what classifies the three levels of nursery care. Level I provides basic obstetrical and neonatal services excluding assisted ventilation, Level II Special Care Nursery provides up to, but not necessarily all inclusive of intravenous therapy, supplemental oxygen, continuous positive airway pressure, and short-term (≤ 7 days) assisted mandatory ventilation. Level III and IV include those NICU facilities capable of providing the same services as those listed under Level II, and provide assisted ventilation for greater than 7 days.

The bed breaks were decided upon by analyzing the data for the natural break by NICU level of care. Table 20 lists the frequency of cases from each hospital broken by bedsize and by the NICU levels. There is a natural break at less than 80 beds, 81 to 260 beds, and greater than 261 beds. Therefore, the bed size factor included three ranges of bed size. The bed size groups were established in the dataset using the total population received from the DFWHC (N=364,594, including the six missing hospitals data). The rationale for using the entire dataset to establish the bed size group was that the NICU level data was used to reflect resource available as it relates to bed size in order to determine meaningful groups. The additional data within the larger dataset was useful to this purpose. Note that in Table 20 there are 6.7% of the total cases with missing data (coded as 9). The researcher did not exclude those cases from the analysis on bed size group and allowed those hospitals with missing data to cluster according to bed size within the hospitals

that did have NICU data within the same bed size groupings. For example, the hospital in Table 20 with 183 beds and 10,578 births fell into the cluster of hospitals in group 2; therefore, this hospital was assigned to category 2.

Table 20

Bedsizes by NICU Level Analysis for Bed Size Break

Bedsizes	NICU Levels					Total
	1	2	3	4	9	
20					1083	1083
29					1486	1486
43	3537					3537
45					976	976
49	3163					3163
50					1	1
62	1192					1192
75					1799	1799
77					3782	3782
83		7370				7370
99		9535				9535
113		3461				3461
121			5677			5677
124	2432					2432
129		3845				3845
133		2566				2566
137		11108	7674			18782
138		1563				1563
145					1	1
146		8176				8176
155			11921			11921
157		4017				4017
159	3305					3305
180		6240				6240
183					10578	10578
185		6204				6204

Table 20 (continued)

Bedsizes	NICU Levels					Total
	1	2	3	4	9	
194		4175				4175
198		7080				7080
205		1846				1846
222		2727			4922	7649
235		7569				7569
260		5663				5663
266			803			803
285			15543			15543
360			10903			10903
508			23347			23347
530			12548			12548
665				21043		21043
708			62137			62137
892			16660			16660
Totals	13629	93145	212149	21043	24628	364594

Note: Bed size breaks are based on NICU levels of care established from the Perinatal Committee on Perinatal Health (1993). Group 9 reflects missing data. Two of the hospitals had one birth each.

Rural hospitals were defined according to the Texas Department of Health definition of “rural” area. According to the Texas Department of Health definition, “rural area” is a county that had a population in the most recent decennial U.S. Census of 150,000 or less, or part of a county with a population of greater than 150,000 and is not delineated as urbanized by the United States Census Bureau (Ellison, 2002). Table 21 indicates the 12 counties within which the 41 hospitals in the DFWHC reside, and the county designated as urban or rural based on the TDH definition of less than 150,000 population in the 2000 Census.

Table 21

DFWHC Counties with Population Census Rural or Urban Designation

Hospital County	Pop 2000 Census	Urban/Rural
Collin	491,675	Urban
Dallas	2,218,899	Urban
Denton	432,976	Urban
Ellis	111,360	Rural
Erath	33,001	Rural
Grayson	110,595	Rural
Hunt	76,596	Rural
Johnson	126,811	Rural
Kaufman	71,313	Rural
Lamar	48,499	Rural
Tarrant	1,446,219	Urban
Titus	28,118	Rural

Ownership type is defined as a categorical variable with the categories reported by the hospital in the American Hospital Association's Annual Survey and reported in the 2003 Guide to American Hospital Association Hospitals. The categories were coded as follows: 1 for "For Profit," 2 for "Non-for-Profit," and 3 for "Public." Teaching status was also identified by using the 2003 hospital approval codes from the *American Hospital Associations Guide 2003-2004* (2003). If the hospital is designated by the American Medical Association to participate in residency training by the Accreditation Council for Graduate Medical Education then the facility was identified as a teaching facility.

Logistic Regression Modeling Methods

This study utilized logistic regression modeling techniques described by Hosmer and Lemeshow (2000) in their text, *Applied Logistic Regression* (2nd ed.) to examine the study hypotheses. The dependent variable of primary cesarean delivery, “yes” or “no,” and the covariate of interest, induction of labor “yes” or “no” was examined while controlling for other extraneous variables expected to modify or confound the effect. Logistic regression is the appropriate method to use for analysis with this study because logistic regression reports odds ratios of events, and controls for the effect of other variables on those odds when the extraneous variables are introduced into the model (Hosmer & Lemeshow, 2000). Logistic regression also allows for effect modification to be analyzed on a covariate of interest, in this case, induction of labor upon primary cesarean delivery. Previous studies have focused on using predictive models and risk adjustment methods to examine cesarean delivery rates. Studies using predictive models for examining cesarean delivery rates have also used stratification methods (Elliott, Russell, & Dickason, 1997; Poma, 2000) and Logistic Regression (Aron et al., 1998; Elliott et al.; 1997; Maslow & Sweeney, 2000; Seyb et al., 1999) to examine the effects of various predictors on mode of delivery. Most of the studies focus on a method to adjust cesarean delivery rates for reports to physicians, hospitals, and payers for clinical outcomes measurement. Many of the studies for examining predictors of cesarean delivery have focused on adjusting for risk and comorbidity in a predictive model to obtain a model best suited to predict cesarean delivery. Each of the models have slight variation as to how the research team prepared the models and selected the predictor variables used in the models.

Interaction and confounding were evaluated during the analysis of data to determine if interaction terms were needed. Interaction is present when the effect of one variable is not constant across different levels of another variable, also referred to as effect modification

(Portney & Watkins, 2000). Effect modification was examined by creating interaction terms for induction of labor and other covariates determined to be important confounders. The interaction terms were introduced into the logistic regression model to determine if the interaction terms were significant. An interaction term was considered significant if the p value was .01. or less (Hosmer & Lemeshow, 2000).

Confounding is present when an independent variables is associated with both the outcome variable (primary cesarean delivery) and the variable of interest (induction of labor), thereby confounding the effect. This influence alters the separate effects of the independent variables upon the dependent variable creating an obscured effect (Portney & Watkins, 2000). Confounding might be a problem with complications and comorbidities of the baby and mother. For this reason, complications and comorbidities were combined under the variable “risk factor” and those cases with one or more risk factors for cesarean delivery were excluded from the analysis to control for this issue. It was anticipated that some interaction and confounding of independent variables would be present based on the work done by three different studies examining obstetrical outcomes done by Seyb et al. (1999), Alexander et al. (2001), and Dublin et al. (2003).

To control for extraneous effects of complications and comorbidities and to examine the confounding effects of the independent variables, a logistic regression modeling process was used. The risk factors modeling process proceeded as follows:

1. The initial model was fit, containing only induction of labor as the explanatory variable and primary cesarean delivery as the response variable (the crude model), and the coefficient for induction of labor recorded (the crude coefficient).

2. The covariates were added, one at a time, into the crude model, estimating the coefficient for induction of labor in each new model, and recording the percent change from the crude coefficient.

3. Possible confounders were flagged if the covariates included introduced a percent change greater than 10% in the coefficient for induction of labor.

4. The covariate that elicited the greatest change at step 3 was added into the crude model. This model is referred to as “the base model”. Using this model, the adjusted coefficient for induction of labor was obtained, and is referred to as the “base coefficient.”

5. From the remaining covariates flagged in step 3, the covariate with the greatest percent change was added into the base model from step 4. If the adjusted coefficient for induction of labor changed by greater than 10% from the crude model, and changed by greater than 5% from the base coefficient, then the covariate was kept in the model and the base model was updated to include the covariate, and the base coefficient to the current adjusted coefficient. Otherwise the base model remained the same as in step 4.

6. The next covariate in the flagged list was then considered as in step five. This process was repeated until there were no longer any covariates for consideration in the flagged list.

7. Then, the covariates that had been set aside were added back into the model one at a time, and any covariates that fit the criteria outlined in step 5 remained in the model.

8. For the continuous variables, maternal age and baby’s birth weight, the correct parametric form to be used was identified (see Special Considerations in the following section).

9. The presence of any effect modifiers was then determined by assessing the significance of all interaction terms between induction of labor and the other covariates in the model. An interaction was kept in the model if it was statistically significant at the .01 level. (Hosmer & Lemeshow, 2000).

Special Considerations

An assumption to be satisfied with logistic regression is that continuous variables are linear in the logit (Hosmer & Lemeshow, 2000). If the assumption is violated then Hosmer and Lemeshow (2000) advise appropriate transformations may be considered using fractional polynomials. For continuous variables, methods to assess the linearity in the logit were deployed using quartile plots and lowess plots of the logit to determine if linearity was present.

An additional consideration examined and addressed is the issue of logistic regression having problems with zero cases falling into a given cell. In the event of this type of numerical problem, categories would have been collapsed. However, this was not an issue in this study primarily due to the large study population ($n = 160,533$).

The modeling process described above provided the adjusted odds ratio of primary cesarean delivery for induction of labor while controlling for potential confounders or effect modifiers. Effect modifiers were addressed by calculating the estimates of odds ratios at specific levels of the effect modifiers. The four hypotheses were tested using a final model derived from these methods.

Conclusion

This study is important because it provided further evidence and understanding of the effect of labor induction on the odds of primary cesarean delivery. This study helps fill a gap in the scientific evidence regarding how earlier induction of labor and elective induction of labor might be influencing the increase in the primary cesarean delivery rates in the United States. This study also contributes to added information such that interventions can be developed to address the issues of early induction of labor. This is particularly important for those cases that do not appear to have a medical indication for induction of labor. Additionally, the healthcare industry lacks sufficiently diverse and representative clinical obstetrical databases to examine these trends,

and the etiology behind the increases in cesarean delivery rates with sufficient sample size to control for client and system characteristics. This study utilized secondary data analysis providing a database with scope and size to allow for control of system characteristics and patient characteristics that influence the effect of labor induction on primary cesarean delivery contributing to the scientific literature attempting to explain the relationship. Furthermore, this study provides a baseline for future studies to determine the effect of ACOG's landmark opinion statement concerning a woman's right to choose an elective cesarean delivery. The statement by ACOG late in 2003 is likely to increase the trends of elective induction of labor and perhaps elective cesareans; therefore this study provides a good baseline to examine the effect of that opinion statement on overall effect of frequency.

CHAPTER IV

FINDINGS

Study Design

The study design was a retrospective, explanatory design using secondary data analysis with a database comprised of hospital discharge data, birth certificate data, variables from the AHA Annual Hospital Survey data and the DFWHC NICU Survey (2002). The purpose of the study was to explain the effect of labor induction on the odds of primary cesarean delivery while controlling for other covariates that might influence the relationship, and to test four hypotheses related to this purpose. The research question was: “What is the effect of labor induction on the odds of primary cesarean delivery after controlling for confounding and effect modifying factors that influence the relationship?”

Feasibility of Using Hospital Discharge Data and Birth Certificate Data

To evaluate the feasibility of using the hospital discharge data and the birth certificate data for the study, a pilot study was done to examine the agreement on key outcome variables and demographics comparing the birth certificate and discharge data on selected variables of interest. The pilot study examined the feasibility of using the merged database of birth certificate data and hospital discharge data for obstetrical outcome analysis. Key variables were selected from literature review to determine the agreement between the two data sources. All analyses for the reported study were performed using the Statistical Package for Social Sciences, Version 12.0 (SPSS, 2003), and Stata SE 8.0 (Stata, 2003).

Data Collection and Treatment of Data

The data were obtained from the Dallas/Fort Worth Hospital Council (DFWHC), as discussed previously, with a special request to the organization's Executive Committee and Board for acquisition of the data for use with a pilot study investigating the feasibility with a larger study to follow examining obstetrical outcomes (the reported study). The data from the DFWHC included AHA Annual Survey data, DFWHC NICU Survey data (2002), birth certificate and hospital discharge data. The DFWHC required a review and approval of the Texas Woman's University Institutional Research Review Board (IRB). Since the data contained no personally identifying health information on the patient and no identifying information on individual physicians, the pilot study received IRB approval for an exempted review from the Texas Woman's University Institutional Review Board, as did the full-scale study.

The DFWHC staff prepared the database containing the mother's hospital discharge data matched to the baby's birth certificate record with the preparation and matching steps discussed in Chapter III. The database contained 4 years of data, 1999, 2000, 2001, and 2002. The physician and patient names and all identifying information were eliminated from the data file. The staff identified each unique birth with a case control number assigned to the case, and the mother's and baby's identifying information was deleted from the file. The staff provided the research data file to the researcher on a CD in an SPSS format. The hospital characteristics and Neonatal Intensive Care (NICU) levels for each of the hospitals (self-reported by hospital) were also included on the CD. Hospital Characteristics from the American Hospital Association Annual Survey and the NICU levels were merged by the researcher and the data prepared for analysis as discussed previously. The database was used for the pilot and also was used for the reported study to examine the effect of labor induction on primary cesarean delivery.

The birth certificate and discharge data for the 4-year period had a 92.7% match of baby birth certificate to the mother's discharge record for the 4-year period for hospitals within the DFWHC in which births occur that provide birth certificate data. Any cases that did not have a match were excluded from the examination of agreement between like variables, but were analyzed in the pilot study for any bias that might be introduced into the proposed study from the exclusion of these cases.

Feasibility Testing

Feasibility of using these data for the reported study was confirmed by exploring the agreement between the two datasets on variables that reside in both the birth certificate record and the hospital discharge record. The research question for the pilot study was: "What is the consistency or agreement between the hospital discharge data and the birth certificate data when common factors are identified between both data sources?" In the pilot study the researcher explored the data, checking for discrepancies and deciding what was the most valid data to use for the expanded study by evaluating the effect of labor induction on the odds of primary cesarean delivery. A better understanding of gaps in the data or potentially erroneous and inconsistent data was helpful in determining the feasibility. The data were examined for consistency across the two sources where duplication of information was possible. For example, both the data sources attempt to record information on the delivery mode for the mother and induction of labor. These areas were selected as areas of investigation to determine the feasibility for the expanded study given these variables are important variables in the reported study. Additionally, the researcher desired to establish the best method for minimizing the introduction of error with cases that did not agree on primary cesarean delivery and labor inductions.

The different delivery modes were examined in both the Birth Certificate files and the discharge data to identify the consistency in both sources. Consistency was defined as agreement on

the mode of delivery. For example, in the case of the delivery mode, consistency would be “yes” or “no” to the presence of primary cesarean delivery in the birth certificate and hospital discharge data.

Methodology for the Pilot Study

The researcher utilized SPSS 12.0 and Stata 8.0 for analysis for the pilot study. The researcher explored the data comparing the matched cases with those that did not have a birth certificate match. Out of 364,594, there were 37,082 cases that did not have a match. The 37,082 cases were not used in the analysis of agreement, but were examined for any bias that this omission might have introduced.

Examination of unmatched compared to matched cases. The original dataset provided by the Council included six hospitals that did not report birth certificate data to DFWHC because they were reported to be recent members to the Data Initiative and have not submitted their birth certificate data to the Council, representing 11,168 cases. Of the six hospitals two of the facilities had one birth each (see Table 20). Once these cases were subtracted from the original file of 364,594, the remaining cases represented 96.9%, a sample of 353,426. Since there was not a possibility of matching on cases without birth certificate data, those cases were excluded from the analysis of agreement of hospital discharge data to birth certificate data. The remaining cases without a matching birth certificate and hospital discharge data record represented 25,914 cases. The cases that did not match may have had missing or inaccurate vital information upon which the match occurs, such as first name, last name, or street address information. The 25,914 cases subtracted from the 353,426 cases resulted in a matched sample of 327,512. This represents a match rate of 92.7% (327,512/353,426).

The remaining 25,914 unmatched cases were examined to determine the percentage of cases that would be excluded due to exclusion criteria for the study such as a risk factor for cesarean delivery or abortion diagnoses or procedure code. Of the 25,914 cases, 9001 had risk factors for

cesarean delivery; therefore, the 9001 were cases that would have been excluded from the study population. Additionally, the full 4-year dataset provided by the DFWHC for the hospital discharge data have a small number of cases ($n = 274$) coded as vaginal deliveries that were also coded as abortive, ectopic or molar pregnancies, yet recorded as a birth in the ICD-9-CM codes. These cases are questionably coded as vaginal deliveries and would seldom have a birth certificate completed depending on the age of the aborted fetus. Therefore, these cases would have been excluded based on the exclusion criteria of the study. After all exclusion criteria were accounted for, the remaining cases without a birth certificate match represented 16,668 unmatched cases.

The 16,668 unmatched cases (that might otherwise have been candidates for the study) were comprised of a racial and ethnic breakdown of 45.91% Hispanic, 7.89% Black, 32.14% White, 14.06% Other, and 0.4% missing. Whereas, the matched population racial and ethnic makeup is 30.24% Hispanic, 12.03% Black, 44.83% White, 12.91% Other, and 0.4% missing. Table 22 provides the percentage statistics on the matched compared to unmatched cases with 95% confidence intervals surrounding the proportion (racial and ethnic category count/the total population = proportion by category). The predominant unmatched cases are Hispanic origin with 45.91%. This finding corroborates with those of Gyllstrom et al. (2002) with their study results indicating that unmatched women were predominantly Hispanic. Gyllstrom et al.'s findings indicated that this may be associated with immigration issues, which could also be the case in this north Texas population used for the reported study. The proportion of each racial categories comparing matched with unmatched populations is significantly different when examining 95% confidence intervals. In all categories, frequency proportions are different when comparing within categories and across the matched compared to unmatched cases. For example, the Hispanic

matched population was 30.24% of the total matched cases (CI: 30.04%; 30.43%); whereas, the unmatched population was 45.91% (CI: 45.16%; 46.67%).

Table 22

Frequency by Race & Ethnicity of Matched versus Unmatched Cases

Unmatched				
	Count	Proportion	lower ci	upper ci
White	5,338	32.14%	31.43%	32.85%
Black	1,310	7.89%	7.48%	8.30%
Hispanic	7,626	45.91%	45.16%	46.67%
Other	2,335	14.06%	13.53%	14.59%
Total	16,609			
Matched				
	Count	Proportion	lower ci	upper ci
White	93,853	44.83%	44.61%	45.04%
Black	25,180	12.03%	11.89%	12.17%
Hispanic	63,306	30.24%	30.04%	30.43%
Other	27,035	12.91%	12.77%	13.06%
Total	209,374			

Note. All racial and ethnic categories are significantly different with matched versus unmatched cases.

In order to determine if these racial and ethnic differences represented a potential for bias, the researcher also examined the primary cesarean rates (primary cesareans/births) and the 95% confidence intervals surrounding the point estimates to determine if these differences were significant when examining cesarean rates. Table 23 reflects the findings from this analysis. There were no significant differences in categories of race and ethnicity for matched compared to unmatched categories when comparing 95% confidence intervals. For example, the white

unmatched population was not significantly different from the white matched sample with the white matched sample cesarean rate of 11.69% (95% CI: 11.48, 11.90), whereas, the unmatched sample had a primary cesarean rate of 12.01% (95% CI: 11.14, 12.88). Similarly, the “Other” racial and ethnic group also reflected no significant differences with a matched cesarean rate of 10.69% (95% CI: 10.33, 11.06) and the unmatched with a 9.64% (95% CI: 8.44, 10.83). Based on this analysis, the researcher concludes that the unmatched cases did not introduce statistical bias from the omission of cases without a matching birth certificate. Additionally, it does not appear that in this study the Hispanic population introduced any bias when examining cesarean rates, as was reported by Gyllstrom et al. (2002). It is interesting to note that in the matched cases the white and black populations are significantly different from one another, yet the unmatched whites and blacks are not significantly different from one another. This may reflect the wider confidence interval on the black population in the unmatched population. However, it may also introduce some slight bias within the matched study population as the rates for cesarean are different between white and blacks.

Table 23

Primary Cesarean Rate and 95% Confidence Intervals

	Matched Cases ($n = 209,503$)			95% Confidence Interval	
	numerator	denominator	point estimate	lower ci	upper ci
White	10971	93853	11.69%	11.48%	11.90%
Black	3346	25180	13.29%	12.87%	13.71%
Hispanic	5188	63306	8.20%	7.98%	8.41%
Other	2891	27035	10.69%	10.33%	11.06%

Table 23 (continued)

	Unmatched Cases (<i>n</i> = 16,668)			95% Confidence Interval	
	numerator	denominator	point estimate	lower ci	upper ci
White	641	5338	12.01%	11.14%	12.88%
Black	177	1310	13.51%	11.66%	15.36%
Hispanic	636	7626	8.34%	7.72%	8.96%
Other	225	2335	9.64%	8.44%	10.83%

Note. There were no significant differences across categories for primary cesarean rates.

Validity of the data. As discussed in Chapter III, the combined data set has many variables that can be used to examine obstetrical outcomes. The data were cross-checked and recoded from both sources to establish like variables for comparisons of agreement. The discharge data contain two variables relating to the mode of delivery. Cesarean delivery is coded in the hospital discharge data by ICD-9-CM codes 74.0, 74.1, 74.2, 74.4, and 74.99. For the matched cases, containing both a mother's hospital discharge data record and a baby's birth certificate record, a cesarean delivery was identified from hospital discharge codes in 87,079 of the cases out of the 327,512, representing a total cesarean delivery (defined as primary cesarean delivery + repeat cesarean delivery) rate of 26.6%.

The hospital discharge data also indicate if the patient had a prior cesarean delivery (history of prior cesarean delivery) as designated by ICD-9-CM codes 654.20-654.23 with 43,725 cases out of 327,512 (13.4%). The combined fields of cesarean delivery and prior cesarean delivery can be used to identify repeat cesarean deliveries, vaginal births and primary cesarean delivery. Table 24 outlines the logic used to identify the delivery outcome variables. Repeat

cesarean deliveries represented a total of 36,075 (11%), vaginal birth after cesarean delivery (VBAC) 7,650 (2.3%), primary cesarean deliveries accounted for 51,004 cases (15.6%), and vaginal births were noted in 240,433 (73.4%).

The birth certificate contains four variables indicating mode of delivery, primary cesarean delivery, vaginal birth, repeat cesarean delivery, and vaginal birth after cesarean delivery. The variables indicating mode of delivery were utilized to examine the feasibility of using the data for examination of the larger study evaluating the effect of labor induction on primary cesarean delivery. Although all of these variables were not used in the larger study, they were examined in the pilot study to determine the validity of using matched hospital discharge data and birth certificate data to examine obstetrical outcomes.

The birth certificate record is completed by a birth certificate clerk or healthcare professionals checking a box for the appropriate mode of delivery. Out of the 327,512 matched births, the birth certificate data recorded 47,860 births (14.6%) as primary cesarean deliveries, 32,966 (10.1%) as repeat cesarean deliveries; 241,944 (73.9%) as vaginal birth; and 4,478 (1.4%) as vaginal birth after cesarean delivery. A computed variable was created from the birth certificate data comprised of primary cesarean delivery plus repeat cesarean delivery to derive a total cesarean delivery count similar to the variable in the hospital discharge data. The birth certificate had 80,826 total cesarean deliveries out of the 327,512 (24.7%). Table 24 also outlines the logic used to calculate the birth certificate outcome variables.

Induction of labor also is recorded in both the hospital discharge data and the birth certificate data. Induction of labor is coded on the medical record by use of the procedure codes and the diagnosis codes. The procedure data captures induction of labor as either a surgical or medical procedure. Artificial rupture of membranes is coded with ICD-9-CM procedure code 73.01. Medical induction of labor is coded as 73.4. Insertion of prostaglandin suppository is

coded as 96.49. Failed medical induction of labor is coded with a diagnosis code of 659.10, 659.1, 659.11, or 659.13. Failed mechanical or surgical induction of labor is coded as 659.0, 659.01, 659.02, or 659.03. Induction of labor was identified in the hospital discharge data by the procedure or diagnoses codes and coded as "Induction of Labor Hospital Discharge Data," 1 for "yes" induction of labor was recorded; otherwise, 0 for "no." Induction of labor is also recorded under the procedural information on the birth certificate data by a check box indicating "yes" the procedure was done; otherwise, the birth certificate data collector leaves the check box blank.

After all variables were coded to 1 for "yes" or 0 for "no" for the mode of delivery and induction of labor, a two-by-two cross tab analysis was performed and the Kappa statistics for each respective set of data was obtained to determine the level of agreement. Cohen's Kappa measures the agreement between the evaluations of two raters of the same object or event (Carletta, 1996). In this case, the coder in medical records is one of the raters and the birth certificate data collection agent is the other. A value of 0 indicates the agreement is no better than chance and 1 indicates the raters are in perfect agreement (Carletta, 1996).

The researcher examined the like demographic and outcome variables for agreement using the Kappa statistic for two-by-two tables. The Kappa score for total cesarean delivery for the entire matched population of birth certificate and the hospital discharge data comparison was .94. Whereas, the potential study population after exclusions and missing data were removed ($n = 199,343$) was also .94. This was because the repeat cesareans and VBAC deliveries (history of prior cesarean delivery) are excluded from the study population, so the remaining cases in the potential study population are only those cases that are candidates for a primary cesarean delivery. Therefore, the Kappa scores are reflecting agreement on the same cases when measuring total cesarean agreement and primary cesarean agreement. The Kappa scores for the entire matched population for vaginal delivery were .91, for primary cesarean delivery .90, repeat

cesarean delivery .89, vaginal birth after cesarean delivery .60, and induction of labor .45.

Whereas, the potential study population Kappa scores for vaginal delivery were .95, for a primary cesarean delivery .95, and for induction of labor .45. The repeat cesarean deliveries and VBAC deliveries are not reported because all cases with a previous history of previous cesarean were excluded in the study population. All Kappa Scores were significant ($p < .001$). Kappa score findings are noted in Table 24.

Table 24

Outcome Variable Definitions and Coding Schemes for the Two Data Sources with Kappa Scores

Variable	Birth Certificate Data	Hospitals Discharge Data	Kappa Scores Total HDD & BC File	Kappa Scores for Study Population
Primary Cesarean Delivery	1=yes, 0=no recoded from the Original BC data Y equals "Yes" if mode of delivery is primary cesarean delivery	Calculated field from Cesarean section equals "Yes" and prior cesarean delivery equals "No" then 1=yes, 0=no	.90	.95
Repeat CS	1=yes, 0=no recoded from the Original BC data Y equals "Yes" if mode of delivery is repeat cesarean delivery	Calculated field from prior cesarean delivery equals "Yes" (identified with ICD- 9-CM codes 654.20-654.23) and cesarean delivery equals "Yes" (identified with ICD- 9-CM codes 74.0, 74.1, 74.2, 74.4, 74.99) then 1=yes, 0=no	.89	excluded
VBAC	1=yes, 0=no recoded from the Original BC data Y equals "Yes" if mode of delivery is vaginal delivery after prior cesarean delivery	Recoded field Cesarean section equals "no" and prior cesarean delivery equals "yes", then 1=yes, 0=no	.60	excluded
Vaginal Del	1=yes, 0=no recoded from the Original BC data Y equals "Yes" if mode of delivery is vaginal delivery	Recoded field Cesarean Delivery is not equal to "yes" then 1=yes, and 0=no	.91	.95
Total CS	1=yes, 0=no calculated field if primary cesarean delivery equals "Yes" or repeat cesarean = yes then totcsbc = yes, else no	Delivery by cesarean section coded by ICD-9-CM codes of 74.0, 74.1, 74.2, 74.4, 74.99 then 1=yes, and 0=no	.94	.95
Induction	1=yes, 0=no from the Original BC data Y equals	Induction designated as a medical induction by ICD-9- CM codes diagnoses codes 659.11, 659.13, 659.0- 659.03, procedure codes 73.01, 73.4, 96.49	.45	.45

Note: "Excluded" indicates these cases were excluded from the study examining the effect of labor induction on primary cesarean delivery. BC is an abbreviation for Birth Certificate; CS is an abbreviation for Cesarean Section. All Kappa statistics were significant ($p < .001$).

Primary Cesarean had a high degree of agreement with a Kappa statistic of .90 with the entire hospital discharge data and birth certificate data file, and a .95 Kappa statistic with the potential study population once exclusion criteria and all missing data for variables identified as potential confounders and effect modifiers were taken into account. The raw rate of cases that agreed on whether the woman had a primary cesarean delivery or not is reflected in Table 25. Note the raw rate of agreement (agree on no cesarean + agree on yes cesarean/study population) in the potential study population is 99.0%, yet the Kappa Statistic reflects a Kappa score of .95, this is because the Kappa statistic examines the agreement once chance or random error is taken into account by using the actual and expected ratios in a cross tabulation (Cohen, 1960).

Table 25

Primary Cesarean Delivery Agreement Analysis on Raw Rates Cross Tabulation

		Primary CS BC Data (Outcome)		Total
		No	Yes	
Primary CS HDD Data	No	178,396	267	178,663
	Yes	1,661	19,019	20,680
Total		180,057	19,286	199,343

Note: CS abbreviation for cesarean; HDD abbreviation for hospital discharge data; BC abbreviation for birth certificate data. Kappa statistic .95 $p < .001$.

Induction of labor had the weakest Kappa statistic, indicating substantial disagreement between the two data sources. The disagreement was mainly from the induction of labor “yes” category of data. Agreement was stronger for the induction of labor “no” category. The two-by-two table results are shown in Table 26. The total population ($n = 327, 512$) reports a Kappa of .454; whereas, the considered study population ($n = 199,343$) reports very similar results with a Kappa of .449, both significant ($p < .001$). Table 24 reflects rounding, however, extending the

Kappa score to three decimals reflects slight differences with the study population having a slightly decreased Kappa, both reflecting poor agreement. The null hypothesis for the Kappa statistic is that the agreement is purely by chance. In this case, the researcher rejects the null hypothesis. There was a significant difference in both populations, but substantially poor agreement with a Kappa score less than .60 considered to be questionable with a reliable Kappa score considered .60 or higher (DiGiuseppe et al., 2001). The study population of 199,343 was considered as the “potential study population” because it was undecided at this point how the researcher would elect to identify induction of labor and primary cesarean delivery, because the disagreement on induction of labor and primary cesarean delivery had to be addressed prior to final determination of the study population.

Table 26

Induction of Labor Agreement Analysis Total Population Compared to Study Population

Total HDD & BC Data File		Induction HDD		Total	Kappa Statistic	p Value
		No	Yes			
	No	239,377	25,758	265,135		
Induction BC data	Yes	28,444	33,933	62,377		
Total		267,821	59,691	327,512	0.454	0.000
Potential Study Population		Induction HDD		Total	Kappa Statistic	p Value
		No	Yes			
	No	137,249	17,586	154,835		
Induction BC data	Yes	19,850	24,658	44,508		
Total		157,099	42,244	199,343	0.449	0.000

Note: HDD was an abbreviation for hospital discharge data and BC was an abbreviation for birth certificate data.

The disagreement between induction of labor in the birth certificate data and the hospital discharge data was an important consideration, particularly given that induction of labor is the intervention of interest in the reported study. Further analysis was done to examine the appropriateness of using the hospital discharge data, the birth certificate data, or both to determine whether or not a delivery was induced or had a primary cesarean delivery. For the agreement analysis, the researcher created four variables from both data sources, examining the agreement between induction of labor and primary cesarean delivery in the birth certificate data and the hospital discharge data. The variables were as follows: (a) Agreement on Induction of labor: cases with induction of labor agreement from both data sources; (b) Agreement on Primary Cesarean Delivery: cases with primary cesarean agreement from both data sources, (c) Agreement on *both* Induction of labor *and* Primary Cesarean Delivery: cases with total agreement on both primary cesarean and induction of labor (Kappa score of 1); and (d) Either Source indicated Induction of labor *or* Primary Cesarean Delivery. Table 27 highlights these four variables and the agreement rate. The agreement rate in the table is defined as the percentage of cases within the study population that would be included under this election of agreement.

Table 27

Agreement Analysis

Variables	Count of Cases	^a Percent of Population	Definition
Agreement on Induction	161,907	81.20%	Cases with induction agreement from both data sources.
Agreement on Primary Cesarean Delivery,	197,415	99.00%	Cases with primary cesarean agreement from both data sources.

Table 27 (continued)

Variables	Count of Cases	^a Percent of Population	Definition
Agreement on <i>both</i> Induction Primary <i>and</i> Cesarean Delivery	160,553	80.50%	Cases with total agreement on both primary cesarean and induction (Kappa score on induction and Primary CS of 1)
Agreement on Induction <i>or</i> Primary Cesarean Delivery	199,343	100%	Cases with induction agreement or cases with primary cesarean agreement, but both might not have agreed, (cases might not overlap in agreement)

Note: Potential study population once exclusions and missing data are taken into account. ($N=199,343$ was the denominator). ^aPercent of Population was defined as the percentage of cases within the potential study population that would be included under this election. CS was an abbreviation for cesarean delivery.

The researcher considered using the total file of hospital discharge data and birth certificate data ($n = 199,343$) and electing to identify the best source for identifying the cases with a primary cesarean delivery and induction of labor. Table 28 reflects the considered study population and the variability in raw rates of labor induction and primary cesarean introduced when different sources are considered as the “correct” source for indicating whether the woman had a primary cesarean delivery or an induction of labor. Note the variability in the induction of labor rates depending on the source of the information, ranging from a rate of 15.2 to as high as 31.1%. This variability and the poor Kappa statistics for induction of labor reflect potential error from one source or the other. The researcher considered various approaches to reducing the introduction of error and which approach would minimize this limitation.

The researcher examined how the rates of labor induction and rates of primary cesarean delivery were impacted when agreement was determined by the following methods: (a) agreement on primary cesarean delivery, (b) agreement on induction of labor, (c) either source indicating primary cesarean delivery or induction of labor, and finally (d). agreement on both sources. Table 28 contains each of the methods with Kappa statistics reported, and the degree to which each method impacts the overall primary cesarean delivery rates and labor induction rates. The logic the researcher used to develop the methods are reflected in Table 28 and is illustrated in the Venn diagram in Figure 8. In Figure 8 there are five scenarios noted as “a” through “e.” The scenarios are as follows: (a) denotes all cases with total agreement on both the primary cesarean variable; (b) denotes all cases with agreement on primary cesarean delivery, but not necessarily induction; (c) denotes all cases with induction of labor agreement, but not primary cesarean delivery; (d) denotes all cases with agreement on primary cesarean delivery, but not on induction of labor; and, finally (e) denotes all cases that do not agree on primary cesarean or induction of labor.

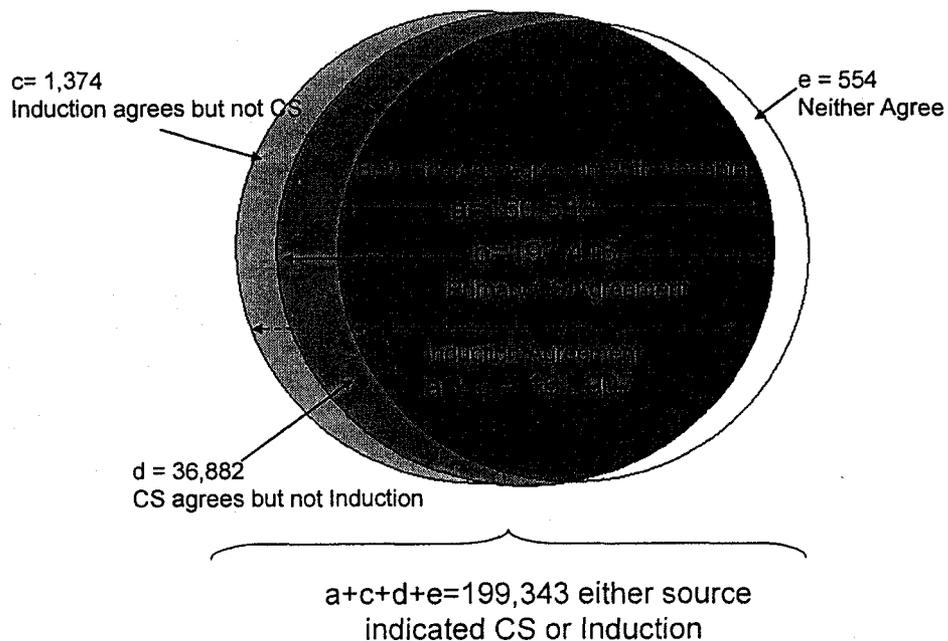


Figure 8. Venn Diagram of Agreement Analysis Methods Development:

Note. $N = 199,343$ uses either source to identify inductions or primary cesarean delivery.

Table 28

Agreement Impact Analysis

Method	Agreement Induction of labor as reported by Kappa	Agreement Primary Cesareans as reported by Kappa	Primary Cesarean Rate	Induction Rate	Sample
1. Agreement Primary Cesarean Delivery	0.452	1.000	9.6%	21.1% - 31.1%	197,415
2. Agreement Induction of labor	1.000	0.949	8.9% - 9.7%	15.2%	161,907
3. Either Source Identifies Induction of labor and Primary Cesarean Delivery	0.449	0.946	9.7-10.9%	21.2-31.1	199,343
4. Agreement of Both Data Sources	1.000	1.000	8.9%	15.3%	160,533

Note. HDD indicates Hospital Discharge Data and BC indicates Birth Certificate Data. All Kappa statistics were significant with $p < .001$. Ranges in rates depend on the approach to identifying the variable within the method.

The disagreement with the induction of labor variable is clearly a key limitation of using both data sources to indicate that the case was an induction of labor. Data integrity is an essential component to address when examining any study using readily available electronic sources such as the hospital discharge data and the birth certificate data. Without accurate data the reliability and validity of the study are compromised. Reliability is reflected in a Kappa score of .60 or better (DiGiuseppe et al., 2001). Therefore, the induction of labor Kappa scores indicate the reliability of the induction of labor variable was an issue in using all $n = 199,343$ cases or using agreement on primary cesarean delivery with $n = 197,415$. Without reliable data the validity of the study is impacted.

Because the goal of the study was to isolate as purely as possible the effect of labor induction on primary cesarean delivery, the importance of correctly identifying cases as induction of labor and primary cesarean deliveries was paramount. If the researcher introduced cases that may not be correctly identified, potential error would have been introduced into the measurement process with some methods compared to others introducing larger bias than others.

What was unknown in this study was the degree of false positive and false negative introduced by one data source or the other, and which data source may be considered the “gold standard.” Given the hospital discharge data is used for billing, there are set rules for coding procedural information, and the provider is likely to get less reimbursement when a coder fails to code a primary cesarean delivery when, in fact, it was done. Therefore, it is likely that the hospital discharge data would be more accurate than the birth certificate with regards to cesarean delivery. Additionally, the overall agreement with primary cesarean delivery reflected significant agreement with a Kappa of .95 (see Table 24) for the potential study population ($n = 199,343$).

However, the induction of labor variable introduced a different issue. The provider’s reimbursement is not impacted when a coder fails to code induction of labor, because their

reimbursement rates do not change with induction of labor, but only when they have an operative delivery as opposed to a vaginal delivery. It appears that given the significant disagreement (Kappa of .45), the cases with disagreement introduce potential error. If the researcher elected to use cases with total agreement, then potential errors of omission might be introduced in a systematic way; however, it is less likely that if both sources agree, the information provided is incorrect. If bias were introduced with this election than it would likely be labor inductions that were not identified in either source, given the low rate of labor induction with this election (15.3%). The main issue with this election was the loss of cases that reduced the population size, as well as the reduction in the raw rate of labor induction and primary cesarean delivery. However, the researcher concluded it was more likely that with inclusion of the cases with disagreement, the potential error introduced was the greater limitation. With this election, if the researcher elected to indicate the woman was induced when either data source indicated an induction of labor was done, the election may introduce false positives, meaning the data indicates the procedure was done and it was not, and false negatives with the data sources indicating the woman was not induced when she was induced. Clearly either decision creates some limitation to the study and presents opportunity for further research to validate which decision is the better option (discussed further in Chapter V).

In examining the literature, two studies provided information to the researcher for consideration in making this decision regarding identifying induction of labor and primary cesarean delivery in the potential study population. An important study (Keeler et al., 1997) examining cesarean delivery using Washington State hospital discharge data and birth certificate data provided some insight with using both data sources to indicate a procedure was done (method 3). Keeler et al.'s study (1997) indicated that prediction of cesarean delivery was better with both sources providing procedure and risk information rather than if one or the other alone

was used. Unfortunately, Keeler et al. (1997) did not examine modeling with total agreement, meaning that both data sources agreed on all variables introduced into the model. Other researchers have indicated that birth certificate data reflects considerable error (Polancich, 2003; Restrepo, 2003).

Another study that provided information upon which to base this decision was the DiGiuseppe et al. (2001) study. The DiGiuseppe et al. (2001) study tested various models for predicting cesarean delivery and recommended using common variables within the hospital discharge data and the birth certificate data rather than birth certificate data alone. Their research indicated that the predictive model with variables with better agreement correlated ($r = .88$) with the abstracted medical record model when examining hospital z score rankings for the hospitals based on the model results. Therefore, the two studies identified examining agreement of birth certificate and hospital discharge data and modeling primary cesarean delivery and Induction of labor was *not* very helpful given that one study elected to use variables if either source indicated the condition was present (method 3), and the other elected to code induction of labor if both sources indicated the intervention was present (method 4). However, the researcher felt that the DiGiuseppe et al. (2001) study was more compelling given that the researchers validated results with medical record abstracting. This study would support using total agreement as the study population ($n = 160,533$).

The researcher also examined the data for patterns in hospital variability for all hospitals in the study ($n = 41$ hospitals) with regards to agreement using all potential cases ($n = 199,343$). The researcher performed a cross tabulation with a Kappa statistic on each of the hospitals to identify any systematic bias. For many of those hospitals with poor Kappa scores ($< .25$), it appears there may be a bias towards reporting induction of labor more frequently in one data source compared to the other. Table 29 highlights the results from this analysis. Note that

Hospital EE had a Kappa score of 0.051 and reports induction of labor in 1.68% of the cases in birth certificate data and reports induction of labor in 25.68% in hospital discharge data. In contrast, Hospital R, with a Kappa score of 0.126, reports induction of labor more frequently in the birth certificate data, with induction of labor reported in 45.55% of the cases in the birth certificate data and induction of labor reported in 6.07% in the hospital discharge data. It appears that a substantial component of the disagreement might actually be introduced by hospital preference for reporting, given that some hospitals appear to have a propensity to report in one data source compared to the other.

Table 29

Hospital Kappa Statistics on Agreement for Induction in BC Data and HDD

Hospital	Kappa	% Induction BC	% Induction HDD
A	0.591	9.44%	9.70%
B	0.157	17.80%	25.48%
C	0.24	16.99%	4.00%
D	-.007 ^a	22.98%	17.88%
E	0.49	18.09%	16.38%
F	0.596	40.16%	38.38%
G	0.305	60.37%	34.06%
H	0.226	67.18%	55.64%
I	0.295	15.58%	9.89%
J	0.084	14.07%	17.72%
K	0.518	33.47%	35.45%
L	0.015	0.37%	15.28%
M	0.206	20.35%	10.87%
N	0.164	13.46%	13.96%
O	0.676	34.54%	39.35%
P	0.126	34.38%	7.76%
Q	0.413	40.39%	23.38%
R	0.126	45.55%	6.07%
S	0.693	30.83%	27.72%
T	0.352	29.09%	11.35%
U	0.632	20.02%	17.19%

Table 29 (continued)

Hospital	Kappa	% Induction BC	% Induction HDD
V	0.381	38.98%	16.94%
X	0.201	31.38%	9.85%
Z	0.581	24.76%	20.93%
AA	0.416	31.00%	22.07%
BB	0.485	26.49%	31.53%
CC	0.718	47.87%	43.34%
DD	0.017	0.43%	16.77%
EE	0.051	1.68%	25.68%
FF	0.208	14.32%	39.35%
GG	0.639	44.83%	39.69%
HH	0.245	25.78%	8.11%
II	0.492	35.68%	22.65%
JJ	0.287	26.89%	19.09%
KK	0.377	45.75%	26.78%
LL	0.442	28.87%	34.13%
MM	0.407	22.55%	10.15%
NN	0.781	42.00%	35.41%
OO	0.585	43.19%	37.63%
PP	0.433	25.19%	40.73%
QQ	0.437	22.25%	14.68%

Note. ^a Kappa Statistic for Hospital D was not significant $p = .667$.

The researcher followed the hospital analysis with a review of the data involving cases that had disagreement between the two sources, with investigation of 100 randomly selected cases that disagreed on either hospital discharge data or birth certificate data. When examining the disagreement on mode of delivery, the researcher noted that the hospital discharge data appeared to be more consistent throughout the coding scheme (up to nine diagnoses and six procedures on each record) when primary cesarean delivery was coded, or vaginal delivery was coded. The consistency was determined by other clinical factors within the ICD-9-CM codes that indicated the case was appropriately coded. For example, when the birth certificate data indicated that the case was a cesarean delivery and the hospital discharge data indicated vaginal delivery, the cases

often had more than one code that indicated a likely vaginal delivery, such as a case coded as a vaginal delivery, episiotomy, first, second, third degree tears or forceps delivery. Table 30 reflects two cases with this scenario; note that both cases were vaginal deliveries according to the hospital discharge data and that the cases were complicated by vaginal and rectal tears, indicating that these cases were likely to have been vaginal deliveries even though birth certificate data indicated they were primary cesarean deliveries. Conversely, a case identified as a vaginal delivery in the birth certificate and the hospital discharge data indicated a primary cesarean delivery, cases often reflected complicated deliveries and longer length of stays, with such things as postoperative hemorrhage and maternal anemia coded.

Table 30

ICD-9-CM Procedure and Diagnosis Descriptions for Cases Coded as Vaginal Delivery in Hospital Discharge Data and Cesarean in Birth Certificate

ICD-9-CM	Description
Diagnosis Code:	Case Example #1
659.71	Abnormality In Fetal Heart Rate Or Rhythm, Delivered, With Or Without Mention Of Antepartum Condition
664.21	Third-degree Perineal Laceration, With Delivery Perineal laceration, rupture, or tear (following episiotomy) involving: anal sphincter, rectovaginal septum, sphincter NOS
661.01	Primary Uterine Inertia, With Delivery Failure of cervical dilation; Hypotonic uterine dysfunction primary; Prolonged latent phase of labor
V27.0	Mother With Single Liveborn
Procedure Code:	
75.62	Repair of current obstetric laceration of rectum and sphincter ani

Table 30 (continued)

ICD-9-CM	Description
Diagnosis Code:	Case Example #2
665.41	High Vaginal Laceration, With Delivery Laceration of vaginal wall or sulcus without Mention of perineal laceration
V27.0	Mother With Single Liveborn
Procedure Code:	
75.69	Repair of other current obstetric laceration ^a Episioperineorrhaphy Repair of: pelvic floor, perineum, vagina, vulva Secondary repair of episiotomy

Note. ^aEpisioperineorrhaphy is an operative procedure to suture a laceration of vulva or perineum (*ICD-9-CM Millennium Edition International Classification of Diseases 9th Revision Clinical Modifications (6th ed.)*, 2003, p. 646).

The length of stay also provided information regarding the cases with disagreement. The length of stay for the cases with disagreement on primary cesarean delivery (BC = primary cesarean versus HDD = no primary cesarean delivery) reflected a 2.4 day length of stay compared to a 3.6 day length of stay, respectively. Therefore, the length of stay data appears to be correct when the hospital discharge data identified primary cesarean delivery, given one would expect that a cesarean delivery has a longer length of stay. This analysis would indicate that the hospital discharge data has a higher degree of validity for primary cesarean delivery than does the birth certificate data.

However, induction of labor presented a different issue. When cases that disagreed were analyzed for consistency of coding information that might reflect the accurate procedure information, some bias was identified. The hospital discharge data codes an ICD-9-CM code of

658.11 indicating the woman had premature rupture of membranes. This diagnosis presented a trend that may be clinically significant in the cases with disagreement. Given that the premature rupture of membranes would indicate that the woman was beginning the process of labor, this diagnosis actually introduces some clinical ambiguity.

Disagreement likely reflective of clinical definition issues for induction of labor. Williams *Obstetrics* (Cunningham et al., 2001) discusses the lack of homogeneity of cases with premature rupture of membranes because these cases are often associated with preterm delivery. These deliveries are complicated, according to Cunningham et al. (2001), by preterm cervical dilatation, anatomical incompetence of the cervix, shortening of the cervix, uterine abnormalities (fundal), fetal anomalies, multifetal pregnancies, severe maternal illness (including infection), and maternal systemic disorders. Additionally, there is debate regarding whether or not obstetricians consider a woman that is augmented when failing to progress post-premature rupture of membranes as an induction of labor or an augmentation. Some practitioners would indicate that the case was an induction of labor, while others would identify the woman as in labor requiring augmentation. The key issue is the practitioners' definition of onset of labor. It appears that this area may account for some of the disagreement between the two data sources.

To explore this issue, the researcher examined the cases with disagreement to determine if augmentations might be a component of the cases with disagreement. The birth certificate record reflects whether or not a woman's labor was augmented. Therefore, those cases which the hospital discharge record indicated were induction of labor and the birth certificate data indicated were not induction of labor, the researcher examined the augmentation field in the birth certificate data to determine what percentage of the cases with disagreement reflected that an augmentation was done. Of the 37,436 cases that disagreed on induction of labor, 17,586 (47%) were identified as induction of labor on the hospital discharge data. Of those 17,586 cases, 23.8% (4,194) of

those cases were identified as augmentations in the birth certificate data. These cases may be reflective of a clinical bias driven by definition of onset of labor. Of the 4,194 cases, 11.3% were coded in the hospital discharge data as premature rupture of membranes. This analysis is reflected in Table 31. Based on this analysis, the cases lacking agreement on induction of labor appear to represent some systematic bias by hospital reporting and a bias relating to ambiguity of definitions for cases that are augmentations.

Table 31

Augmentation of Labor Examining Disagreement with HDD and BC Data

			Augmentation of labor BC Data		
			No	Yes	Total
Induction HDD	No	Count % within Induction	15,922 80.20%	3,928 19.80%	19,850 1.00
	Yes	Count % within Induction	13,392 76.20%	4,194 23.80%	17,586 100.00%
Total		Count % within Induction	29,314 78.30%	8,122 21.70%	37,426 100.00%

Note. HDD is an abbreviation for hospital discharge data and BC is an abbreviation for birth certificate data.

Based on the analyses and the review of the literature, the researcher elected to examine the effect of four methods for identifying induction of labor and primary cesarean delivery to determine what effect the different methods had on the relationship between induction of labor and primary cesarean delivery. This was done by performing preliminary modeling of the crude effect of labor induction on primary cesarean delivery and all potential confounders. Table 32 below reflects the four methods modeled. Method one used only cases with agreement on primary

cesarean delivery, with a population of $n = 197,415$. The remaining 1,928 cases (199,434-197,415) represent those cases that disagreed on primary cesarean delivery. The researcher elected to model induction of labor by two methods, one using hospital discharge data as the determinant for induction of labor and one using birth certificate as the determinant for induction of labor. Method two used only cases that agreed on induction of labor with a population of $n = 161,907$. The remaining 37,436 cases represent disagreement on induction (199,343-161,907). The researcher elected to model the outcome of interest by two methods, one using hospital discharge data as the determinant for primary cesarean delivery and one using birth certificate as the determinant for primary cesarean delivery. Method three used cases with either data source indicating primary cesarean delivery *or* induction of labor, with a population of $n = 199,343$. The researcher elected to model induction of labor by two methods, one using hospital discharge data as the determinant for induction of labor and one using birth certificate as the determinant for induction of labor. Method four used cases with agreement on *both* primary cesarean delivery *and* induction of labor, with a population of $n = 160,533$. The researcher recognizes there are a number of different permutations that could have been selected to model under the various methods, but the primary purpose with this analysis was to determine if the selection of the data source and the determinant for induction of labor and primary cesarean delivery made a difference with preliminary modeling of labor induction on primary cesarean delivery controlling for each of the covariates.

Table 32

Four Methods on Agreement Preliminarily Modeled

Method	Description of Method	Population
Method 1	Primary Cesarean Agreement	N=197,415
	Induction determined by HDD	n=41,692
	Induction determined by BC	n=44,236
Method 2	Induction Agreement	N=161,907
	Primary Cesarean determined by HDD	n=15,463
	Primary Cesarean determined by BC	n=14,487
Method 3	Primary Cesarean or Induction Agreement	N=199,343
	Induction Determined by HDD	n=42,244
	Induction Determined by BC	n=44,508
Method 4	Both Agree	N=160,553
	Primary Cesarean	n=14,288
	Inductions	n=24,523

Modeling Technique for Agreement Analysis

Prior to deciding which method to use for the final study examining the effect of labor induction on primary cesarean delivery, the researcher went through the first stages of modeling several data approaches. The preliminary modeling proceeded with an initial model fit, containing only induction of labor as the explanatory variable and primary cesarean delivery as the response variable (the crude model), and the logistic regression coefficient for induction of labor recorded (the crude coefficient). Then, the covariates were added, one at a time, into the crude model, estimating the coefficient for induction of labor in each new model, and recording the percent change from the crude coefficient. The researcher hypothesized the following: There is no difference between the methods for identifying induction of labor and primary cesarean delivery

when examining the changes in the logistic regression coefficient for induction of labor on primary cesarean delivery for the covariates of interest.

The initial modeling was based on methods proposed by Hosmer and Lemeshow (2000) to fit a crude and base model. The initial model was fit containing only induction of labor as the explanatory variable and primary cesarean delivery as the response variable. This is defined as “the crude model.” The coefficient for induction of labor was recorded. The coefficient is defined as “the crude coefficient.” The covariates (potential confounders) were individually entered into the crude model, estimating the coefficient for induction of labor in each new model, and recording the percent change from the crude coefficient. The percent change in the coefficient was calculated by the following formula: $(\text{Original Coefficient} - \text{New Coefficient}) / \text{Original Coefficient} \times 100$. Table 33 reflects the results from method one. Note that with method one (primary cesarean agreement), there are two scenarios that were examined, one where induction of labor was identified by hospital discharge data and the other where induction of labor was identified by birth certificate data. Method two utilized cases with agreement on induction of labor. Table 34 reflects the results from this analysis. Note that once again with this method, there were two scenarios examined: one with primary cesarean identified by hospital discharge data and the other with primary cesarean identified by birth certificate data. The third method examined using cases with either source indicating a primary cesarean delivery or induction was done as was done by Keeler et al. (1997). In this method induction of labor was identified by two scenarios, induction of labor using hospital discharge data and induction of labor using birth certificate data. The primary cesarean delivery was identified by using the hospital discharge data to limit the number of permutations tested under this method. Results are reflected in Table 35.

The final method used the population of cases with total agreement for both primary cesarean delivery and induction of labor. In other words, birth certificate data indicted the case

was an induction of labor or primary cesarean, and the hospital discharge data agreed with birth certificate information. This method reduces the population to $n = 160,533$. Table 36 reflects results from this analysis. Note that with this method, only one scenario for identifying induction of labor and primary cesarean delivery was necessary given that both variables were in agreement.

Table 33

Method One: Primary Cesarean Agreement (n=197,415)

	A. Induce = HDD n=41,692		B. Induce = BC n=44,236	
	Estimate	Diff	Estimate	Diff
Induction (only) Crude Coefficient	0.414		0.477	
Medical Indication for Induction	0.294	29.05%	0.392	17.74%
Dystocia	0.473	-14.23%	0.529	-10.89%
Race & Ethnicity	0.370	10.47%	0.439	7.94%
Gestation	0.393	4.88%	0.453	5.04%
Baby Weight	0.379	8.34%	0.444	6.96%
Maternal Age	0.395	4.44%	0.465	2.42%
Nulliparity	0.389	5.97%	0.466	2.36%
Fetal Distress	0.419	-1.21%	0.472	1.11%
Private Payer	0.344	16.93%	0.428	10.36%
Ownership	0.367	11.17%	0.437	8.46%
Urban	0.413	0.14%	0.481	-0.84%
Teaching Status	0.382	7.76%	0.445	6.74%
Bed Size	0.397	4.10%	0.455	4.66%

Note. Medical indication for induction is the variable with the greatest change in the coefficient for induction of labor.

Table 34

Method Two: Induction of Labor Agreement (n=161,907)

	A. Primary CS = HDD n=15,463		B. Primary CS = BC n=14,487	
	Estimate	Diff	Estimate	Diff
Induction (only) Crude Coefficient	0.466		0.527	
Medical Indication for Induction	0.340	27.14%	0.404	23.35%
Dystocia	0.533	-14.25%	0.597	-13.43%
Race & Ethnicity	0.402	13.74%	0.464	11.84%
Gestation	0.444	4.86%	0.498	5.40%
Baby Weight	0.423	9.30%	0.484	8.14%
Maternal Age	0.442	5.26%	0.503	4.46%
Nulliparity	0.446	4.28%	0.509	3.33%
Fetal Distress	0.469	-0.56%	0.529	-0.50%
Private Payer	0.381	18.22%	0.447	15.18%
Ownership	0.395	15.21%	0.467	11.28%
Urban	0.469	-0.54%	0.528	-0.30%
Teaching Status	0.408	12.56%	0.475	9.84%
Bed Size	0.440	5.54%	0.496	5.74%

Note. Medical indication for induction is the variable with the greatest change in the coefficient for induction of labor.

Table 35

Method Three: Either Source Indicating a Primary Cesarean or Induction of Labor (n=199,343)

	A. Induce = HDD <i>n</i> =44,052		B. Induce = BC <i>n</i> =46,308	
	Estimate	Diff	Estimate	Diff
Induction (only) Crude Coefficient	0.418		0.407	
Medical Indication for Induction	0.299	28.52%	0.322	20.76%
Dystocia	0.470	-12.48%	0.454	-11.63%
Race & Ethnicity	0.374	10.44%	0.369	9.40%
Gestation	0.402	3.74%	0.389	4.33%
Baby Weight	0.385	7.94%	0.374	8.03%
Maternal Age	0.399	4.68%	0.394	3.03%
Nulliparity	0.392	6.14%	0.395	2.79%
Fetal Distress	0.423	-1.27%	0.402	1.28%
Private Payer	0.346	17.23%	0.355	12.72%
Ownership	0.360	13.83%	0.360	11.44%
Urban	0.417	0.22%	0.412	-1.37%
Teaching Status	0.385	7.87%	0.370	9.15%
Bed Size	0.406	2.94%	0.391	3.90%

Note. Medical indication for induction is the variable with the greatest change in the coefficient for induction of labor.

Table 36

*Method Four: Induction of Labor and Primary Cesarean Agreement**(n = 160,533)*

	Estimate	Diff
Induction (only) Crude Coefficient	0.527	
Medical Indication for Induction	0.401	23.92%
Dystocia	0.600	-13.74%
Race & Ethnicity	0.464	12.07%
Gestation	0.498	5.53%
Baby Weight	0.483	8.39%
Maternal Age	0.503	4.58%
Nulliparity	0.508	3.67%
Fetal Distress	0.530	-0.46%
Private Payer	0.444	15.78%
Ownership	0.465	11.77%
Urban	0.529	-0.31%
Teaching Status	0.473	10.26%
Bed Size	0.497	5.83%

Note. Medical Indications for Induction had the greatest change on the induction of labor coefficient, as with all other methods.

To substantiate the validity of using these data sources to examine the effect of labor induction on primary cesarean delivery it was important to examine the question: *“Does the data source make a significant difference when examining the effect of labor induction on primary cesarean delivery?”* The researcher inspected the trends in the coefficient changes for the various scenarios examined to answer this research question. The researcher recognized that there were other scenarios that could have been examined, but concluded that this analysis would determine if the coefficients changed depending on how induction of labor and primary cesarean were identified (meaning which source). To visually see differences in the various methods for identifying induction of labor and primary cesarean delivery in the different data sets available, the researcher visually inspected the coefficient changes in bar charts. The bar charts are reflected in Figures 9, 10, 11, and 12. Each bar represents the coefficient change of the variable on the effect of labor induction on primary cesarean delivery. The contrast between which data source identifies induction of labor is interesting to note.

Visually the various methods have consistent patterns across the covariates with respect to direction for the induction of labor coefficient changes, with the exception of fetal distress and urban hospital characteristic. These two variables have one thing in common. Both variables have very small effects on the induction of labor coefficient. Therefore, the importance of both these potential confounders to the preliminary stage of modeling was likely not to make an important impact on the overall preliminary modeling. An additional issue to note was the large variability with respect to magnitude of effect on the induction of labor coefficient when different scenarios are available with methods one, two, and three. For example, note the medical indication for induction of labor covariate for the four methods. In methods 1, 2, and 3 the medical indication for induction of labor covariate’s effect on induction of labor was just below 30% for 1A, 2A, and 3A with rates of 29.5%, 27.14%, and 28.52%, respectively; whereas, with all other methods the

effect was less than 25% with effect changes ranging from 1.74% to 23.92%. Yet, in all methods medical indication for induction of labor had the greatest effect on the induction of labor coefficient.

Potential confounders in the preliminary steps are identified by any confounder that changes the induction of labor coefficient by more than 10%. A confounder is a variable that is systematically related to the induction of labor covariate impacting (confounding) the effect of labor induction on primary cesarean delivery. There were slight differences in the various methods regarding which covariates are considered potential confounders when the researcher allowed either data source to reach the 10% threshold in methods 1, 2, and 3. Method 1 and 3 are identical with respect to which covariates reached the 10% threshold, and 2 and 4 are identical. Table 37 reflects these findings.

Table 37

Potential Confounders with a 10% Coefficient Change

Method 1	*Medical Indication for Induction, *Dystocia, *Race & Ethnicity, Baby Weight, *Private Payer, *Ownership, and Teaching Status
Method 2	Medical Indication for Induction, Dystocia, Race & Ethnicity, Private Payer, and Ownership
Method 3	Medical Indication for Induction, Dystocia, Race & Ethnicity, Baby Weight, Private Payer, Ownership, and Teaching Status
Method 4	Medical Indication for Induction, Dystocia, Race & Ethnicity, Private Payer, Ownership, and Teaching Status

Note. The variables listed under each method indicate the variables with a change in the crude coefficient by 10% or greater. * Indicates a variable that consistently changed the induction crude coefficient by 10% or greater across all four methods.

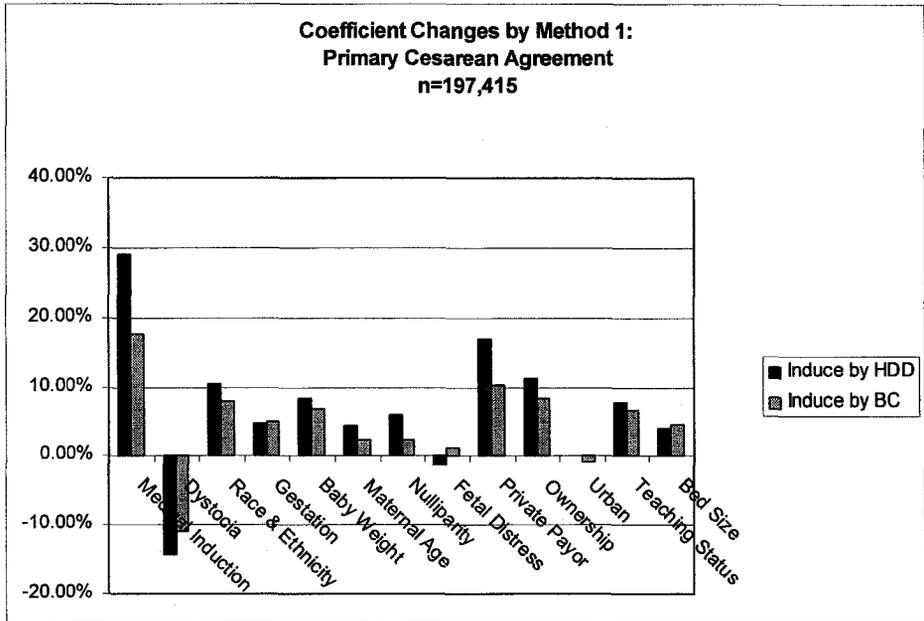


Figure 9. Method 1.

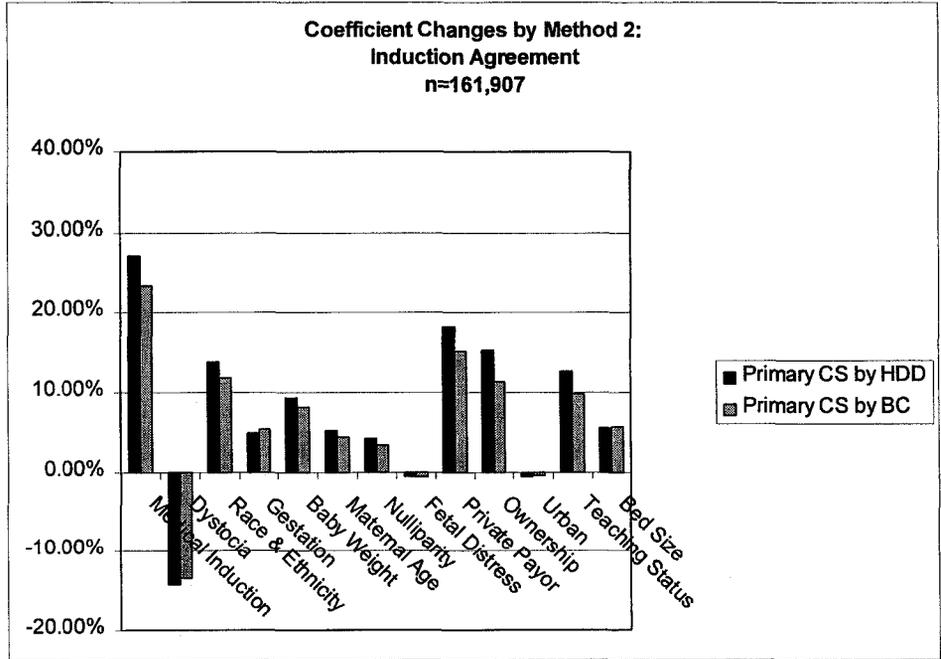


Figure 10. Method 2.

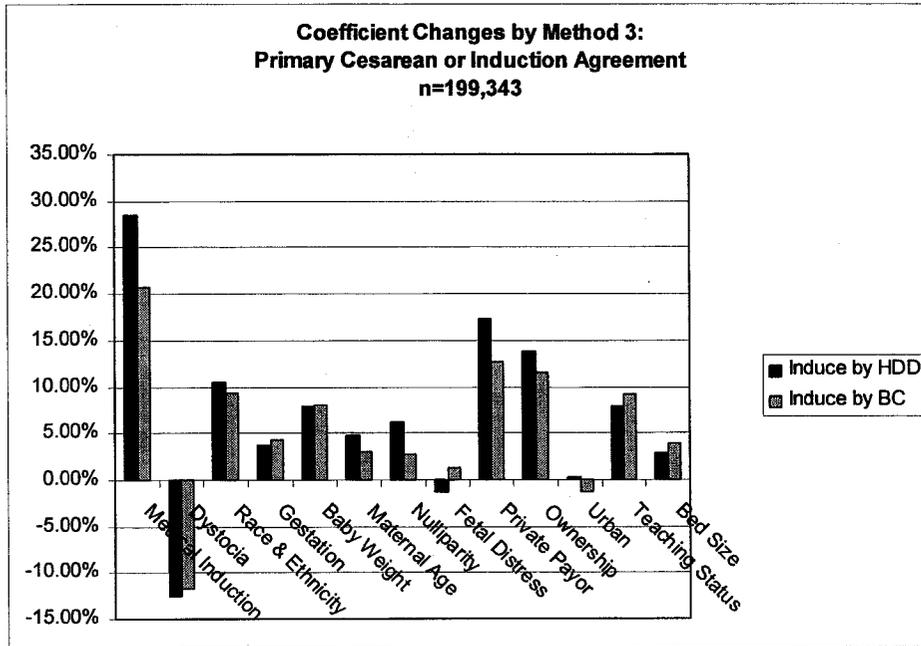


Figure 11. Method 3.

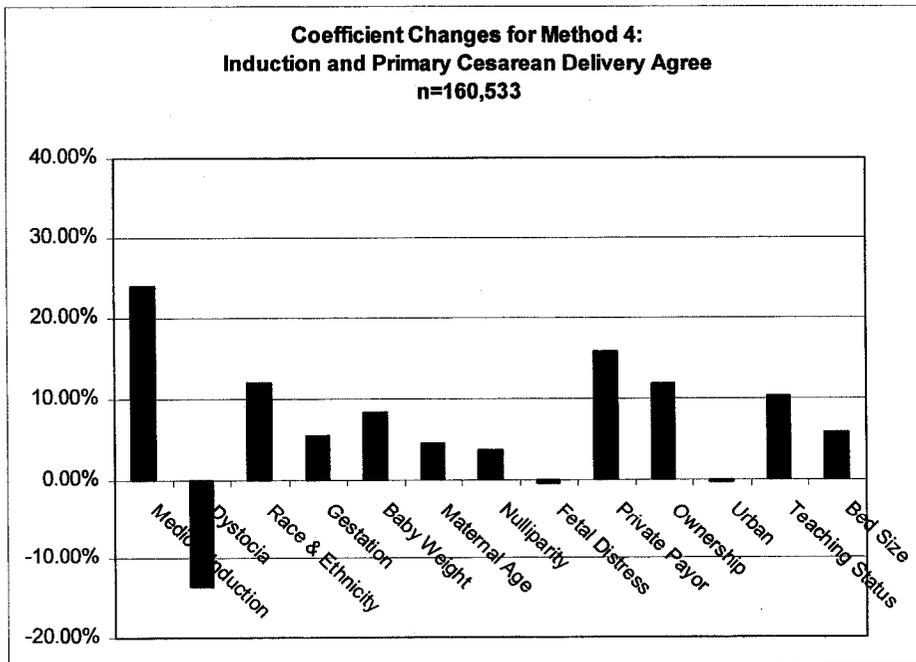


Figure 12. Method 4.

The discrepancies between direction, magnitude and which covariates enter the model due to confounding were problematic and raised the issue of which data source to use to identify the cases under these situations. This variability reinforced using agreement of both data sources, given it is likely that one aspect of this variability was the mixed group of cases with disagreement on induction of labor.

Decision Regarding Selection of Data Set for Analysis

Given the induction of labor disagreement between the two datasets, the clinical ambiguity regarding definitions of labor perhaps relating to augmented cases, and the finding that the various preliminary methods of identifying induction of labor and primary cesarean delivery with the two data sources available may impact the results, the researcher elected to err on the side of caution and include only those cases with total agreement in both data sources. This reduced the total number of cases within the study population to $n = 160,533$, but will establish necessary confidence by the researcher that the cases identified as induction of labor was indeed induction of labor, and the cases identified as primary cesarean delivery also were correctly identified. Therefore, the effect measured by the study and any confounding and effect modification should reflect an isolated effect of cases known to be induction of labor and primary cesarean delivery. The researcher essentially elected the conservative approach to the data. The researcher concluded that this method introduces the least amount of bias given the variability introduced by the various methods with substantial potential variability introduced by the source that identified the induction or the primary cesarean delivery.

The researcher recognizes that the modeling described above was for preliminary screening purposes only to discern which data source might provide the best solution for examining the effect of labor induction on primary cesarean delivery. The researcher acknowledges that to fully test the hypothesis of no difference in the methods modeled and

discussed above, a full application of Hosmer's and Lemeshow's technique should be applied (see Chapter V for further discussion). However, the selected method corroborates with findings from DeGuiseppe et al. (2001). DiGiuseppe et al.'s study examined three predictive pairs of models, one with the full complement of variables in medical records *or* birth certificates, another with variables common to the two data sources, and the third with a limited subset with variables common to both data sources having good agreement (defined as Kappa scores $> .60$) (DiGiuseppe et al., 2001). Their reported study created full models from each of the data scenarios and compared the ability of the models to discriminate. They then compared the differences between models examining hospitals risk adjusted cesarean rates to determine which of the models performed best when compared to a model using data from a medical record abstraction database. They found that the model limited to variables with better agreement had higher correlations between models for the hospitals risk adjusted rates than the other two data scenarios. Their conclusion was that models created with variables demonstrating agreement yield results that are more similar to rankings based on abstracted medical records, which is considered "the Gold Standard" for validity (Iezzoni, 1997). DiGiuseppe et al.'s findings support using the reduced data file ($n = 160,533$) with both birth certificate and hospital discharge data in agreement on primary cesarean delivery and induction of labor.

Description of the Population

The demographics were analyzed based on intervention of interest, outcome of interest, client and system characteristics. The intervention of interest in the study was induction of labor and the outcome of interest was primary cesarean delivery rates. The demographics of the study population are reflected in Table 38, 39, and 40.

Intervention and Outcome of Interest: Demographics

The rate of primary cesarean delivery in the study population was 8.9% representing 14,288 deliveries out of the 160,533 study population. The labor induction rate for women having primary cesarean deliveries was 22.43%, compared to women that did not have a primary cesarean with the labor induction rate being 14.58%. Table 38 reflects the labor induction rate for the study population, the Pearson chi square (χ^2 620.454, $N = 160,533$, $df = 1$, $p < .001$) indicates significant association between induction of labor and primary cesarean delivery.

Table 38

Primary Cesarean Delivery by Induction of Labor for the Study

Population

		Induction of labor		Total	χ^2	df	p value
		No	Yes				
Primary Cesarean	No	Count	124,927	21,318	146,245		
		% within Primary CS	85.42	14.58	100		
	Yes	Count	11,083	3,205	14,288		
		% within Primary CS	77.57	22.43	100		
Total		Count	136,010	24,523	160,533	620.454	1
		% within Primary CS	84.72	15.28	100		0.000

Note. CS indicates cesarean delivery.

Examining the crude odds of a primary cesarean delivery within the study population comparing induced women to women who are not induced indicated an increased likelihood of having a primary cesarean by 70% (OR = 1.70; 95% CI: 1.63, 1.77; $p < .001$) for women whose labor was induced compared to women who were not induced. It is important to understand what may be confounding or modifying the effect of labor induction on primary cesarean delivery in order to better understand what constitutes a safe effective delivery. Additionally, it is

inappropriate to interpret an odds ratio if effect modification is present with one or more of the covariates (Hosmer & Lemeshow, 2000). Therefore, this study examined both client and hospital characteristics that could modify or confound the relationship.

Client Characteristic Demographics

Continuous client characteristics: Maternal age and baby weight. The study had two continuous client characteristics variables: maternal age and baby weight in grams. The demographics of these two characteristics are reflected in Table 39. The average age of all subjects was 26.07 ($SD = 5.96$). The women who were included in the sample ranged from 11 to 50 years of age. Similarly, the women who were induced ranged from 11 to 49 years of age with a mean age of 27.27 ($SD = 5.94$); whereas, women who had a spontaneous delivery had a mean age of 26 ($SD = 5.92$). Women that had a primary cesarean delivery ranged from 13 to 48 years of age with an average age of 26.73 ($SD = 6.21$). The independent-samples t-test comparing means for the two groups of cases comparing induced women's age and non-induced women indicated a significant difference between the two groups ($t = 34.60, p = .001$; unequal variances not assumed Levene's Test for Equality of Variances, $p < .01$).

The mean weight in grams for the neonates reported in the study population was 3416.53 ($SD = 450.41$). Whereas, the mean weight in grams for an induced delivery was 3487.74 ($SD = 448.63$), and the mean weight in grams for a spontaneous delivery was 3403.70 ($SD = 449.54$). The independent-samples t-test comparing means for the two groups comparing induced women to women who were not induced for baby weight in grams, indicated a significant difference between the two groups ($t = 26.96; p < .001$; assuming equal variances with Levene's Test for Equality of Variances $p = .689$). Women delivering by primary cesarean delivery had larger neonates with the mean baby weight in grams being 3528.50 ($SD = 528.10$) grams. There also were significant differences with baby weight in grams for women delivering by primary

cesarean delivery compared to women who were not delivered by primary cesarean delivery measured by an independent t-test ($t = 26.96, p < .001$; assuming unequal variances with Levene's Test for Equality of Variances $p < .001$). Table 39 reflects these population differences.

Table 39

Demographics Descriptive Statistics for Maternal Age and Baby Weight in Grams

	<i>N</i>	Minimum	Maximum	Mean	<i>SD</i>
Maternal age	160,533	11	50	26.07	5.95
Induction of Labor	24,523	11	49	27.27	5.94
Primary CS	14,288	13	48	26.73	6.21
Baby Weight in Grams	160,533	1,063	7,858	3,416.53	450.41
Induction of Labor	24,523	1,275	5,953	3,487.74	448.63
Primary CS	14,288	1,162	7,858	3,528.50	528.10

Categorical client characteristics for the study population. Categorical client characteristics for the study were: nulliparity, gestation, fetal distress, dystocia, medical indication for induction, race, and ethnicity. These demographic characteristics are reflected in Table 40. Within the study population of 160,533 deliveries, 88,802 (55.32%) were multiparous women, whereas, 71,731 (44.68%) were nulliparous women. Fetal distress comprised a very small proportion of the cases with less than 1% ($n = 570$). Whereas, medical indication for induction of labor was present in 16.09 % of the cases ($n = 25,833$) and dystocia 13.37% of the cases ($n = 21,461$).

Table 40

Categorical and Dichotomous Client Characteristic Demographics of the Study Population

Demographics of the Study Population			
Characteristic		Frequency	Percent
Nulliparity	No	88,802	55.32%
	Yes	71,731	44.68%
	Total	160,533	100.00%
Estimated Gestation	37 weeks	11,321	7.05%
	38 weeks	29,226	18.20%
	39 weeks	42,215	26.29%
	40 weeks	64,093	39.92%
	41 weeks	11,198	6.97%
	42 weeks	2,480	1.54%
	Total	160,533	100.00%
Fetal Distress	No	159,963	99.64%
	Yes	570	0.36%
	Total	160,533	100.00%
Dystocia	No	139,072	86.62%
	Yes	21,461	13.37%
	Total	160,533	100.00
Medical Indication for Induction	No	134,700	83.90%
	Yes	25,833	16.09%
	Total	160,533	100.00%

Table 40 (continued)

Demographics of the Study Population			
Characteristic		Frequency	Percent
Racial and Ethnicity	White	67,827	42.25%
	Black	19,435	12.11%
	Hispanic	52,844	32.92%
	Other	20,427	12.72%

Race and ethnicity were combined and reported based on categories of white, black, Hispanic, and other. White represented 42.25% of the study population, 12.11% Black, 32.92% Hispanic, and 12.72% other.

Gestational age in the study population ranged from 37 weeks gestation to 42 weeks gestation. In the study population, as would be expected, the largest proportion of births was 40 weeks gestation with 39.92% of the births. This was followed by 39 weeks gestation at 26.29% of the births. This is interesting to note given that one might expect to see more births in the 41 to 42 week gestation range. Primary cesarean rate proportions were not significantly different for women 37 to 40 weeks gestation, and for 41 and 42 weeks as evidenced by the overlap in 95% confidence intervals for 37 to 40 weeks gestation, and for 41 and 42 weeks gestation. The primary cesarean rate proportions by gestational age in weeks are reflected in Table 41 with the 95% confidence intervals.

Table 41

Primary Cesarean Rate and 95% Confidence Intervals

	Numerator	Denominator	Point estimate	95% Confidence Interval	
				Lower ci	Upper ci
37 weeks	1017	11,321	8.98%	8.46%	9.51%
38 weeks	2460	29,226	8.42%	8.10%	8.74%
39 weeks	3635	42,215	8.61%	8.34%	8.88%
40 weeks	5234	64,093	8.17%	7.95%	8.38%
41 weeks	1580	11,198	14.11%	13.46%	14.75%
42 weeks	362	2,480	14.60%	13.21%	15.99%

System Characteristics Demographics

System characteristics for the study were: private payer, rural versus urban hospital, hospital ownership, teaching status of the hospital, and bed size. These demographic characteristics are reflected in Table 42. Within the study population of 160,533 deliveries 50.7% had private insurance ($n = 81,398$), whereas, 49.3% did not have private insurance ($n = 79,135$). Of the study population 42.3% ($n = 67,831$) of the cases occurred at a teaching hospital. Hospital ownership was distributed with 27% ($n = 43,270$) of the births occurring in a public hospital, 55.3% ($n = 88,827$) in a non-profit hospital, and 17.7% ($n = 28,436$) in a for-profit hospital. Urban hospitals had 92.6% ($n = 148,629$) of the births in the study population with rural hospital births representing 7.4% ($n = 11,904$) of the births.

Bed group was delineated based on NICU levels and the methodology is discussed in Chapter III. Bed groups were determined by NICU levels and methodology and rationale was

fully discussed in Chapter III. The bed groups were: less than 80 beds 3.5% ($n = 5,566$), 81 to 260 beds 38.1% ($n = 61,241$), and greater than 260 beds 58.4% ($n = 93,726$). As would be expected the largest proportion of births occurred in the larger facilities.

Table 42

System Characteristics Demographics of the Study Population

Characteristic		Frequency	Percent
Private Payer	No	79,135	49.30%
	Yes	81,398	50.70%
	Total	160,533	100.00%
Ownership	Public	43,270	26.95%
	Non-profit	88,827	55.33%
	For-profit	28,436	17.71%
	Total	160,533	100.00%
Urban	No	11,904	7.42%
	Yes	148,629	92.58%
	Total	160,533	100.00%
Teaching Status	No	92,702	57.75%
	Yes	67,831	42.25%
	Total	160,533	100.00%
Bed Size	< 80 beds	5,566	3.47%
	81-260 beds	61,241	38.15%
	> 260 beds	93,726	58.38%
	Total	160,533	100.00%

Hypotheses Testing

It is important to understand the influence of the various covariates on the effect of labor induction on primary cesarean delivery. Initial hypotheses testing examined the various client and system characteristics prior to modeling. The final conclusions for hypotheses testing resulted from a full logistic regression modeling approach recommended by Hosmer and Lemeshow (2000), controlling for client and system characteristics that impact the relationship. Therefore, hypotheses testing proceeded with preliminary analysis and concluded with final results for all four hypotheses using a full logistic regression model.

Hypothesis Number One

Hypothesis number one is stated as follows: Client characteristics (including parity, gestation, race/ethnicity, maternal age, medical indication for induction, dystocia, fetal distress, and baby weight) confound the effect of labor induction on the odds of primary cesarean delivery. Hypotheses number one was initially examined by investigating the impact of individual client characteristics on the effect of labor induction on primary cesarean delivery.

Dystocia. Within the study population, 21,461 deliveries had dystocia or failure to progress. Of the 21,461 deliveries, 37.37% ($n = 8,019$) had a primary cesarean delivery. Table 43 reflects the results from a cross tabulation analysis of primary cesarean delivery by induction of labor stratified by dystocia and failure to progress. The chi-square analysis indicates significant association between primary cesarean delivery rates and induction of labor for women with and without dystocia. Although the difference in primary cesarean rates (Figure 13) was not as clinically significant for women without dystocia, the association was significant ($\chi^2 34.67$, $N=139,072$, $df 1$, $p < .001$). However, the women that were diagnosed with dystocia, and had an induced delivery resulted in a primary cesarean delivery rate 60.87% compared to a 32.89%

primary cesarean rate for women that were not induced. This association was significant (χ^2 965.65, $N = 21,461$, $df = 1$, $p < .001$).

The error bar chart in Figure 13 demonstrates the visual differences for primary cesarean delivery rates between those women induced compared with those women that were not induced stratified by dystocia, with clear delineation evidenced by the lack of overlap in the confidence intervals for dystocia with three distinct clusters: women induced with dystocia, women not induced with dystocia, and women without dystocia. This analysis also indicated that dystocia is likely to confound or modify the effect of labor induction on primary cesarean delivery. When examining induction of labor and primary cesarean delivery with dystocia, it is particularly important to control for other factors that may influence the success of an induction of labor (such as baby weight). This is important because it is difficult to distinguish whether induction of labor is acting independently to increase the odds of a primary cesarean in the face of dystocia, or whether some other covariate is involved. Hence, it is necessary to model induction of labor and primary cesarean delivery controlling for multiple factors, including effect modification and all confounders.

Table 43

Primary Cesarean Delivery by Induction of Labor Stratified by Dystocia and Failure to Progress

				Primary Cesarean		Total	χ^2	df	p value
Dystocia & Failure to Progress		No	Yes						
No	Induction	No	Count	112,829	5,155	117,984			
			% within Induction	95.63	4.37	100			
	Yes	Count	19,974	1,114	21,088				
		% within Induction	94.72	5.28	100				
Total		Count	132,803	6,269	139,072				
		% within Induction	95.49	4.51	100	34.67	1	0.000	
Yes	Induction	No	Count	12,098	5,928	18,026			
			% within Induction	67.11	32.89	100			
	Yes	Count	1,344	2,091	3,435				
		% within Induction	39.13	60.87	100				
Total		Count	13,442	8,019	21,461				
		% within Induction	62.63	37.37	100	965.65	1	0.000	

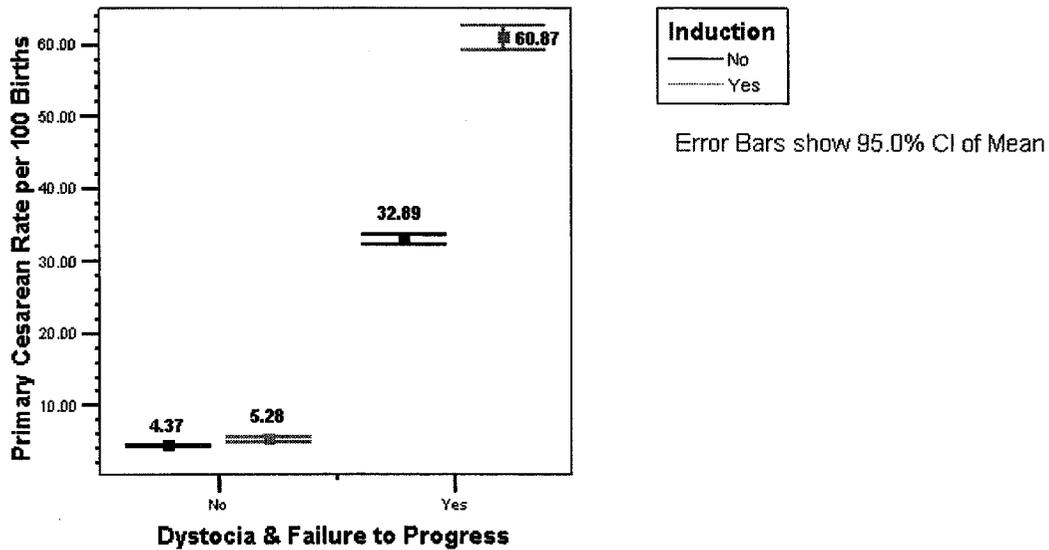


Figure 13. Rates of primary cesarean delivery by induction of labor and stratified by dystocia.

Medical indication for induction. A key factor examined in this study was whether or not the woman had a medical indication for induction. The medical indication for induction factor was present in the study population for 16.1% the women in the population ($n = 25,833$). Table 44 indicates that of the 25,833 women who had a medical indication for induction 21.64% had a primary cesarean delivery rate compared to women without a medical indication for induction that had a 10.25% primary cesarean delivery rate. Table 44 displays a cross tabulation of labor induction by primary cesarean delivery stratified by medical indication for induction. This analysis indicated a significant association between induction of labor and primary cesarean delivery for women with ($\chi^2 39.98, N = 25,833, df = 1, p < .001$) and without medical indications for induction of labor ($\chi^2 350.68, N = 134,700, df = 1, p < .001$).

Table 44

Cross Tabulation of Primary Cesarean Delivery by Induction of Labor Stratified by Medical Indication for Induction

				Primary Cesarean			χ^2	df	p value
Medical Indication for Induction				No	Yes	Total			
No	Induction	No	Count	108,717	7,522	116,239			
			% within Induction	93.53	6.47	100			
		Yes	Count	16,568	1,893	18,461			
			% within Induction	89.75	10.25	100			
Total			Count	125,285	9,415	134,700			
			% within Induction	93.01	6.99	100	350.68	1	0.000
Yes	Induction	No	Count	16,210	3,561	19,771			
			% within Induction	81.99	18.01	100			
		Yes	Count	4,750	1,312	6,062			
			% within Induction	78.36	21.64	100			
Total			Count	20,960	4,873	25,833			
			% within Induction	81.14	18.86	100	39.98	1	0.000

Figure 14 indicates distinct differences in these populations by rates of primary cesarean delivery with four isolated clusters significantly different from one another. The differences are indicated by the confidence intervals lack of overlap. If a woman had a medical indication for an induction, one would expect that she would have an increased risk associated with the pregnancy; because these differences may reflect co-morbidities. However, women without an indication for induction of labor have a significantly higher rate of primary cesarean delivery at 10.25% compared to women that were not induced, and had no medical indication for induction with a cesarean rate of 6.47%, as evidenced by the lack of overlap of the 95% confidence intervals in Figure 14. This preliminary analysis indicates medical indication for induction confounds the relationship of labor induction and primary cesarean delivery.

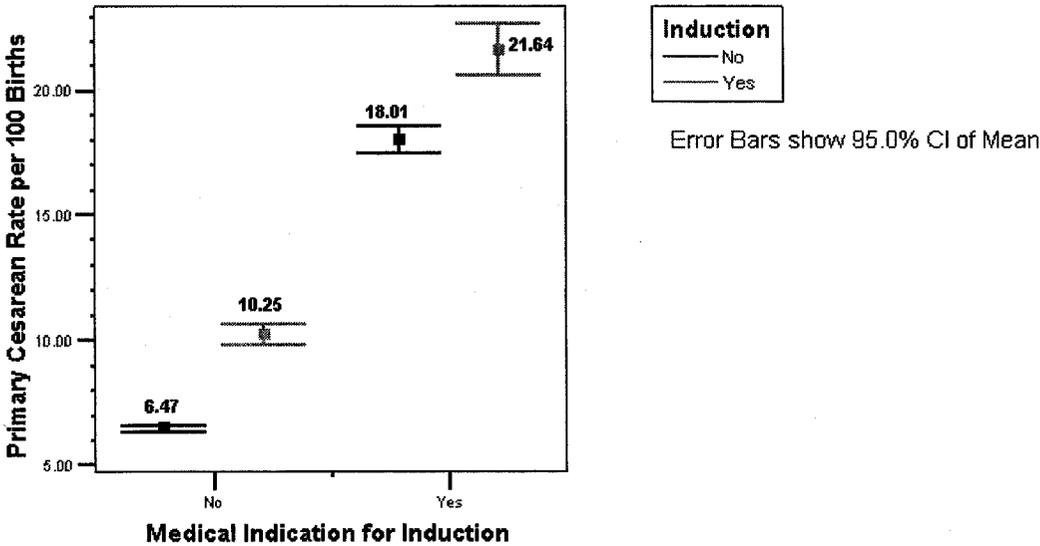


Figure 14. Primary cesarean delivery by induction of labor stratified by medical indication for induction.

Fetal distress. Another important factor considered in this study was fetal distress. The researcher elected to include this risk factor in the study even though this diagnosis reflects a complicated birth. The researcher decided to include fetal distress, because it is possible that some episodes of fetal distress may actually be precipitated by induction of labor. While that determination was not the purpose of this study, the researcher believed that it was important to discern if fetal distress had an impact on the relationship of labor induction and primary cesarean delivery. The study findings indicate that this variable did not confound the relationship of labor induction on primary cesarean delivery, indicating that fetal distress did not impact the relationship.

The study population had a very small proportion ($n = 570/160,533$), less than 1% of cases, diagnosed with fetal distress. Therefore, the findings relating to fetal distress as a confounder are subject to small cell size issues with this one factor. However, they warrant discussion and inclusion in the study, particularly given the importance to the neonatal outcome. Table 45 reflects the results of a cross tabular analysis of primary cesarean delivery by induction of labor stratified by fetal distress. The chi-square analysis of the cross tabulation reflected in Table 45 indicates there was not a significant association between primary cesarean delivery and induction of labor ($\chi^2 .828$; $N = 570$; $df = 1$; $p = .363$) for births with fetal distress. However, the association between induction of labor and primary cesarean delivery was significant ($\chi^2 624.83$; $N = 159,963$; $df = 1$; $p < .001$) for women without fetal distress. As one might expect, in the face of fetal distress the primary cesarean delivery rates are high regardless of whether or not the woman had an induced labor or not, with primary cesarean delivery rate for women with fetal distress at 42.0% for women that are not induced and 47.2% for women that are induced.

Figure 15 further highlights the impact of fetal distress on primary cesarean delivery. The wide 95% confidence interval is important to note and is reflective of the low cell sizes of events

of fetal distress within the study population. The overlap in confidence intervals indicate no significant difference between women with induction of labor compared to women without induction of labor with regards to primary cesarean delivery rates.

Table 45

Primary Cesarean by Induction of Labor Stratified by Fetal Distress

				Primary Cesarean			χ^2	Df	p value	
Fetal Distress				No	Yes	Total				
No	Induction	No	Count	124,648	10881	135,529				
			% within Induction	91.97	8.03	100				
		Yes	Count	21,271	3,163	24,434				
			% within Induction	87.05	12.95	100				
	Total			Count	145,919	14,044	159,963			
				% within Induction	91.22	8.78	100	624.83	1	0.000
Yes	Induction	No	Count	279	202	481				
			% within Induction	58.00	42.00	100				
		Yes	Count	47	42	89				
			% within Induction	52.81	47.19	100				
	Total			Count	326	244	570			
				% within Induction	57.19	42.81	100	0.828	1	0.363

Note. Significant association between induction and primary cesarean delivery for women without fetal distress present as measured by χ^2 .

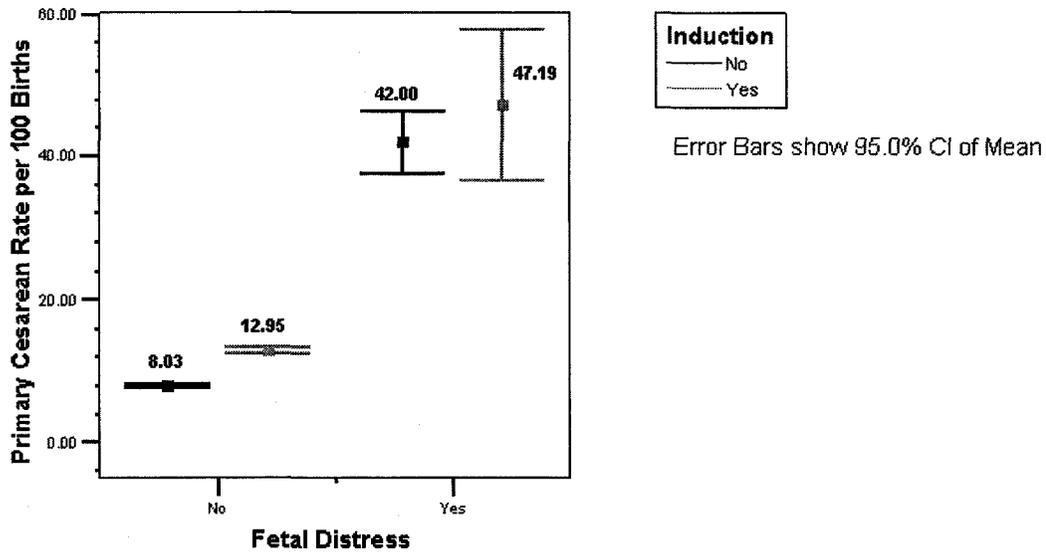


Figure 15. Primary cesarean delivery rates by induction of labor stratified by fetal distress.

Race and ethnicity. Figure 16 highlights the various clusters across race and ethnicity and the differences in various populations with regards to primary cesarean delivery and the effect of labor induction on the relationship. Figure 16 shows considerable variability with induced women and the respective primary cesarean delivery rates for within each racial and ethnic category. It also points to distinct differences across the different groups. Whites are distinctly different with higher rates of labor induction and less risk associated with cesarean. Blacks and Hispanics had remarkably higher rates of cesarean when women were induced compared to women that were not induced. Hispanic and other race and ethnicity do not demonstrate significant differences in primary cesarean rates for women induced, as evidenced by the overlap in the confidence intervals with primary cesarean rates of 14.72 and 13.82, respectively. Additionally, white and black women that are not induced are not significantly different from one another with regards to primary cesarean delivery rates with rates of 9.82 and 10.05, respectively. This preliminary

analysis indicated that race and ethnicity are likely to confound or modify the effect of labor induction on primary cesarean delivery.

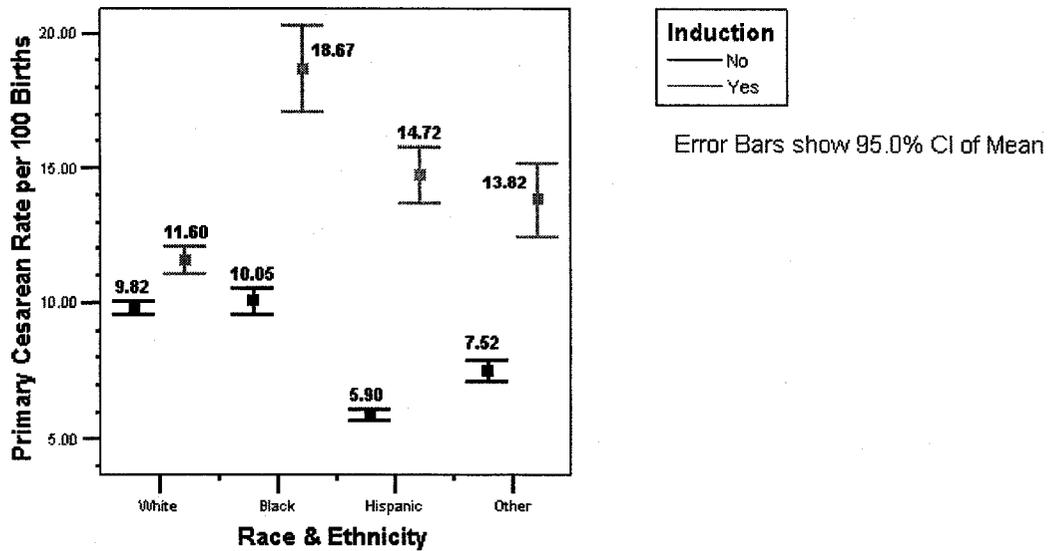


Figure 16. Primary cesarean delivery by induction of labor stratified by race and ethnicity.

Gestational age in weeks. The gestational age at delivery was distributed across the sample as follows: 7.1% of women were delivered at 37 weeks gestation, 18.3% women delivered at 38 weeks gestation, 26.4% delivered at 39 weeks gestation, 39.6% at 40 weeks gestation, 7% at 41 weeks gestation, and 1.5% at 42 weeks gestation. As one might expect, labor induction rates varied across gestational ages with some trend toward an increase in labor induction rates as the gestational age ascends. This pattern was consistent except at 39 and 40 weeks gestation with a slight drop in labor induction rates from 17.8% at 38 weeks to 16.8% at 39 weeks and 12.1% at 40 weeks. Table 46 demonstrates the distribution of gestational ages by percent of the total sample and the variability of labor induction rates across gestational ages.

Table 46

Labor Induction Rate by Gestational Age

Gestation in weeks	Induction	By Weeks of Gestation (denominator)	Induction Rate	Gestation as % of Total Births
37	1,284	11,321	11.34%	7.05%
38	5,230	29,226	17.90%	18.21%
39	7,166	42,215	16.98%	26.30%
40	7,739	64,093	12.07%	39.93%
41	2,435	11,198	21.74%	6.98%
42	669	2,480	26.98%	1.54%
Total	24,523	160,533	15.28%	100.00%

Table 47 examines the primary cesarean delivery rates for gestational ages controlling for induction of labor across the strata. The chi-square analysis indicates a significant association between primary cesarean delivery and induction of labor across all gestational ages ($p \leq .001$).

Table 47

Primary Cesarean Delivery By Induction of Labor Stratified by Gestation

Weeks Gestation	Primary Cesarean			χ^2	df	p value		
	No	Yes	Total					
37	Induction	No	9233	804	10037	102.46	1	0.000
		Yes	1071	213				
	Total	10304	1017	11321				
38	Induction	No	22097	1899	23996	44.07	1	0.000
		Yes	4669	561				
	Total	26766	2460	29226				
39	Induction	No	32159	2890	35049	34.97	1	0.000
		Yes	6421	745				
	Total	38580	3635	42215				
40	Induction	No	52194	4160	56354	382.87	1	0.000
		Yes	6665	1074				
	Total	58859	5234	64093				
41	Induction	No	7669	1094	8763	87.85	1	0.000
		Yes	1949	486				
	Total	9618	1580	11198				
42	Induction	No	1575	236	1811	13.20	1	0.000
		Yes	543	126				
	Total	2118	362	2480				
			85.40	14.60	100.00			

Figure 17 is an error bar chart examining the differences across gestational ages. Note the similarities in the primary cesarean rates for women that are not induced, particularly for earlier gestational ages 40 weeks gestation and less. However, the rates of cesarean increase significantly comparing each gestational age for women induced compared to women that are not induced, evidenced by no overlap in the 95% confidence intervals for all gestational ages. There were significantly higher rates of cesarean for induced women 41 and 42 weeks gestation comparing within categories; however, the induced women at 41 weeks and 42 weeks gestation are not significantly different from one another with respect to primary cesarean delivery rates (19.96% and 18.83%, respectively), as were women at 38 and 39 weeks gestation (10.73% and 10.40%, respectively). Also note that the women not induced for 41 and 42 weeks also are not statistically different from one another comparing across groups (12.48% and 13.03%, respectively). This becomes an important observation during modeling because the variable for “40 weeks or less gestation” models similarly during the final modeling process, and results in the decision to collapse the 40 weeks or less gestational age into a dichotomous variable 40 weeks or less gestational age: “yes” or “no.”

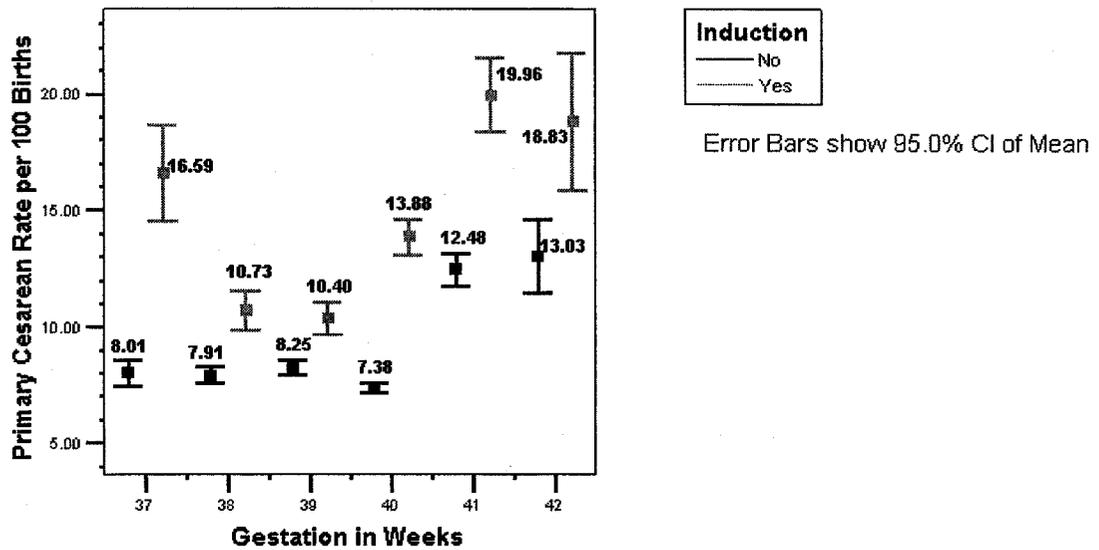


Figure 17. Primary cesarean delivery by induction of labor stratified by gestation in weeks.

Gestational age was investigated by Heffner, Elkin, and Fretts (2003), in their study examining the impact of gestational age, and maternal age on the effect of labor induction on cesarean delivery in a retrospective study on 14,409 delivering in one of two metropolitan hospitals in Boston from 1988 through 1999. Heffner et al. (2003) found that maternal age and gestational age over 40 weeks *independently* increased the risk of cesarean delivery in both nulliparous and multiparous women. However, they noted that although the relative risk is similar for nulliparous and multiparous women, the frequency is much greater for nulliparous women. In reporting their study they created a graph indicating that gestational age modifies the effect of labor induction on primary cesarean delivery. The researcher replicated their graphic approach with the study data, displayed in Figure 18. This graphic reinforces the findings of Heffner et al. Their findings indicated that there was an obvious magnitude of risk implications for nulliparous

women induced compared to nulliparous women that were not induced, and magnified the differences between nulliparous women and multiparous women. This analysis would indicate that gestational age confounds or (more likely) modifies the effect of labor induction on primary cesarean delivery. Logistic regression methods are required to clarify the two (gestational age in weeks and parity) covariates influence on induction of labor and primary cesarean delivery. Stratification methods could be used as were used by several researchers (Alexander et al., 2001, Dublin et al., 2000); however, multiple interaction terms were discovered during modeling in the final stages requiring logistic regression methods to adequately control for all confounders and effect modifiers examined in this study. In Figure 18, for nulliparous women, note once again the similarities between gestational ages 40 weeks or less compared to 41 and 42 weeks.

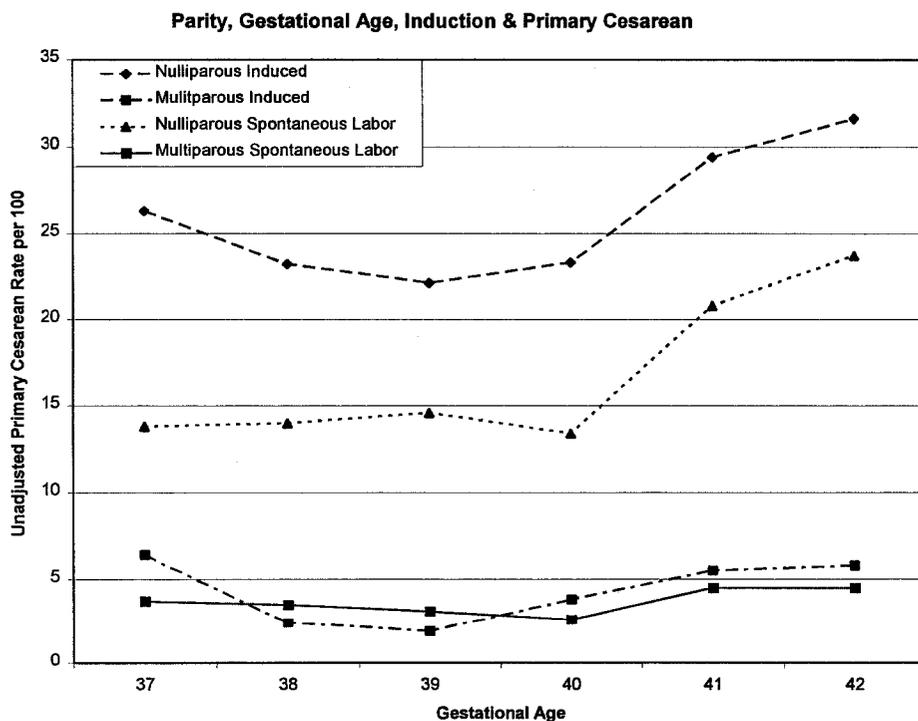


Figure 18. Parity, gestational age, induction of labor, and primary cesarean delivery.

Baby weight and maternal age. According to *Williams Manual of Obstetrics* (Leveno et al., 2001), low birth weight is defined as a birth weight below 2,500 grams. Macrosomia is defined as the birth weight threshold of 4,500 grams (p. 428). Therefore, the researcher grouped baby's birth weight into the following categories: $\leq 2,500$ grams was group one; 2,501 to 4,499 was group two; and, $\geq 4,500$ grams was group three. Table 48 illustrates the frequency distribution for the study population's baby weight groups. The groupings were necessary because a basic assumption of logistic regression requires that all continuous independent variables be linear in the logit. Baby weight in grams failed this assumption; therefore, the researcher elected to create clinically meaningful categories. The analysis of linearity in the logit for continuous variables and the tests for this assumption are discussed further in the modeling section of hypotheses testing.

Table 48

Baby Weight in Grams Grouped into Three Groups

Baby Weight in Grams	Frequency	Percent
2500 grams or less	2,785	1.75
2501 to 4499 grams	155,726	97.00
4500 grams or greater	2,022	1.25
Total	160,533	100.00

The analysis of association between induction of labor and primary cesarean delivery examining baby weight groups reflected a significant association between induction of labor and primary cesarean delivery for baby weight less than or equal to 2,500 grams with a chi-square 15.58 (1, $N = 2785$), $p < .001$ and baby weights ranging from 2,501 grams to 4,499 grams with a chi-square = 621.24 (1, $N = 155,726$), $p < .001$. Yet, no significant association with baby weight

4,500 grams or greater chi-square = .000 (1, $N = 2104$) = .06, $p = 1.0$ between primary cesarean delivery and induction of labor for baby weight greater than 4,500 grams (see Table 49).

Table 49

Primary Cesarean Delivery by Induction of Labor Stratified by Weight Groups

Baby Birth Weight in Grams		Primary Cesarean		Total	χ^2
		No	Yes		
2500 grams or less	Induction	No	2,134	273	2407
		Yes	308	70	378
	Total	2,442	343	2785	15581*
2501 to 4499 grams	Induction	No	131,934	131,934	131,934
		Yes	20749	3043	23,792
	Total	142,308	13,418	155,726	621.243*
4500 grams or greater	Induction	No	1,234	435	1,669
		Yes	261	92	353
	Total	261	92	353	.000

Note. * p < .001, 4500 grams or greater was not significant p = 1.

An analysis of differences in primary cesarean delivery rates for induced women compared to women that were not induced (examining error bar charts with 95% confidence intervals) reflected that baby weights of equal to or less than 2,500 grams had significant differences in primary cesarean delivery rates, with 18.5% primary cesarean rates for induced women compared to 11.3% for women that were not induced. Women with baby weights ranging from 2,501 grams to 4,499 grams also had significantly different primary cesarean delivery rates for induced women compared to women that were not induced with primary cesarean rates of 12.8% and 7.9%, respectively. These differences are determined by the lack of overlap on the 95% confidence intervals and are reflected in Figure 19. It is interesting to note that birth weights of 4,500 grams and greater, have precisely the same primary cesarean rates whether induced or not induced with a primary cesarean rate of 26.1%.

This preliminary analysis would indicate that baby weight is influencing the relationship of primary cesarean delivery and induction of labor for weight groups 1 and 2, with differences in other covariates being critical to this analysis, particularly for the babies equal to or less than 2,500 grams that may have medical indication for induction of labor requiring a delivery of a baby not yet full term. The logistic regression model allowed the researcher to control for this type of confounding relationship.

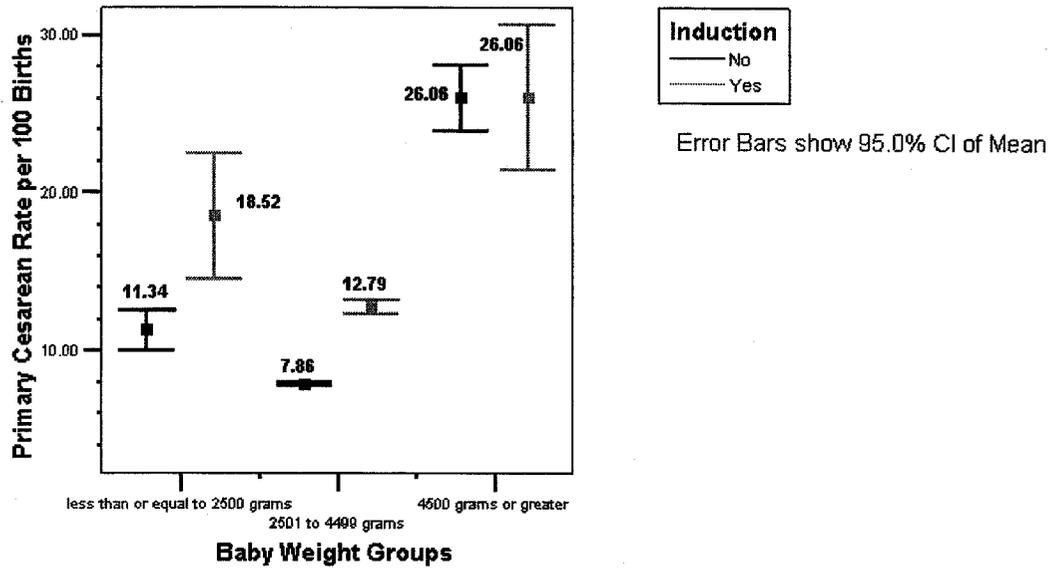


Figure 19. Primary cesarean delivery by induction of labor stratified by baby weight in grams.

Maternal age. For comparability, the researcher elected to utilize age groups examined by Gabbe et al. (2002) as groups of potential risk. Gabbe et al. (2002) reported that older nulliparous women constitute a growing proportion of laboring women and their deliveries are often complicated by dystocia, and medical complications, such as preeclampsia and gestational diabetes. They further noted that these conditions often result in a cesarean delivery for the older first-time mothers. Using CDC birth statistics, Gabbe et al. (2002) examined primary cesarean rates by the groups reflected in Table 50.

Table 50

Total Cesarean Birth Rates by Age of Mother Reported by Gabbe et al. (2002)

Age	Cesarean Birth Rate 1991 (reported in Gabbe et al., 2002)	Cesarean Birth Rates reported by CDC in 2002 Final Birth Report
< 20 years	18.2%	18.0%
20 to 24 years	21.0%	21.4%
25 to 29 years	24.3%	25.3%
30 to 34 years	26.7%	29.9%
≥ 35 years	28.4%	
35-39 years		35%
40-54 years		40.7%

Note. Table partially recreated from Gabbe et al. (2002, p. 542), 1991 CDC birth statistics reported. The CDC reported 2002 data with two additional age breaks of 35-39 years and 40-54 years.

The decision to break maternal age into groups was done primarily because maternal age violated the logistic regression assumption of linearity in the logit. This violation is discussed during the modeling process as the assumption is tested with both univariate models and the full model. The frequency distribution for the age groupings is reported in Table 51.

Table 51

Frequency Distribution for Five Age Groups of Risk

Age Groups	Frequency	Percent
less than 20 years	24,003	15.0
20 to 24 years	45,221	28.2
25 to 29 years	44,566	27.8
30 to 34 years	31,963	19.9
35 years and older	14,780	9.2
Total	160,533	100.0

The error bar chart in Figure 20 displays the primary cesarean rates for induced compared to women that were not induced stratified by the age groups. Groups 1 through 4 are statistically different primary cesarean rates for induced women compared to those there were not induced as evidenced by the lack of overlap with the 95% confidence intervals across groups. However, group 5 (≥ 35 years) does not display significant differences as evidenced by the overlap in confidence intervals. This analysis would indicate that older women are more likely to have a primary cesarean whether the women are induced or not. This may be an indication of higher risk for older women. Additionally, induced women in groups 4 and 5 are statistically similar primary cesarean rates based on the overlap of the 95% confidence intervals for both groups with primary cesarean rates of 11.47 and 12.09, respectively.

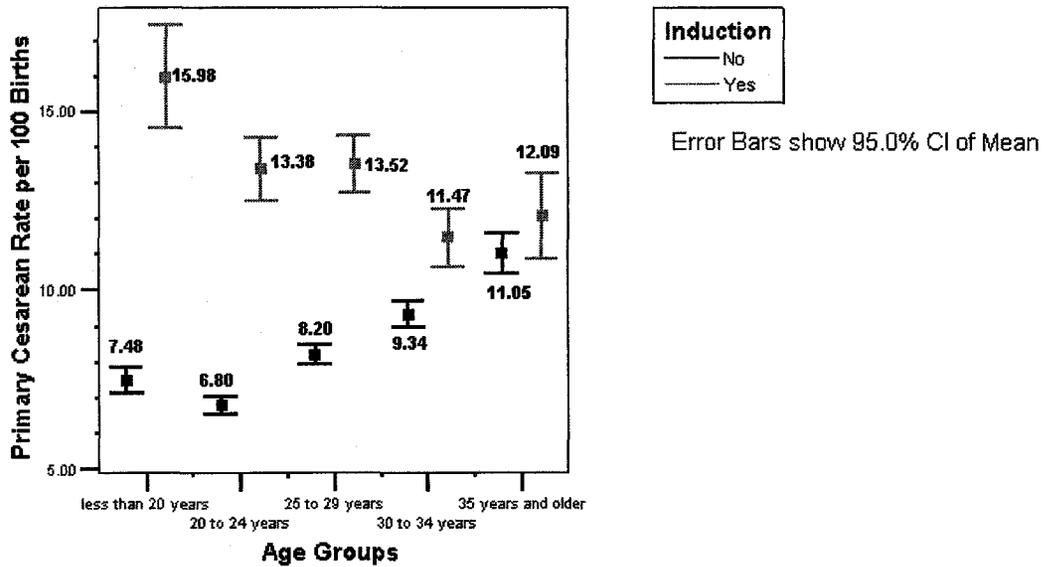


Figure 20. Error bar chart for induction of labor on primary cesarean delivery stratified by age groups.

Parity, age, primary cesarean delivery, and induction of labor. The researcher also examined age groups stratified by nulliparous and multiparous births in a graph examining induced women compared to those that had a spontaneous onset of labor. Figure 21 demonstrates the dramatic effect that nulliparity has on primary cesarean delivery, regardless of labor induction. It also demonstrates the distinct differences in ages for nulliparous women as reported by Gabbe et al. (2002). This analysis not only supports the assumption that age groups confound the relationship of labor induction and primary cesarean delivery, but also supports the differences hypothesized in the second hypothesis.

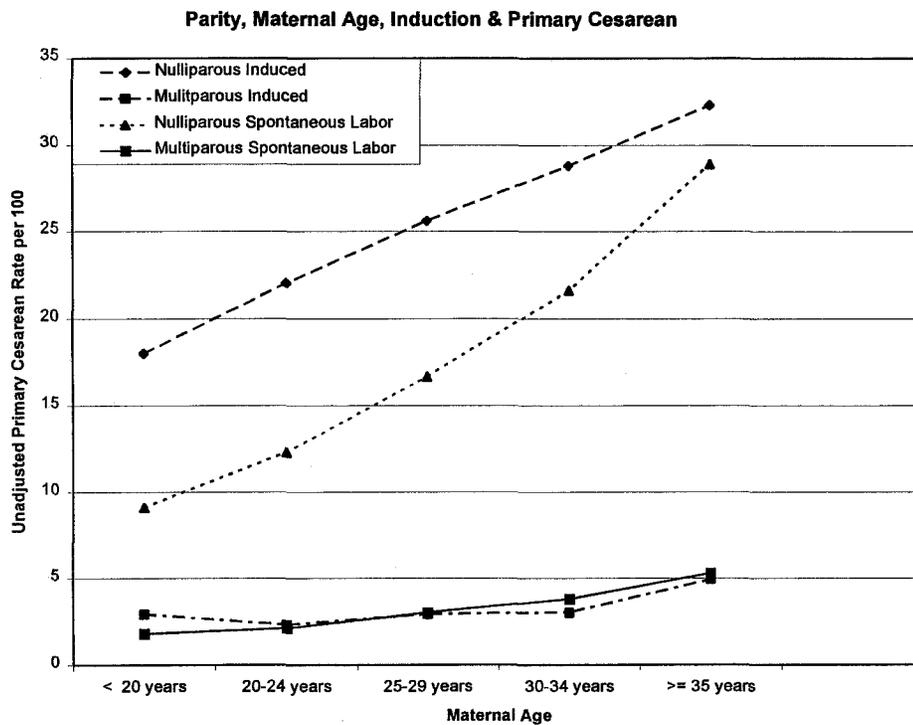


Figure 21. Parity, maternal age, induction of labor and primary cesarean delivery.

Hypothesis Number Two

Hypothesis number two was a subset of hypothesis number one, relating to the specific client characteristic of parity. Hypotheses number two was stated as follows: Induction of labor for nulliparous (in comparison to multiparous) women increase the odds of a primary cesarean delivery after controlling for client and system characteristics. Logistic regression was used to test the hypothesis fully so that other client and system characteristics could be controlled. However, preliminary analysis is reported in the following section.

Nulliparous women in the study population had labor induction rates of 16.15% compared to 14.55% for multiparous women. Table 52 illustrates the differences in primary cesarean delivery rates for nulliparous women compared to multiparous women and the

relationship to induction of labor. Primary cesarean rates for nulliparous women are higher regardless of whether they are induced; and there was a significant relationship between those that are induced and those that are not induced, with rates varying respectively from 24.1% (induced) to 14.5% (not induced). A chi-square analysis was done to preliminarily examine the association between nulliparous women compared to multiparous women induced compared to not induced and the respective primary cesarean rates. This analysis indicated there was a significant association with a χ^2 analysis ($1, N = 71,884$) = 674.76, $p < .001$) between primary cesarean delivery and induction of labor for nulliparous; however, no significant association ($1, N = 89,316$) = .008, $p = .929$) was identified between multiparous women (nulliparous “No” in Table 52) that were induced compared to those that were not induced.

This analysis indicates that nulliparity was potentially confounding or modifying the effect of labor induction and primary cesarean delivery. What could not be distinguished with this crude analysis examining nulliparity was whether parity is a confounder or effect modifier. Logistic regression methods advised by Hosmer and Lemeshow (2001) distinguish between effect modification and confounding and recommend methods to address both. A variable that is a confounder is associated with both the outcome variable (primary cesarean delivery) and the variable of interest (induction of labor). A variable that would modify the effect is a situation in which the covariate and the variable of interest interact and “modifies” or changes the effect on the outcome with variability across different strata (Hosmer & Lemeshow, 2000). A logistic regression model was used to test all hypotheses with the final model including all covariates including confounders and effect modifiers. However, this preliminary analysis indicated that nulliparity impacts the effect of labor induction on primary cesarean delivery.

Table 52

Primary Cesarean Delivery by Induction of Labor Stratified by Parity

Nulliparity			Primary Cesarean		Total	χ^2	df	p
	No	Yes	No	Yes				
No	Induction No	Count	73505	2372	75877			
		% within	96.87	3.13	100			
	Yes	Count	12520	405	12925			
		% within	96.87	3.13	100			
Total	Count	86025	2777	88802				
		% within	96.87	3.13	100	0.002	1	0.959
Yes	Induction No	Count	51422	8711	60133			
		% within	85.51	14.49	100			
	Yes	Count	8798	2800	11598			
		% within	75.86	24.14	100			
Total	Count	60220	11511	71731				
		% within	83.95	16.05	100	*672.87	1	0.000

Note. * Indicates a significant association between induction of labor and primary cesarean delivery for nulliparous. $\chi^2 = 672.87$; $p < .001$.

Hypothesis Number Three

Hypothesis number three was also a subset of hypothesis number one, relating to the specific client characteristic of gestational age in weeks. Hypotheses number three was stated as follows: Induction of labor for women 40 weeks gestation or less increases the odds of a primary cesarean delivery after controlling for system and client characteristics that influence the relationship. As with the previous hypothesis, hypothesis number three cannot be fully tested

without controlling for other client characteristics and system characteristics that impact the relationship. It is important to understand how an early induction of labor (40 weeks or less) may be influencing the odds of a primary cesarean delivery.

In the study population the majority of births took place in women 37 to 40 weeks gestation, with 91.5% ($n = 146,855$) and the remaining 8.5% ($n = 13,678$) after 40 weeks gestation (41 and 42 weeks gestation). For the 91.5% of women that gave birth at 40 weeks gestation or earlier, 14.6% ($n = 21,419$) of the women were induced. Table 53 examines the association of primary cesarean delivery and induction of labor stratified by gestation 40 weeks or less. The results of this analysis indicate a significant association for primary cesarean delivery with ($\chi^2 445.62$; $df 1$; $p = .000$) and without ($\chi^2 100.38$; $df 1$; $p = .000$) a woman being 40 weeks gestation or less.

Table 53

Primary Cesarean Delivery by Induction of Labor Stratified by Gestation 40 Weeks or Less

Gestation 40 weeks or less			Primary Cesarean			χ^2	df	p	
			No	Yes	Total				
37-40 weeks	Induction	No	Count %	9244 87.4%	1330 12.6%	10574 100.0%	100.375	1	0.000
		Yes	Count %	2492 80.3%	612 19.7%	3104 100.0%			
	Total	Count %	11736 85.8%	1942 14.2%	13678 100.0%				
41-42 weeks	Induction	No	Count %	115683 92.2%	9753 7.8%	125436 100.0%			
		Yes	Count %	18826 87.9%	2593 12.1%	21419 100.0%			
	Total	Count %	134509 91.6%	12346 8.4%	146855 100.0%				

Primary cesarean delivery rate differences for induced women compared to women that were not induced were also examined stratified by 40 weeks gestation or less. The results of this analysis are reflected in Figure 22 indicating that there are significant differences at the 95% confidence interval for all four groups: women induced 41 to 42 weeks gestation, women induced 37 to 40 weeks gestation, women not induced 41 to 42 weeks gestation, and women not induced 37 to 40 weeks gestation as evidenced by the lack of overlap in the confidence intervals. This analysis also indicated that there are significant differences between women induced compared to women that are not induced for both groups as evidenced by the lack of overlap between the 95% confidence intervals in Figure 22 for both groups.

This preliminary analysis would indicate that the rate of a cesarean is higher for induced women 41 to 42 weeks gestation compared to induced women 40 weeks gestation or less with primary cesarean rates of 19.72% and 12.11%, respectively. However, this does not take into account other client and system characteristics that confound the relationship. This is particularly important when trying to understand if induction of labor has an independent effect on the odds of a primary cesarean delivery, and specifically in this hypothesis testing, for women 40 weeks gestation or less.

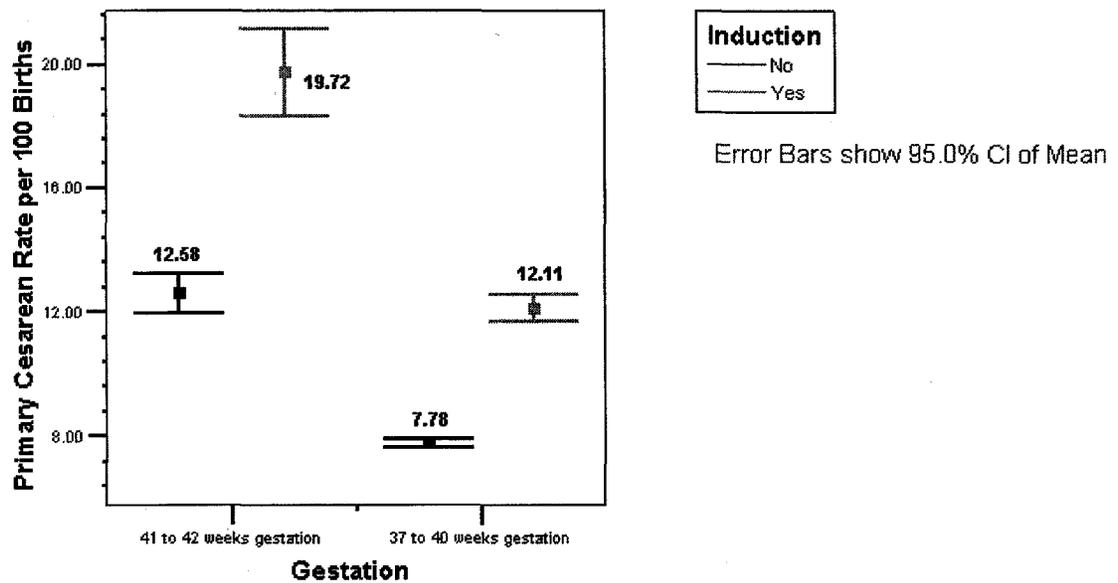


Figure 22. Primary cesarean delivery by induction of labor stratified by gestation.

Hypothesis Number Four

Hypothesis number four was stated as follows: System characteristics (including hospital bed size, urban versus rural status, ownership type, teaching status, and payer type) confound the effect of labor induction on the odds of primary cesarean delivery. This hypothesis was initially analyzed by examining the independent effect of each of the system characteristics on the relationship of labor induction and primary cesarean delivery with final testing of the hypothesis done using a full logistic regression model allowing all covariates to enter the model that confound or modify the effect of labor induction on primary cesarean delivery.

Hospital bed groups. The bed size was broken into three categories that reflect small, medium, and large hospitals with categories of less than 80 beds, 81 to 260 beds, and greater than

260 beds. The groupings were defined by neonatal intensive care capabilities with methods for determination discussed in detail in Chapter III. The study population was distributed more heavily in the larger facilities with 58.4% of the deliveries occurring in hospitals with bed sizes greater than 260. The remaining births were distributed predominantly in the medium size facility with 38.1% in the hospitals with bed sizes ranging from 81 to 260 beds and the smallest proportion with 3.5% delivering in hospitals with less than 80 beds. This would be expected given that larger volumes of births would be expected in the large tertiary care facilities. The variation across bed sizes reflects higher primary cesarean delivery rates for induced women compared to women that were not induced with significant association reflected in chi-square analysis when examining the relationship of labor induction and primary cesarean delivery across hospital bed size groupings. Table 54 reflects the primary cesarean rates of cesarean for induced women compared to non-induced women by hospital bed size.

Table 54

*Primary Cesarean by Induction of Labor Stratified by
Hospital Bed Groups*

Bed Group				Primary Cesarean		Total	χ^2	df	p
				No	Yes				
< 80 beds	Induce	No	Count % within induce	4284 92.7%	338 7.3%	4622 100.0%	7.659	1	0.006
		Yes	Count % within induce	850 90.0%	94 10.0%	944 100.0%			
	Total	Count % within induce	5134 92.2%	432 7.8%	5566 100.0%				
81-260 beds	Induce	No	Count % within induce	42420 90.8%	4312 9.2%	46732 100.0%			
		Yes	Count % within induce	12719 87.7%	1790 12.3%	14509 100.0%			
	Total	Count % within induce	55139 90.0%	6102 10.0%	61241 100.0%	119.374			

Table 54 (continued)

Bed Group				Primary Cesarean		Total	χ^2	df	p
				No	Yes				
> 260 beds	Induce	No	Count	78223	6433	84656			
			% within induce	92.4%	7.6%	100.0%			
	Yes	Count	7749	1321	9070				
		% within induce	85.4%	14.6%	100.0%				
Total		Count	85972	7754	93726	523.779	1	0.000	
		% within induce	91.7%	8.3%	100.0%				

Additionally, an analysis of differences in primary cesarean rates for induced women compared to women that were not induced was done across all three hospital bed size groups, using error bar charts and confidence intervals surrounding rate differences. The 95% confidence intervals control for cell size differences across hospital bed size with two groups reflecting significant differences of primary cesarean delivery rates for women induced compared to women that were not induced for groups 2 and 3 (the larger facilities). The third group with smaller hospital bed size (< 80 beds) demonstrated no significant difference for primary cesarean rates as evidenced by a slight overlap with the 95% confidence intervals. Induced women had primary cesarean rates of 9.96% (95% CI: 8.05, 11.87) and non-induced women had primary cesarean rates of 7.31% (95% CI: 6.56, 8.06). These similarities and differences are illustrated in Figure 23. It is interesting to note that the smaller bed size hospitals have lower rates of primary cesarean delivery associated with induction of labor although not significantly different from primary cesarean rates for induced women in bed group 2 (81 to 260 beds). This may be reflective of a lower risk population, or reflective of smaller hospitals' physician practice patterns.

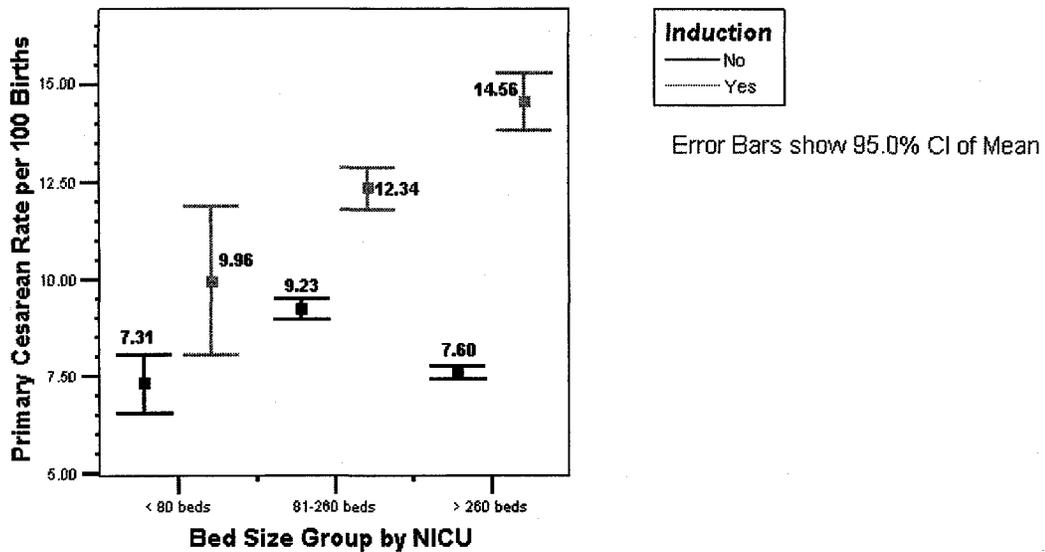


Figure 23. Primary cesarean delivery rates by induction of labor stratified by hospital bed size.

Urban versus rural. Births within urban hospitals made up the predominant proportion of births with very few rural hospital births, 92.6% and 7.4%, respectively. However, it was important to understand the association of primary cesarean delivery and induction of labor for the two types of hospitals and any differences that were present between the two with regards to the relationship of labor induction and primary cesarean delivery. Table 55 reflects the findings from a chi-square analysis examining the association between primary cesarean delivery and induction of labor stratified by urban and rural hospital. The associations were significant for primary cesarean delivery and induction of labor for urban hospitals (χ^2 621.99, *df* 1; *p* value = .000) and rural (χ^2 13.86; *df* 1; *p* value = .000) facilities. Figure 24 demonstrates the significant differences examining error bar charts and 95% confidence intervals. The non-induced women did not have significant differences comparing primary cesarean rates for urban compared to rural hospitals, 8.17 and 7.82, respectively. However, the induced women across urban compared to

rural hospitals did demonstrate significant differences as evidenced by the lack of overlap of the 95% confidence intervals in Figure 24 with primary cesarean rates of 13.34 and 10.26, respectively.

Table 55

Primary Cesarean Delivery by Induction of Labor Stratified by Urban versus Rural

Hospital

Urban				Primary Cesarean			χ^2	df	P
				No	Yes	Total			
No	Induction	No	Count	8,997	763	9,760	13.855	1	0.000
			% within	92.2%	7.8%	100.0%			
	Yes	Count	1,924	220	2,144				
	% within	89.7%	10.3%	100.0%					
Total			Count	10,921	983	11,904			
			% within	91.7%	8.3%	100.0%			
Yes	Induction	No	Count	115,930	10,320	126,250	621.988	1	0.000
			% within	91.8%	8.2%	100.0%			
	Yes	Count	19,394	2,985	22,379				
	% within	86.7%	13.3%	100.0%					
Total			Count	135,324	13,305	148,629			
			% within	91.0%	9.0%	100.0%			

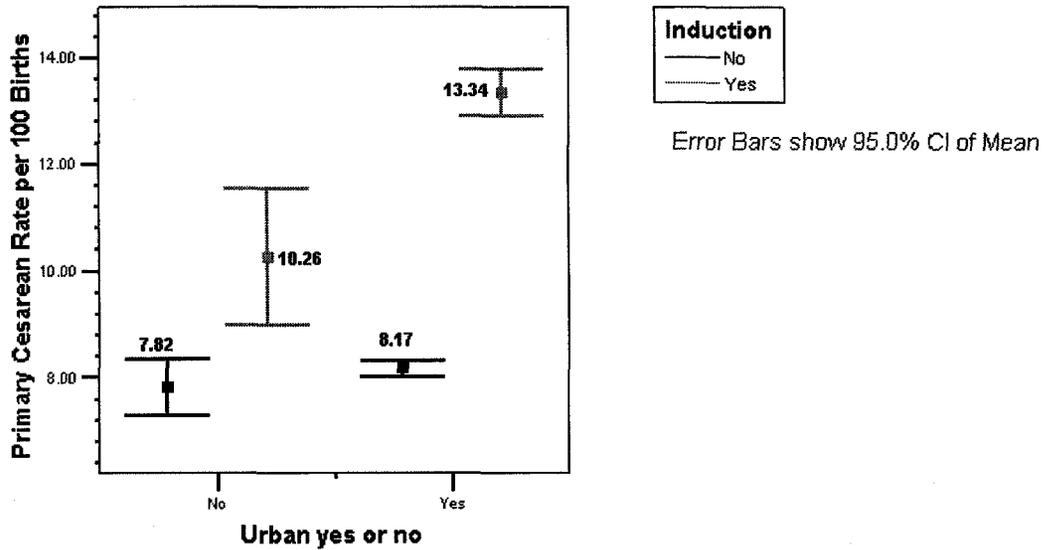


Figure 24. Primary cesarean delivery by induction of labor stratified by urban yes or no.

Hospital ownership. Hospital ownership strata are examined for association between induction of labor and primary cesarean delivery in Table 56. All strata indicated a significant association between primary cesarean delivery and induction of labor by hospital ownership type. Figure 25 reflects the differences in the primary cesarean rates for women induced compared to women not induced stratified by hospital ownership. All three hospitals types demonstrated significantly different rates of primary cesarean delivery for induced women compared to women that were not induced. Figure 25 demonstrates these differences between hospital ownership for induced compared to non-induced women and primary cesarean rates. The disparity between the public hospitals for primary cesarean delivery rates for labor induction at 19.8% compared to no induction of labor at 5.8% was interesting to note. Additionally, it was the significant differences in non-profit and for-profit hospitals with regards to induced women and the primary cesarean

rates of 13.12 and 10.19, respectively. Yet, non-induced women were not significantly different when examining primary cesarean delivery rates between non-profit and for-profit hospitals with rates of primary cesarean of 9.26 and 8.90, respectively.

Table 56

Primary Cesarean Delivery by Induction of Labor Stratified by Hospital Ownership

Ownership				Primary Cesarean		Total	χ^2	df	p
				No	Yes				
Public	Induce	No	Count	38451	2344	40795	748.74	1	0.000
			% within	94.3%	5.7%	100.0%			
	Yes	Count	1986	489	2475				
		% within	80.2%	19.8%	100.0%				
	Total	Count	40437	2833	43270				
		% within	93.5%	6.5%	100.0%				
Non-Profit	Induce	No	Count	66077	6745	72822	217.89	1	0.000
			% within	90.7%	9.3%	100.0%			
	Yes	Count	13905	2100	16005				
		% within	86.9%	13.1%	100.0%				
	Total	Count	79982	8845	88827				
		% within	90.0%	10.0%	100.0%				
For Profit	Induce	No	Count	20399	1994	22393	9.40	1	0.002
			% within	91.1%	8.9%	100.0%			
	Yes	Count	5427	616	6043				
		% within	89.8%	10.2%	100.0%				
	Total	Count	25826	2610	28436				
		% within	90.8%	9.2%	100.0%				

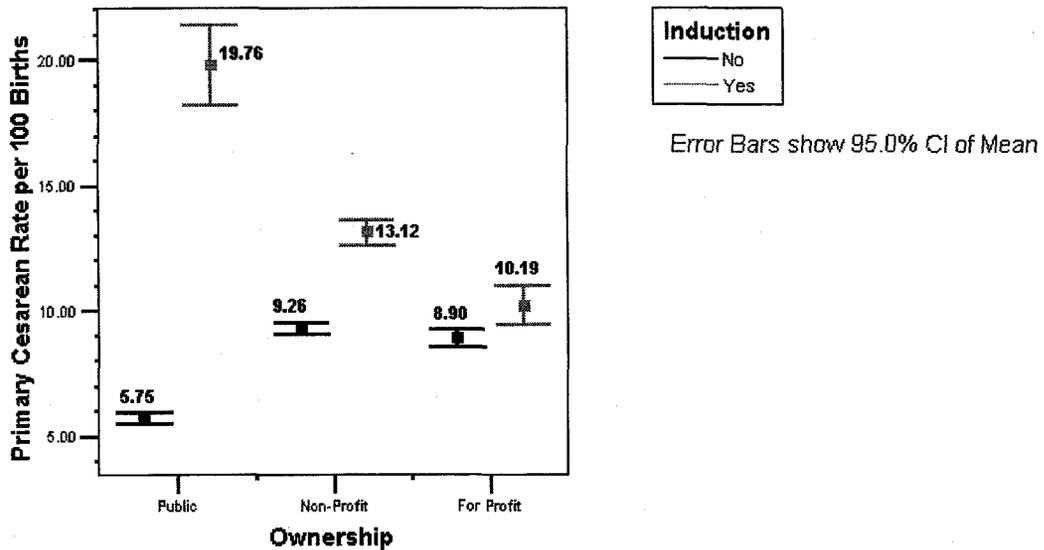


Figure 25. Primary cesarean delivery by induction of labor stratified by hospital ownership.

Teaching status. Examining teaching status both independently and within the final model was informative. Teaching status associations are displayed in Table 57. The chi-square analysis for primary cesarean delivery and induction of labor reflected a significant association between the two with (χ^2 173.94; df 1; $p = .000$) and without (χ^2 620.14; df 1; $p = .000$) teaching status.

Table 57

Primary Cesarean Delivery by Induction of Labor Stratified by Teaching Status

Teaching Hospital			Primary Cesarean			χ^2	df	p	
			No	Yes	Total				
No	Induce	No	Count	65504	6585	72089	163.03	1	0.000
			% within induce	90.9%	9.1%	100.0%			
	Yes	Count	18112	2501	20613				
	% within induce	87.9%	12.1%	100.0%					
Total	Count	83616	9086	92702					
	% within induce	90.2%	9.8%	100.0%					
Yes	Induce	No	Count	59423	4498	63921	626.01	1	0.000
			% within induce	93.0%	7.0%	100.0%			
	Yes	Count	3206	704	3910				
	% within induce	82.0%	18.0%	100.0%					
Total	Count	62629	5202	67831					
	% within induce	92.3%	7.7%	100.0%					

Figure 26 examines the differences in primary cesarean delivery rate for induced women compared to those not induced stratified by teaching status. Similarly to public hospital, teaching status reflects large differences, both strata (teaching yes and no) are significantly different primary cesarean delivery rates for induced compared to women that were not induced. However, similarly to the public hospital differences the teaching status had much greater differences with a 18.01% primary cesarean delivery rate for induced women, compared to 7.04% for women that were not induced. For teaching status and hospital ownership it was important to understand what other covariates may effect this relationship with logistic regression methods needed to fully clarify this issue. These variables may reflect other client and system characteristics, rather than an independent effect on the relationship.

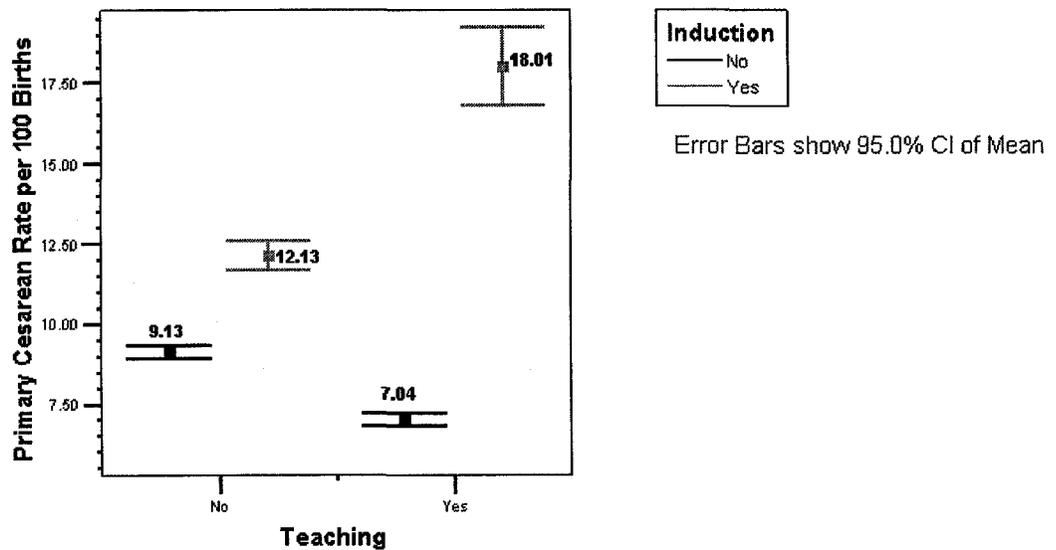


Figure 26. Primary cesarean delivery by induction of labor by teaching status.

Private payer. Private payer was used as a proxy to access to care issues and may be reflective of a hospital's patient population. Therefore, it is important to understand any differences with the association for private payer when examining the effect of labor induction and primary cesarean delivery. Table 58 reflects the association between primary cesarean delivery and induction of labor for women that had private pay insurance compared to other sources of payment including government and charity care. The chi-square analysis indicated significant association between primary cesarean delivery and induction of labor with (χ^2 81.98, *df* 1, *p* < .000) and without (χ^2 638.08, *df* 1, *p* < .000) private pay. Figure 27 reflects the differences in primary cesarean delivery rate for private pay insurance compared to other. It was interesting to note the distinct spread for primary cesarean rates for induction of labor yes or no, when the woman does not have private pay insurance. The private payer was significantly different for both conditions (induction of labor compared to no induction of labor) as evidenced by the 95% confidence intervals lack of overlapping intervals. However, the degree of difference between primary cesarean rates for induced women compared to women that were not induced with no private payer was very distinct, with 14.32% primary cesarean rates compared to 6.37%, respectively.

Table 58

Primary Cesarean Delivery by Induction of Labor Stratified by Private Payer

Private Payer				Primary Cesarean			χ^2	df	p
				No	Yes	Total			
No	Induce	No	Count	67208	4573	67208	638.08	1	0.000
			% within induce	93.6%	6.4%	93.6%			
		Yes	Count	6301	1053	6301			
			% within induce	85.7%	14.3%	85.7%			
	Total		Count	73509	5626	73509			
			% within induce	92.9%	7.1%	92.9%			
Yes	Induce	No	Count	57719	6510	57719	81.97	1	0.000
			% within induce	89.9%	10.1%	89.9%			
		Yes	Count	15017	2152	15017			
			% within induce	87.5%	12.5%	87.5%			
	Total		Count	72736	8662	72736			
			% within induce	89.4%	10.6%	89.4%			

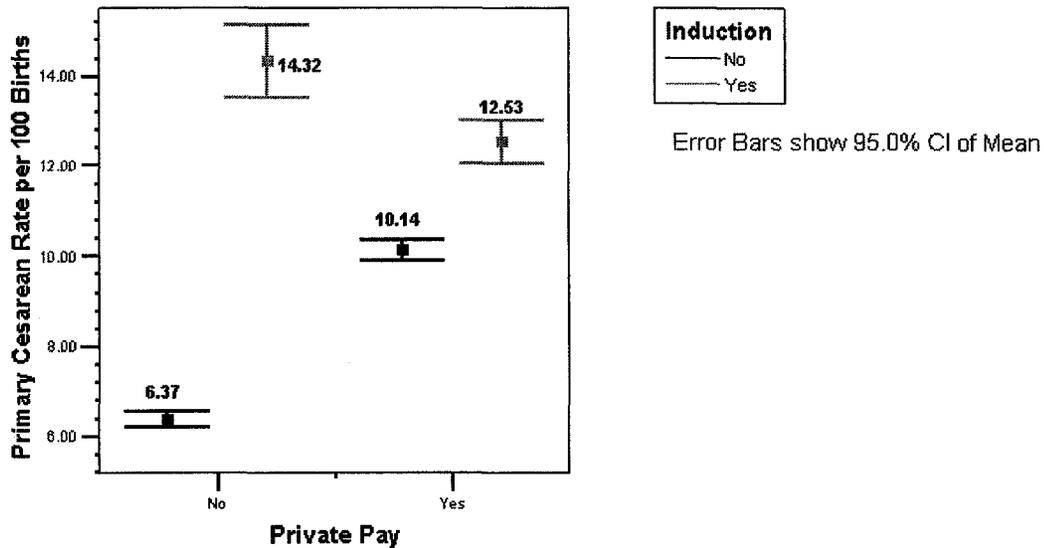


Figure 27. Differences in primary cesarean rates for private payer.

Logistic Regression Modeling and Final Hypotheses Testing

The research question that this study focused upon was: “What is the effect of labor induction on the odds of a primary cesarean delivery after controlling for confounding or effect modifying factors that influence the relationship?” Four hypotheses were analyzed using the final model created from logistic regression methods as described by Hosmer and Lemeshow (2000) and outlined in Chapter III. The four hypotheses were initially examined without the benefit of logistic regression as described in the previous section; however, to fully examine all hypotheses concerning the relationship of labor induction on primary cesarean delivery, logistic regression methods were necessary to control for all confounders, and effect modifiers. Hosmer and Lemeshow (2000) recommend a forward selection followed by backward elimination in a

stepwise logistic regression which is described in the following section. These methods are discussed in this section, concluding with an interpretation of the four hypotheses based on the final model.

Manual Forward Selection Followed by Backward Elimination

Manual forward selection. The initial process was to build a model with both client and system characteristics selected with equal chances for both types of covariates to enter the model in order to assess the influence of each of the covariates on the relationship of labor induction on primary cesarean delivery. This process was the foundation for testing the four hypotheses in the study. Decisions regarding which covariates entered the model first were decided based on empirical criteria. The criteria were determined by examining the covariates' effect on the induction of labor coefficient and basing the order of entry on the empirical rankings of the effect differences.

Chapter III reviewed steps utilized to model the effect of labor induction on primary cesarean delivery controlling for client and system characteristics. The steps outlined in Chapter III were followed with both client and system characteristics. The researcher began with the results from the crude model described in Chapter III developed for the study population ($n = 160,533$). The crude model was the model with induction of labor introduced as the independent variable into a logistic regression model with primary cesarean delivery as the outcome. The crude coefficient for the induction of labor effect on primary cesarean delivery was $\beta = 0.527$. The next step of modeling introduces each of the client and system characteristics into the crude model one at a time, to note the magnitude of the individual effect on the crude coefficient. This effect reflects the individual covariates' effect on the relationship of labor induction and primary cesarean delivery. A variable was considered a confounder if it changed the induction of labor crude coefficient by more than 10%.

The covariate that elicited the greatest response with this first step of modeling was medical indication for induction of labor with a coefficient change of 23.92%. Therefore, medical indication for induction was introduced into the crude model with induction, and this model was identified as “the base model.” The induction of labor coefficient with medical indications for induction in the model was considered “the base coefficient.” The base coefficient was $\beta = 0.401$. Using the base model, each of the remaining client and hospital characteristic variables were introduced one at a time into the base model and the change on the induction of labor coefficient noted. From the remaining covariates, the researcher examined each covariate in turn to determine which of the covariates changed the effect on the crude model by greater than 10% and changed the base coefficient by greater than 5%. Then, out of this group of covariates the covariate with the greatest response from both the previous base model (with medical indication for induction of labor) and the crude model (with induction of labor and primary cesarean delivery) was selected.

The researcher selected the next covariate to enter the model based on the greatest empirical change on the crude and base coefficient. The base model was updated to include the second covariate, and the base coefficient was adjusted to include the newly adjusted coefficient. The next covariate in the list was then considered in the same manner. These steps continued until all client and system characteristics were considered and covariates that changed the crude and base coefficient by more than 10% and 5%, respectively, were entered into the model. The results from this process are listed in order of entry in Table 59. Because maternal age was an important demographic characteristic and also showed remarkable differences in preliminary demographic analysis, the researcher elected to enter maternal age in the final step to this process despite the modest changes to the previous base coefficient. Additionally, the covariate was not addressed (at this point in modeling) as to the lack of linearity in the logit of this continuous covariate. The

initial stages of model building described herein occurred with the two continuous variables in the model as continuous variables. Table 59 displays the results from this manual stepwise forward modeling with each of the changes on the crude and base coefficients.

Table 59

Order of Entry for Covariates in the Logistic Regression Model

	Crude Coefficient	Estimate	Diff
Medical Indication for Induction	0.527	0.40132	23.92%
	Induction Coefficient	Change from the Crude	Change in the Previous Base
Private Payer	0.297	43.61%	25.88%
Dystocia	0.407	22.78%	-36.93%
Teaching	0.344	33.98%	15.54%
Gestation	0.305	42.13%	11.26%
Race & Ethnicity	0.278	47.24%	8.84%
Baby Weight in Grams	0.263	50.10%	5.41%
Nulliparity	0.264	49.89%	-10.28%
Maternal Age	0.256	79.36%	3.10%

Note. There was not a base change for medical indication for induction of labor because the base is defined as the model with induction of labor and the covariate that changed the base with the greatest magnitude on the crude model, which was medical indication for induction.

Backward elimination. The next step was to remove each of the covariates from the model to confirm that the order of entry did not impact the effect on the induction of labor coefficient. The researcher did this by removing the first variable into the model to detect differences, then put it back into the model and removed the next variable that entered the model. This continued until all variables exited the model to determine the effect of the elimination. The

same guidelines were used to confirm the importance of the variable, greater than a 10% change in the crude coefficient and 5% change in the base coefficient after removal. The results from the backward elimination are listed in Table 60. Note that the forced backward elimination indicates that private payer may not be as important as originally noted. This was determined by the small change in the base coefficient of -.74%. Note also that the nulliparity coefficient also had a very small change of -2.19%, as did maternal age with -3.20%. Nulliparity and maternal age are important client characteristics for consideration; therefore, the researcher did not consider eliminating the three client characteristics, but elected to eliminate private payer at this step.

Table 60

Covariate Backward Elimination

Covariate Elimination Order	Estimated Coefficient with Elimination	Change in Crude	Change in Base
Eliminate Medical Indication for induction	0.368	30.25%	-43.63%
Eliminate Private Payer	0.258	51.08%	-0.74%
Eliminate Dystocia	0.196	62.83%	23.44%
Eliminate Teaching	0.301	42.96%	-17.46%
Eliminate Gestation	0.285	45.96%	-11.29%
Eliminate Race & Ethnicity	0.275	47.80%	-7.49%
Eliminate Baby Weight	0.280	46.88%	-9.39%
Eliminate Nulliparity	0.262	50.38%	-2.19%
Eliminate Maternal Age	0.264	49.89%	-3.20%

Addressing the Continuous Variables: Maternal Age and Baby Weight

The next step was to address the maternal age and baby weight in grams lack of linearity in the logit. This stage of modeling requires that this assumption be checked with the full preliminary model. The model was considered preliminary because it was not yet determined how best to handle these continuous variables. Three methods were considered to examine the linearity assumption: quartile plots, lowess smoothing plots, and fractional polynomials.

Quartile design variables with plots for examining linearity of the logit. The first method was to examine the quartile plots of the beta coefficients for age and baby weight in grams in quartiles using the coefficients from the preliminary full model. This method created design variables based on the quartiles of the distribution. This method breaks the continuous variable into quartiles for x where x is age and baby weight in grams. A design variable is created taking into account levels 1 through 4 corresponding to the quartiles, referred to in this discussion as Q_x . The researcher then replaces x with Q_x in the model using Q_1 as the referent group. In this study, Q_1 was weight group 1 and age group 1. The estimated coefficients for Q_x are then plotted versus the quartile midpoint (Lemeshow, 2004). Tables 61 and 62 illustrate the design variables created by the researcher to examine this assumption.

Table 61

Design Variables by Quartiles for Maternal Age

Age Group	Interval	Midpoint	age_2	age_3	age_4
1	11-21	16.5	0	0	0
2	22-26	24.5	1	0	0
3	27-30	28.5	0	1	0
4	31-50	40.5	0	0	1

Note. Age groups with four groups, the midpoints of each group and the dummy variables used for the logistic regression of primary cesarean on age.

Table 62

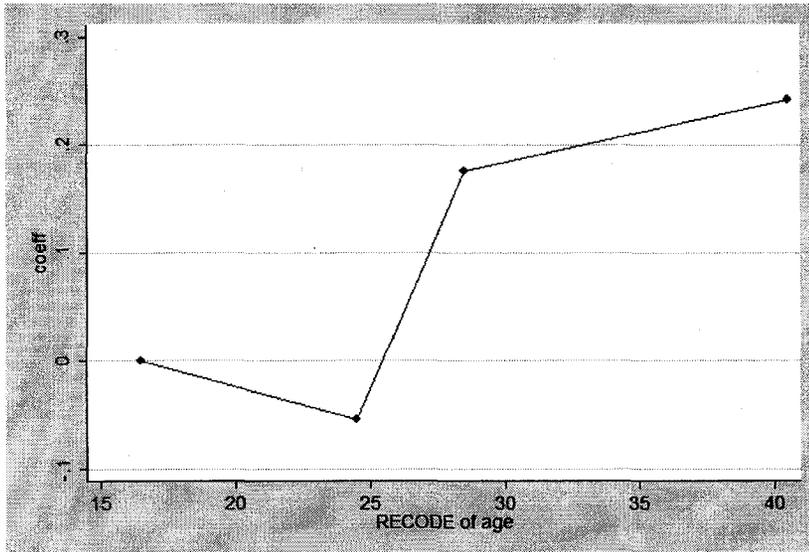
Baby Weight in Grams Design Variables by Quartiles

Baby Weight Group	Interval	Midpoint	wt_2	wt_3	wt_4
1	2409-3118	2763.5	0	0	0
2	3119-3401	3260.5	1	0	0
3	3402-3713	3557.5	0	1	0
4	3714-7858	5786.5	0	0	1

Note. Baby weight with four groups, the midpoints of each group and the dummy variables used for the logistic regression of primary cesarean on age.

Figure 28 contains both of the quartile plots. With this stage of examining maternal age using the model with all covariates, one might consider maternal age to appear as linear in the logit. However, it was important to continue with steps two and three to confirm this assumption was met for the maternal age covariate. However, baby weight in grams clearly appears to be non-linear in its relationship to the logit.

A. Quartile Plot of Maternal Age



B. Quartile Plot of Baby Weight in Grams

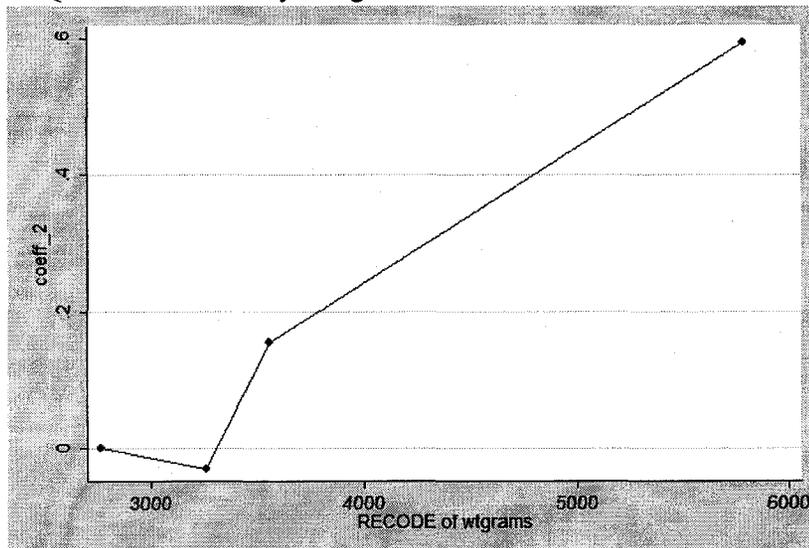


Figure 28. Quartile plots for (A) maternal age and (B) baby weight in grams with the preliminary full model.

Note. Coeff in Figure 28A and coeff_2 are variable names assigned by the researcher to code the estimated coefficients for the quartile design variables for maternal age and baby weight in grams.

Lowess smoothed plot. The second method is a univariate lowess smoothed scatter plot on the logit scale. Some statistical packages offer the capability of producing a smoothed scatter plot. The researcher used Stata 8.0. The lowess command in Stata carries out a locally weighted regression of a y variable on x variable, displays the graph, and optionally saves the smoothed variable. The lowess command carries out a locally weighted regression of the y variable (primary cesarean) on the x variable (maternal age or baby weight in grams) and displays the graph. An important notation by Stata is a warning that the lowess is computationally intensive and may therefore take a long time to run on a slow computer. Lowess calculations on 1,000 observations require estimating 1,000 regressions. Therefore, the lowess calculation required for this study would estimate over 160,000 regressions. The lowess plot took over 8 hours to run on a Pentium 4 computer for each of the two continuous variables. This method generated a lowess plot of the logit to determine if age is linear in the logit. Figure 29 below illustrates the univariable lowess smoothed scatter plot created with this method. Both plots indicate that age is not linear in the logit. However, it was difficult to discern at this stage of the analysis that maternal age was not linear. The lowess plot indicates a slight upward trend, indicating some pull upward. This was more apparent with work discussed later using fractional polynomials.

The purpose of the lowess plot is to compare the univariate lowess to the quartile plot in the first method given the initial method has all covariates in the model. The lowess plot could not be done using the full model. Although there are programs that will run a lowess smoothed plot with a multivariate model, these programs were not available to the researcher. Therefore, the researcher examined the lowess plots with a model containing the maternal age covariate on primary cesarean delivery and the baby weight in grams on primary cesarean delivery in a univariate model, as recommend by Lemeshow (2004) when multivariate modeling plots are not available. Both these plots appear to be non-linear in the logit, although not as distinctly for

maternal age. The plots are illustrated in Figure 29 for maternal age and Figure 30 for baby weight in grams.

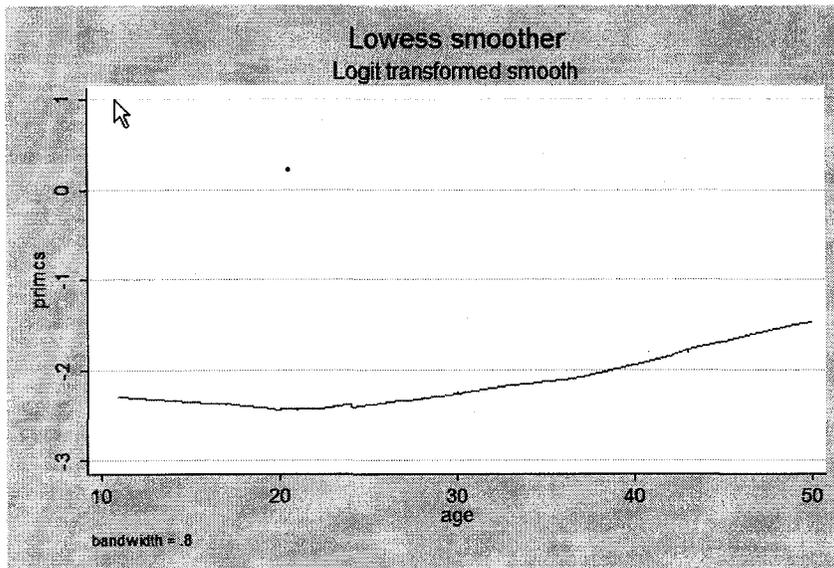


Figure 29. Lowess smoothed plot of maternal age on primary cesarean delivery.

Note. Primcs was an abbreviation assigned by the researcher to designate the primary cesarean outcome.

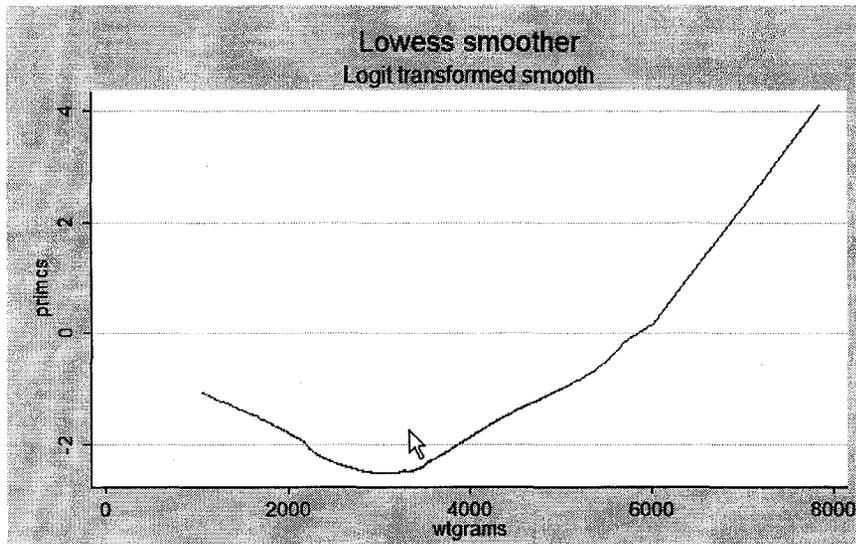


Figure 30. Lowess smoothed plot of baby weight in grams on primary cesarean delivery.

Note. Primcs in Figure 30 and wtgrams are variable names assigned by the researcher to code the primary cesarean delivery outcome and weight in grams.

Fractional polynomials. The last method considered to examine this assumption uses fractional polynomials to examine transformations that create the smallest deviance among the models. The deviance is a summary measure in logistic regression similar to linear regression methods which examine the residuals. The deviance compares observed to predicted values using the likelihood function. Stata has a procedure known as “fracpoly” that allows a researcher to explore the best scale for continuous variables using eight different transformations. From the eight transformations, Stata recommends the model with the smallest deviance with a significant gain (improvement) for the model. Fractional polynomials are similar to conventional polynomials in that they include powers of x , but non-integer and negative powers are also allowed. The result is complex transformations. Fractional polynomial models usually give a better fit than conventional polynomials, according to Lemeshow (2004). The researcher considered fractional polynomial transformations for maternal age and birth weight, but elected

not to use the method for transformations. Lemeshow (2004) noted four limitations regarding fractional polynomials which supported the researcher's decision not to use the method (a) models using fractional polynomials are complicated and difficult to interpret when examining a risk model, (b) models may be influenced by extreme points, (c) the models will not pick up a binary shift, and (d) models may be too specific to the observed data and may not generate well in other data.

These four limitations supported the researcher's decision to eliminate use of the method with number one and four being the most compelling. Because this model is a risk model seeking to explain the effect of labor induction on primary cesarean controlling for system and client characteristics that confound or modify the effect of the relationship, it is very important to be able to interpret the results in clinical terms. Additionally, it is the researcher's hope that the final model will have use outside of the study results to assist clinicians and researchers in better understanding what might increase a woman's odds of a cesarean when she elects an induction of labor. A complex transformation of maternal age or baby weight would not indicate at what age or baby weight a woman might increase her odds. However, the fractional polynomials were run to determine if the linear term or some transformation better fit the data. Lemeshow (2004) advises that this technique can be used to confirm a questionable non-linearity, which was the case with maternal age. The fractional polynomials indicated that the linear term was not the preferred method for maternal age and baby weight in grams, indicating that the variables were not linear in the logit.

Therefore, the researcher elected to create categorical variables from each of the variables using clinically relevant categories, as discussed in the previous section. Baby weight categories were as follows: baby weight in grams $\leq 2,500$ grams was group 1; 2,501 to 4499 was group 2;

and, $\geq 4,500$ grams was group 3. Age groups were as follows: < 20 years, 20 to 24 years, 25 to 29 years, 30 to 34 years, and ≥ 35 years.

Collapsing Categories Considered

The next step was to determine if any of the categories might be appropriately collapsed. This was done by examining the coefficients of each category to determine if two groups were statistically similar ($p > .05$). Stata has a test that allows a researcher to run a logistic regression model and then test one covariate's beta coefficient against another to determine statistical differences. This procedure was done with three variables, gestation, maternal age, and baby weight using the full model.

Gestational age was initially introduced as a categorical variable with 37, 38, 39, 40, 41, and 42 weeks gestation as levels of the variable. However, once in the final preliminary model, 37, 38 and 39 weeks gestation were not significantly different from one another ($p > .05$). Table 63 illustrates the preliminary model results. Note the p value for 38 and 39 weeks gestation are not significantly different from the referent group of 37 weeks ($p > .05$).

Table 63

Preliminary Model Results Examining Categories

Covariates	Coefficient	p value	Odds Ratio	CI low	CI high
Induction	0.286	0.000	1.33	1.27	1.40
Medical indication for induction	0.703	0.000	2.02	1.93	2.11
Teaching	-0.267	0.000	0.77	0.73	0.80
Dystocia	2.317	0.000	10.12	9.72	10.55
Black	0.371	0.000	1.45	1.36	1.54
Hispanic	-0.271	0.000	0.76	0.72	0.81
Other	-0.405	0.000	0.67	0.63	0.71
38 weeks	-0.047	0.292	0.96	0.87	1.04
39 weeks	-0.050	0.246	0.96	0.88	1.03
40 weeks	-0.089	0.032	0.92	0.84	.99
41 weeks	0.424	0.000	1.54	1.40	1.70
42 weeks	0.487	0.000	1.64	1.40	1.91
nulliparity	1.700	0.000	5.48	5.22	5.75
Age group 2: 20 to 24 years	0.244	0.000	1.33	1.20	1.36
Age group 3: 25 to 29 years	0.536	0.000	1.82	1.61	1.81
Age group 4: 30 to 34 years	0.791	0.000	2.34	2.07	2.35
Age group 5: ≥ 35 years	1.106	0.000	3.22	2.79	3.27
Baby weight group 2: 2,501 to 4499 grams	-0.569	0.000	0.57	0.48	0.67
baby weight group 3: $\geq 4,500$ grams	0.694	0.000	2.00	1.63	2.47

Note. Referent groups are White, 37 weeks gestation, weight group < 2,500 grams, and age group 1: < 20 years.

Additionally, the significant differences between coefficients can be tested using a χ^2 test statistic with 1 df in Stata, after running a given model. The test statistic indicated that 37, 38, 39, and 40 weeks were all statistically similar ($p < .01$). It is important to note that the 37 week referent group means that the 38, 39, and 40 weeks are compared to the referent group of 37 weeks. The p value reflected in Table 63 indicates that 38 and 39 weeks gestation are not different from 37 weeks (the referent group), and the χ^2 test was not statistically different for 37, 38, 39, and 40 weeks. Additionally, 41 weeks and 42 weeks gestation were not statistically different from one another using the χ^2 test. Therefore, the researcher elected to collapse 37 through 40 weeks gestation and 41 and 42 weeks into two groups. The result was a dichotomous variable 40 weeks gestation or less, “yes” or “no.” This was advantageous because this supported hypothesis testing given that hypothesis number four examined induction of labor for women 40 weeks gestation or less, the researcher hypothesized that early gestations increase the odds of a primary cesarean delivery after controlling for system and client characteristics that influence the relationship. This early stage of the analysis would indicate that this was not the case for 40 weeks gestation or less with odds ratios less than one for all four gestational ages (37, 38, 39, and 40 weeks). However, this was not the final determination on this hypothesis.

The researcher then examined baby weight in the three clinically relevant levels, $\leq 2,500$ grams was group 1; 2,501 to 4,499 was group 2; and, $\geq 4,500$ grams was group 3. All three groups were significantly different from one another and remained in the model with the three categorical levels. Age group was introduced next with the five age groups: < 20 years, 20 to 24 years, 25 to 29 years, 30 to 34 years, and ≥ 35 years. All five of the age groups were tested, all of which were significantly different from one another. Therefore, age groups stayed in the model as five distinct age groups.

Once final groupings were determined the modeling process was done again, starting with the crude and base model and building the model with each variable having an equal opportunity to enter the model. This was to determine if any of the categories introduced changed the model. Table 64 presents the results from the stepwise forward selection process. The order of entry changed, and the impact of nulliparity changed from -10.28 to -4.75. Race and ethnicity entered sooner, essentially swapping places with teaching. It is likely this was reflective of covariates confounding one another. With these changes baby weight in grams also had a much smaller impact with -.72%. Prior to finalizing the decision as to which variables would stay in the final model, the backward elimination process was done to confirm that order of entry did not impact which variables entered as important to the relationship of labor induction on primary cesarean delivery.

Table 64

Preliminary Full Model with Categorical Variables for Maternal Age, Baby Weight and Gestation

	Crude Coefficient	Estimate	Diff
Medical Indication for Induction	0.527	0.401	23.92%
	Induction Coefficient	Change from the Crude	Change in the Previous Base
Private Payer	0.297	0.436	25.88%
Dystocia	0.407	0.228	-36.93%
Race & Ethnicity	0.356	0.324	12.51%
Teaching	0.317	0.400	11.13%
Gestation 40 weeks or less	0.277	0.475	12.49%
Nulliparity	0.290	0.450	-4.75%
	266		

Table 64 (continued)

	Induction Coefficient	Change from the Crude	Change in the Previous Base
Maternal Age Group	0.281	0.468	3.34%
Baby Weight Groups	0.283	0.464	-0.72%

The backwards elimination process was then done to determine if any variables' contribution to the model was impacted by order of entry. Table 65 presents the results from the backward elimination step. As with the initial modeling, private payer decreased in importance and was eliminated from the model, based on the behavior of the variable in both modeling processes. As with the prior modeling, nulliparity and maternal age did not appear as important added to this list was baby weight in grams. All three covariates appeared not to be impacting the relationship with importance (according to criteria discussed previously). This was reflective of interaction occurring with all three of these variables. Due to the clinical importance of these variables and anticipation of interaction with these covariates and induction of labor, the researcher elected to keep all three of these covariates in the final model, but eliminate private payer.

Table 65

Backward Elimination Model with Categorical Variables for Maternal Age, Baby Weight and Gestation

Covariate Elimination Order	Estimated Coefficient With Elimination	Change in Crude	Change in Base
Eliminate Medical Indication for induction	0.393	0.255	-38.96%
Eliminate Private Payer	0.287	0.456	-1.45%
Eliminate Dystocia	0.232	0.561	18.01%
Eliminate Race & Ethnicity	0.307	0.419	-8.49%
Eliminate Teaching	0.326	0.382	-15.39%
Eliminate Gestation 40 or less	0.320	0.393	-13.28%
Eliminate Nulliparity	0.277	0.475	1.99%
Eliminate Age Group	0.292	0.447	-3.23%
Eliminate Weight Group	0.281	0.468	0.72%

The next step in the process was to enter all remaining variables that did not enter the model to substantiate that the researcher did not miss a variable that might continue to be important to the relationship. Therefore, hospital ownership, urban, bedsize, fetal distress, and private payer were entered together in a final step to examine the change in the crude and base coefficient. The impact on the crude coefficient was 44.67%, but the impact on the base coefficient was only -3.26%. Therefore, the very slight change to the base coefficient confirmed that the additional covariates did not impact the relationship sufficiently to include any additional variables, and the researcher had the full model with all covariates that confound or modify the effect of labor induction on primary cesarean delivery. However, it was important to differentiate

between those variables that confound the relationship, and those that interact with the relationship to modify the effect. This was important, because it is inappropriate to interpret an odds ratio from a logistic regression model that does not address interaction of terms that may be present (Hosmer & Lemeshow, 2000).

Interaction Terms

The final modeling step was to examine interaction terms to determine if any significant interactions were present between covariates in the model and induction of labor. Interaction terms for each of the covariates in the final model were entered into the full model. This process proceeded in similar steps as the forward entry, followed by backward elimination process for each of the covariates. A chi-square Likelihood Ratio test statistic value was used to test the initial full model with the model containing each of the interaction terms. The full model with no interaction was compared to a model with each of the individual interaction terms in the model.

With the first step, the full model was compared using the Chi-Square Likelihood Ratio test statistic value to compare the model without the interaction term to each of the models with their respective interaction terms and the Chi-Square Likelihood Ratio test statistic value recorded, the degrees of freedom recorded and a p value for the chi square distribution was calculated using an excel spreadsheet. The Excel spreadsheet was needed because Stata rounds the p value to .0000, as do most statistical packages. This rounding makes it impossible to determine which of the interaction terms is most important given many were statistically significant with the p value reported as .0000. Excel provided a mechanism for determining which of the p values was the smallest by extending the p value field to include up to 6 digits. Once the smallest p value was identified, the interaction term with the smallest p value was entered into the model (including both original terms) and a Chi Square Likelihood Ratio test statistic (lrtest) value obtained. The lrtest function was used in Stata to generate the Chi Square

Statistic and then the Chi Square Statistics was examined in Excel to determine the p value up to six digits, to differentiate beyond the first four digits. This process continued until all significant induction of labor interaction terms were identified. Lemeshow (2004) recommends a p value of .01 for consideration of significance for interaction terms. There were four interaction terms identified as significant ($p < 0.01$) (a) dystocia by induction of labor, (b) nulliparity by induction of labor, (c) race and ethnicity by induction of labor, and (d) weight groups by induction of labor. The interaction term for gestation less than 40 weeks “yes” or “no” went into the final step of the model with a p value of .03. Given this variable was significant throughout the forward entry process with p values of 0.002 and less, the researcher elected to keep the interaction term in for gestation. The interaction terms that entered the model in order of significance (based on smallest p value rule for the lrtest) were as follows:

- Dystocia by Induction of labor
- Nulliparity by Induction of labor
- Race & Ethnicity by Induction of labor
- Weight Group by Induction of labor
- Gestation 40 weeks or less by Induction of labor

The backward elimination process was then done to confirm that the order of entry did not impact the significance of the interaction term. Backward elimination indicated that all interaction terms were significant (< 0.01) with the exception of the gestation 40 weeks or less dichotomous interaction term ($p = 0.03$). Once again, the researcher elected to keep this interaction term in the model. The final step was to enter all other interaction terms that had not already entered the model to confirm that an interaction was not missing. This step revealed a significant χ^2 (20.67, $df = 6$, $p < .01$). Therefore, the researcher tested the remaining interaction

terms (teaching by induce, medical indication by induce, and age group by induce). At this stage medical indication for induction by induction of labor was entered as the sixth interaction term.

Model Diagnostics

Diagnostics were then performed on the model to determine the fit of the model, and discern if the model had any problems. The first statistic examined was the Hosmer Lemeshow Goodness of Fit Test. Table 66 presents the results from the Hosmer Lemeshow test. The Hosmer Lemeshow test examines the agreement between the observed and expected frequencies in each of 20 cells in Table 65. The different groups represent deciles of risk with examination of how well the observed matches the expected frequencies. According to this test, the model does not fit well with significant differences discerned between the deciles for observed compared to expected (χ^2 31.34; df 8; $p = .0001$) with respect to predicting primary cesarean delivery. The test indicates that the observed and expected frequencies are significantly different from one another; however, one point to note here is that many of the parameters examined in this study were significant due to the large dataset that was used in this study. In fact, the deciles below indicate the observed to expected cells are very close. For example, examine the 9th decile with the observed frequency for primary cesarean delivery ($df = 1$). The observed frequency was 2430, whereas, the expected frequency was 2370.7. This would not be considered a clinically substantial difference, yet the p value reflects the overall difference was significant ($p > .01$). Hosmer and Lemeshow (2000) indicate that this test increases with an ability to detect small differences as the sample size increases. It appears that this was the case with this large dataset.

Table 66

Hosmer and Lemeshow Goodness of Fit

Group	Probability	Observed Primary CS "Yes"	Expected Primary CS "Yes"	Observed Primary CS "No"	Expected Primary CS "No"	Total
1	0.0098	102	126.3	16227	16202.7	16329
2	0.0133	199	184.2	16104	16118.8	16303
3	0.0174	264	234.1	15300	15329.9	15564
4	0.0257	470	440.4	19796	19825.6	20266
5	0.035	364	368.5	11892	11887.5	12256
6	0.0521	615	705	15667	15577	16282
7	0.0727	947	976.3	14555	14525.7	15502
8	0.1102	1385	1450	14762	14697	16147
9	0.2229	2430	2370.7	13439	13498.3	15869
10	0.9479	7512	7432.5	8503	8582.5	16015

Note. Number of observations = 160533, Number of groups = 10, Hosmer-Lemeshow χ^2 (8) = 31.34 and Prob > χ^2 = 0.0001.

Sensitivity and specificity are important to consider when examining the fit of a model.

Hosmer and Lemeshow (2000) indicate that a more complete description of classification accuracy is given by the area under the Receiver Operating Characteristics (ROC) curve. The curve shows how the receiver operates the existence of signal in the presence of noise. This method was derived from signal detection theory. The curve plots the probability of detecting true signal (sensitivity) and false positive (1-sensitivity) for an entire range of possible cut-points. The area ranges from zero to one and provides an ability to determine how well the model discriminates between women who had a primary cesarean compared to those who did not

(Hosmer & Lemeshow, 2000). Figure 31 presents the area under the ROC curve for the final model with client and system characteristics and all statistical interaction terms. The Receiver Operating Characteristics (ROC) curve indicates the model has excellent discrimination with the area under the ROC curve of .85. These results indicate the model was a good predictor of primary cesarean delivery. However, before concluding that a model fits, Hosmer and Lemeshow recommend checking the covariate patterns to make sure the model fits over the entire set of covariate patterns. This was accomplished by a series of specialized measures for regression diagnostics (Hosmer & Lemeshow, 2000).

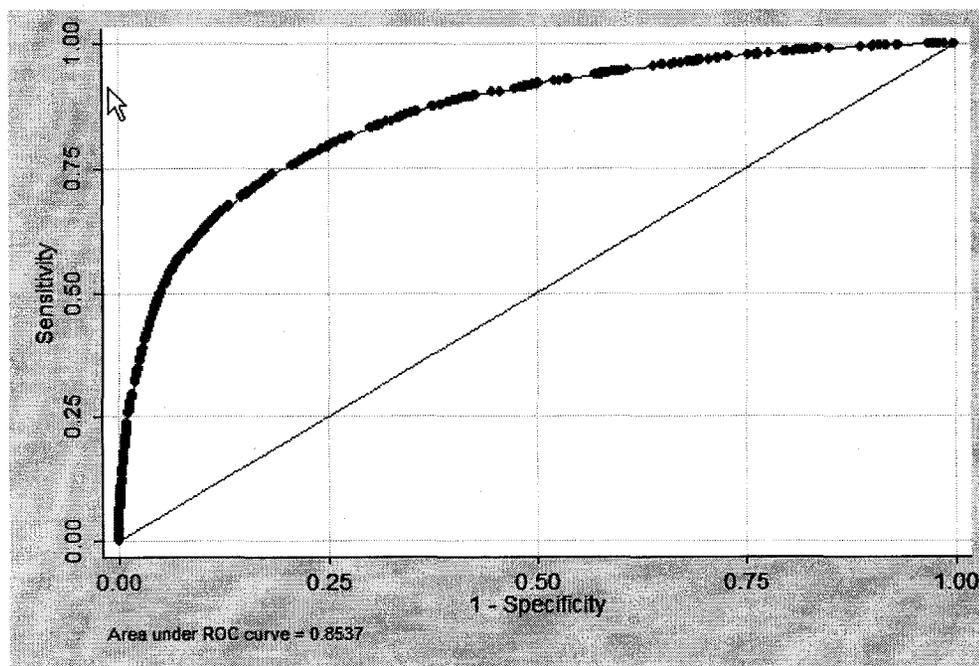


Figure 31. Area under the ROC Curve.

Note. Plot of sensitivity versus 1-specificity for all possible cut points in the study population. The resulting curve is the ROC Curve.

Covariate patterns also were examined to determine if any covariate pattern had a significant impact on the fit of the model. It was determined that no covariate pattern was substantially impacting the fit. The researcher performed the diagnostics by computing the values of the leverage, the change in chi-square (ΔX^2) and the influence diagnostics ($\Delta\beta$) to determine whether or not the statistics isolate poorly fit and influential cases. Figure 32 indicates that there was a covariate pattern that warranted examination. The large circle represented cases with a covariate pattern with high influence. This plot incorporates leverage, residual, and influence, indicating a covariate pattern may influence the model fit and warrant consideration of dropping the cases represented within the covariate pattern (Lemeshow, 2004). H-L ΔX^2 in the Figure 32 represents the change or delta of the deviance plotted against the “Pr” or the probability of a primary cesarean delivery. The large circle indicates that a covariate pattern may be creating significant deviance or change in the predicted probability and warrants investigation as to whether the cases creating this change should be dropped from the model. The researcher investigated these cases, not because of a concern that the cases created poor fit of the model and thus the prediction capability might be influenced, but because the influence of this covariate pattern might represent some abnormality in the data that could have influenced the selection of covariates and the way the covariates entered the model.

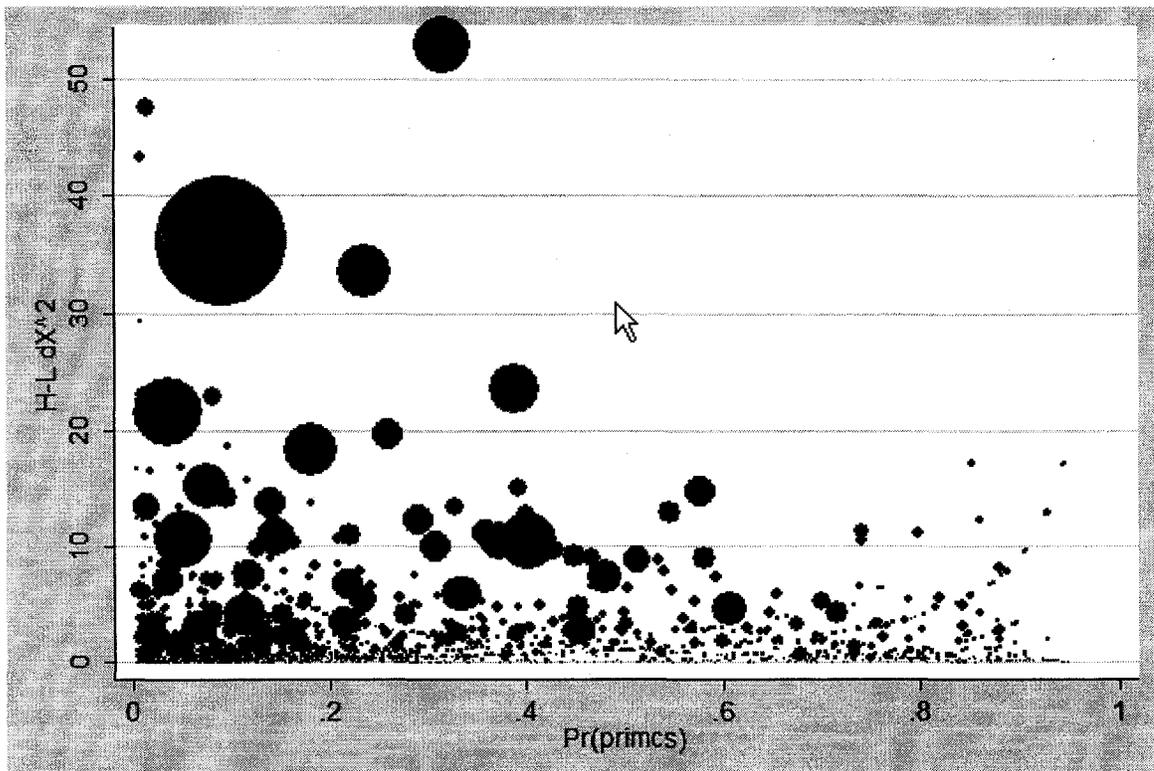


Figure 32. Covariate pattern with large leverage, residual, and influence.

Note. $H-L dx^2$ is the change or delta of the deviance given the covariate pattern presented plotted against the Pr or the probability of a primary cesarean delivery. The large circle represents a pattern with large leverage, residual and influence.

After examining the cases creating this influence, 227 cases were identified with a covariate pattern as follows: Cases with primary cesarean delivery “yes,” induction of labor “no,” medical indication for induction “no,” teaching status “no,” dystocia “no,” race and ethnicity “white,” gestation less than 40 weeks, nulliparous, age group 25 to 29 years, and baby weight between 2,501 and 4,499 grams. Given that these cases are clinically plausible and did not appear to be a data quality issue, the researcher elected to keep the 227 cases in the study. Prior to the final decision the researcher examined the influence that dropping the cases had on the beta

coefficients of the covariates in the model. Table 67 reflects the change on the coefficients after dropping the 227 cases. The coefficient for the interaction term of induce by weight group 2 (baby weight 2,501 to 4,499 grams) changes by 59.28%; however, this was not considered a substantial change given the coefficient was originally a small coefficient at .04. Therefore, this further supported the researcher's decision to keep the 227 cases in the model.

Table 67

Coefficient Changes after Dropping 227 Cases with Influence to the Model Fit

Covariate	With 227	Without 227	Change in Coefficient
Induction	-0.819	-0.813	0.66%
Medical Indication for Induction	0.771	0.796	-3.27%
Teaching	-0.273	-0.255	6.34%
Dystocia	2.126	2.165	-1.87%
Black (hisrace2) compared to white	0.292	0.335	-14.81%
Hispanic (hisrace 3) compared to white	-0.396	-0.363	8.36%
Other (hisrace 4) compared to white	-0.522	-0.473	9.39%
Gestation less than or equal to 40 weeks	-0.454	-0.475	-4.74%
Nulliparity	1.586	1.548	2.43%
20 to 24 years (age group 2) compared to < 20 years	0.282	0.280	0.64%
25 to 29 years (age group 3) compared to < 20 years	0.599	0.521	12.93%
30 to 34 years (age group 4) compared to < 20 years	0.860	0.864	-0.40%
≥ 35 years (age group 5) compared to < 20 years	1.180	1.181	-0.10%
wt group (2) 2,501 to 4499 grams compared to ≤ 2,500 grams	-0.590	-0.613	-3.94%

Table 67 (continued)

Covariate	With 227	Without 227	Change in Coefficient
wt group (3) \geq 4,500 grams compared to \leq 2,500 grams	0.785	0.777	1.06%
Induce*Dystocia	1.105	1.065	3.65%
Induce*Nulliparity	0.729	0.770	-5.60%
Induce*Black	0.376	0.326	13.31%
Induce*Hispanic	0.756	0.712	5.82%
Induce*Other	0.699	0.648	7.35%
Induce*Gestation equal or less than 40 weeks	-0.126	-0.100	20.66%
Induce*Weight Group 2	0.041	0.065	-59.28%
Induce*Weight Group 3	-0.773	-0.759	1.77%
Induce*Medical Indication for induction	-0.194	-0.222	-14.50%

Final Model Interpretation

The final model contained six two-way interactions with the primary covariate of interest, induction of labor. The interactions are known as effect modifiers, and must be taken into account when interpreting any odds ratios involving induction of labor. In particular, the presence of an effect modifier (such as mother's race) indicates that the odds ratio for induction of labor depends on the particular level of the effect modifier (i.e., White, African-American, Hispanic, etc.). Therefore, separate odds ratios must be calculated for each level of an effect modifier. Methods for calculating these odds ratios are discussed in detail in section 3.7 of Hosmer and Lemeshow's (2000) text *Applied Logistic Regression* (2nd ed.). In this study, there were multiple two-way interactions with induction of labor. Therefore, in order to calculate the appropriate odds ratio

(i.e., exponentiated linear combination of parameter estimates) involving any particular interaction with induction of labor in the model, it is necessary to average over all levels of the other interactions with induction of labor in the model.

Maternal age was the only client characteristic that was a straight-forward confounder. Fetal distress did not have a significant impact on the effect of labor induction and primary cesarean delivery and did not enter the final model. Dystocia, parity (nulliparity yes or no), gestation 40 weeks or less, baby weight (three groups), race and ethnicity and medical indication for induction were significant ($p < .05$) effect modifiers. Teaching status was the single system characteristic confounding the effect of labor induction on primary cesarean delivery. The results of the final model are reported in Table 68. These findings were used to examine the four hypotheses. However, it is important to note that given the researcher found interaction with induction of labor and several of the covariates [dystocia, parity (nulliparity yes or no), gestation 40 weeks or less, baby weight (three groups)], race and ethnicity and medical indication for induction), the odds ratios for induction of labor and the interaction covariates cannot be interpreted without special consideration of the interactions. The final model in Table 68 and the respective beta coefficients were used to examine the four hypotheses taking into account these interactions.

Table 68

Final Logistic Regression Model with Six Interaction Terms (N=160,533)

	β	OR	95% Confidence Intervals	
			Lower CI	Upper CI
Induction	-0.819	0.44	0.27	0.73
Medical Indication for Induction	0.771	2.16	2.06	2.27
Teaching	-0.273	0.76	0.73	0.80
Dystocia	2.126	8.38	8.01	8.76
Black (hisrace2) compared to white	0.292	1.34	1.25	1.43
Hispanic (hisrace 3) compared to white	-0.396	0.67	0.63	0.71
Other (hisrace 4) compared to white	-0.522	0.59	0.55	0.64
Gestation less than or equal to 40 weeks	-0.454	0.64	0.59	0.68
Nulliparity	1.586	4.88	4.63	5.15
20 to 24 years (age group 2) compared to < 20 years	0.282	1.33	1.24	1.41
25 to 29 years (age group 3) compared to < 20 years	0.599	1.82	1.70	1.94
30 to 34 years (age group 4) compared to < 20 years	0.860	2.36	2.20	2.54
≥ 35 years (age group 5) compared to < 20 years	1.180	3.25	2.99	3.54
Wt group (2) 2,501 to 4499 gms compared to $\leq 2,500$ gms	-0.590	0.55	0.46	0.67
Wt group (3) $\geq 4,500$ gms compared to $\leq 2,500$ gms	0.785	2.19	1.75	2.75
Induce*Dystocia	1.105	3.02	2.70	3.38
Induce*Nulliparity	0.729	2.07	1.81	2.37
Induce*hisrace2	0.376	1.46	1.23	1.72
Induce*hisrace3	0.756	2.13	1.85	2.45
Induce*hisrace4	0.699	2.01	1.68	2.40

Table 68 (continued)

	β	OR	95% Confidence Intervals	
			Lower CI	Upper CI
Induce*wtgrp2	-0.126	0.88	0.76	1.03
Induce*wtgrp3	0.041	1.04	0.66	1.64
Induce*gestation equal or less than 40 weeks	-0.773	0.46	0.26	0.83
Induce*medinduce	-0.194	0.82	0.73	0.93

Note. Six interaction terms denote by * were: Induction of Labor by Dystocia, Induce by Race and Ethnicity, Induce by Weight Groups, Induce by Gestation less than 40 Weeks, and Induce by Medical Indication for Induction. OR reflects Odds Ratio.

Hypothesis number one. Hypothesis number one is stated as follows: Client characteristics (including parity, gestation, race/ethnicity, maternal age, medical indication for induction, dystocia, fetal distress, and baby weight) confound the effect of labor induction on the odds of primary cesarean delivery. After modeling client and system characteristics and accounting for interaction, induction of labor did not have a significant independent effect on the odds of a primary cesarean delivery ($p = .146$), indicating that this hypothesis was supported. The client characteristics and to a lesser degree the system characteristics, rather than induction of labor alone, increase the odds of a primary cesarean delivery. However, only one of the client characteristics examined confounded the effect of labor induction on primary cesarean delivery. The single client characteristic confounder was maternal age. According to the study results, client and system characteristics confound *and modify the effect* of labor induction on primary cesarean delivery. When induction of labor was isolated using the full model with the six interaction terms and all confounders (maternal age and teaching status), the odds ratio was 1.165

(0.948; 1.430); however, the p value = .146 indicating that induction of labor no longer significantly influenced the effect of labor induction on the odds of primary cesarean delivery, independent of other client and system characteristics. This result aligns with the findings of Alexander et al. (2001) indicating that patient characteristics rather than induction of labor *per se* increase the odds of primary cesarean delivery. The results from the final model would support Alexander et al.'s study results.

The researcher also utilized the final model to compare women with a medical indication for induction with women without a medical indication for induction to determine the effect of labor induction on primary cesarean delivery under both conditions. For women with medical indication for induction, induction of labor did not have a significant effect on the odds of a primary cesarean delivery ($p = .614$). However, women without a medical indication for induction demonstrated different results. The odds of a primary cesarean delivery for women without a medical indication for induction indicated an increased odds for primary cesarean delivery by 1.28 times for women that were induced compared to women that were not induced (OR, 1.283, 95% CI: 1.040, 1.584, $p < .05$). Nulliparous women without a medical indication for induction comparing induced women to women that were not induced had further increased risk of primary cesarean delivery with an odds of 1.848 (95% CI: 1.492, 2.288, $p < 0.001$).

Dublin et al. (2000) stratified by parity and reported risk ratios based on the stratification of nulliparous (RR: 1.77; 95% CI: 1.50, 2.08) and multiparous women (RR: 1.07; 95% CI: 0.81, 1.39). Dublin et al. used the Breslow-Day test of homogeneity and found that nulliparous women and multiparous women had significantly different risk ratios for the association of labor induction and risk of primary cesarean delivery ($p = .001$).

Hypothesis number two. Hypothesis number two is stated as follows: Induction of labor for nulliparous (in comparison to multiparous) women increase the odds of a primary cesarean delivery after controlling for client and system characteristics. This hypothesis was supported with a coefficient for induction of labor of .517 and an odds ratio of 1.678 (CI: 1.364; 2.063, $p = .000$) for women that are nulliparous. These findings indicated that nulliparous women that are induced increased the odds of a primary cesarean by 68%. These findings hold all other client and system characteristics constant and account for the modifying effects of baby weight, gestation, dystocia, medical indication for induction, and race and ethnicity by averaging the interaction effect on induction of labor for nulliparous women.

Hypothesis number three. Hypothesis number three is stated as follows: Induction of labor for women 40 weeks gestation or less increase the odds of a primary cesarean delivery after controlling for system and client characteristics that influence the relationship. This hypothesis was not supported. Once all client and system characteristic confounders and effect modifiers were accounted for, the effect of labor induction was no longer significant ($p = .378$). This would indicate that for women 40 weeks or less induction of labor does not have a significant effect on the risk of primary cesarean. However, nulliparity has a significant influence that warrants discussion under hypothesis number three. Induction of labor for *nulliparous* women 40 weeks gestation or less had a significant effect with an increased odds of a primary cesarean delivery (OR 1.575; 95% CI: 1.287, 1.927, $p < 0.001$).

The odds ratio of 1.575 would indicate that nulliparous women less than 40 weeks gestation (holding all other covariates constant and averaging over all other interaction effects) increase their odds of a primary cesarean by 58%. However, multiparous women did not have an increased odds of primary cesarean delivery when comparing less than 40 weeks gestation for induced women compared to women that were not induced. In fact, there was a protective effect

with a coefficient of -0.275 with an odds ratio of 0.760 (95% CI: $0.610, .945$, $p = .01$). This would indicate that for multiparous women, induction of labor has a significantly protective effect for women 40 weeks gestation or less, decreasing the risk of a primary cesarean delivery by 24%.

After isolating the multiparous effect and averaging over all other interaction effects (including gestation 40 weeks or less), induction of labor did not have a significant effect on primary cesarean delivery after controlling for confounders and all interaction terms ($p = .07$). Additionally, the results of modeling multiparous women greater than 40 weeks gestation also demonstrated that induction of labor no longer had a significant effect ($p = .253$) on the odds of a primary cesarean delivery.

Therefore, the analyses examining the importance of parity indicated that nulliparity had an important overall impact on the odds of a primary cesarean delivery, particularly for induced women compared to women that were not induced. Table 69 reflects the model results on the analysis examining the effect of parity and gestation greater than and less than 40 weeks gestation. Note that the odds ratios for nulliparous women, nulliparous women 40 weeks or less, and nulliparous women greater than 40 weeks are all statistically similar when examining the 95% confidence intervals for all three odds ratios ($1.67, 1.58, \text{ and } 1.79$, respectively). This also further substantiates the findings for hypothesis number two indicating that induction of labor for nulliparous women increases the odds of a primary cesarean delivery after controlling for client and system characteristics.

Table 69

Modeling Parity and Gestation Using the Derived Study Model

Isolated Effect	Coef	Odds Ratio	Std Err	Lower ci	Upper ci	p value
Inductions	0.153	1.165	0.110	0.948	1.430	0.146
Nulliparous	0.517	1.678	0.160	1.364	2.063	0.000
Nulliparous, Gestation \leq 40 weeks (37-40)	0.454	1.575	0.146	1.287	1.928	0.000
Nulliparous, Gestation $>$ 40 weeks (41-42)	0.580	1.787	0.202	1.409	2.265	0.000
Multiparous	-0.212	0.809	0.086	0.646	1.013	0.065
Multiparous, Gestation \leq 40 weeks (37-40)	-0.275	0.759	0.078	0.610	0.945	0.014
Multiparous, Gestation $>$ 40 weeks (41-42)	-0.149	0.862	0.107	0.667	1.113	0.253
Gestation \leq 40 weeks (37-40)	0.090	1.094	0.099	0.896	1.335	0.378

Hypothesis number four. Hypothesis number four is stated as follows: System characteristics (including hospital bed size, urban versus rural status, ownership type, teaching status, and payer type) confound the effect of labor induction on risk of primary cesarean delivery. The single system characteristic that confounded the effect of labor induction on primary cesarean delivery was teaching status. Teaching status had a significant protective effect on the risk of primary cesarean delivery, with a coefficient in the final model of -.273 and an odds ratio of .761 (CI: .726; .798, $p < .001$). All other system characteristics failed to enter the model. Therefore, this hypothesis was weakly supported, reflecting that the major influence on the effect

of labor induction on primary cesarean delivery was driven by client characteristics rather than system characteristics.

Conclusion

In conclusion, induction of labor does not independently affect the odds of primary cesarean delivery after adjusting for client and system characteristics that confound or modify the effect. Key variables that confound the effect of labor induction on primary cesarean delivery are maternal age and teaching status. Covariates that significantly modify the effect of labor induction on primary cesarean delivery were dystocia, race and ethnicity, 40 weeks or less gestation, nulliparity, medical indications for induction, and baby weight. These findings indicate that any study examining the effect of labor induction on the odds of primary cesarean delivery should deploy methods that take into account confounders and effect modifiers.

CHAPTER V

SUMMARY, FINDINGS, AND CONCLUSIONS

Summary of the Study

In summary, the researcher examined the effect of labor induction on the odds of primary cesarean delivery controlling for factors that confound or modify the effect using the researcher's modified version of the Mitchell et al.'s (1998) Health Outcomes Model as a framework to test the following hypotheses:

1. Client characteristics (including parity, gestation, race/ethnicity, maternal age, medical indication for induction, dystocia, fetal distress and baby weight) confound the effect of labor induction on the odds of primary cesarean delivery.

2. Induction of labor for nulliparous women increase the odds of primary cesarean delivery after controlling for client and system characteristics.

3. Induction of labor for women 40 weeks gestation or less increase the odds of a primary cesarean delivery after controlling for system and client characteristics that influence the relationship.

4. System characteristics (including hospital bed size, urban versus rural status, ownership type, teaching status, and payer type) confound the effect of labor induction on the odds of primary cesarean delivery.

The researcher's modified Health Outcomes model by Mitchell et al. (1998) was an ideal framework for this study because the Health Outcomes Model emphasizes multiple contextual variables that influence health care delivery and outcomes. The model proposes that interventions

affect and are affected by both system and client characteristics in producing desired outcomes, and that no single intervention acts directly through either system or client alone (Mitchell et al., 1998). The findings of this study support the model's proposition, given that induction of labor affects and is affected by the client characteristics, and to a lesser degree system characteristics. These study findings and Mitchell et al.'s model provided evidence that the relationship of labor induction and primary cesarean delivery is complex, and cannot be examined without taking into account these complex interrelationships.

The researcher hypothesized that both client and system characteristics would confound the relationship. The researcher did not hypothesize that client relationships would modify the effect of labor induction on the odds of primary cesarean delivery, because the current scientific literature did not support that finding. However, several of the studies inferred effect modification given that they used stratification methods, exclusion criteria, and case control studies. An important finding of this study which was different from other studies examining the effect of labor induction on the odds of primary cesarean delivery was the clear delineation of effect modification for induction of labor with several covariates (dystocia, race and ethnicity, parity, medical indication for induction, baby weight, and gestation).

Confounding and Effect Modification

The researcher's findings regarding effect modification are important to note, because effect modification and confounding are different and imply different information regarding the effect of the variable on the relationship. A variable that would mediate the effect is a situation in which a covariate is associated with both the outcome variable (primary cesarean delivery) and the variable of interest (induction of labor), thereby confounding the effect. Hosmer and Lemeshow (2000, section 3.5) describe methods to control for confounding when examining an

outcome of interest confounded by one or more variables. These methods were deployed in the study and described in Chapter III.

A variable that would modify the effect is a situation in which the covariate and the variable of interest interact and “modify” or change the effect on the outcome with variability across different strata. The effect of the variable is not constant across all levels of another variable. Hosmer and Lemeshow (2000) indicate that adjusting for confounding using a logistic regression model is appropriate when there is no interaction (effect modification) present. They also recommend methods to control for the interactions. These methods were used in the final analysis using a model with all confounding variables (maternal age and teaching status) and all effect modifiers (dystocia, race and ethnicity, parity, medical indication for induction, baby weight and gestation). An example of an effect modifier impacting the analysis of the final results would be the relationship of labor induction on primary cesarean delivery and the modifying effect of baby weight. A modifying effect would indicate that the odds of a primary cesarean is dependent on the baby weight when comparing the odds of primary cesarean delivery for induced women compared to women that were not induced, reflecting differences across the strata of different baby weights. This modification of the effect of labor induction on the odds of primary cesarean delivery should be taken into account with a final model interpretation.

The multivariable logistic regression risk modeling methods deployed as described by Hosmer and Lemeshow (2000) provided a method for the researcher to determine if either the client or system characteristic was a confounding or effect modifying variable and to adjust for that effect (described in the Chapter III in the Analysis Section). Additionally, the methods required examination of continuous variables, such as baby weight, to verify that the variables are linear in the logit. Baby weight in fact was not. It is important to address this violation of a logistic regression assumption prior to entering a variable as a continuous variable. Baby weight

was broken into clinically meaningful groups to address the non-linearity. Hosmer and Lemeshow (2000) also indicated that an effect modifier should be interpreted differently from a confounding covariate when interpreting the final results of a logistic regression model. Using these methods, the researcher's final model provided a mechanism for controlling for the confounding variables and examining the impact of the various effect modifiers to determine how the various effect modifiers influenced the odds of a primary cesarean delivery for women induced compared to women that were not induced. These results help clarify and support several studies (Alexander et al., 2000, 2001), particularly those studies that isolated specific populations with exclusion criteria and stratification methods, and the study also challenges study results in other studies with conflicting findings.

Discussion of Findings

The researcher concludes that the single client characteristic that confounds the effect of labor induction on the odds of primary cesarean delivery was maternal age, and the single system characteristic that confounded the effect of labor induction on the odds of primary cesarean delivery was teaching status. The researcher also identified a number of significant interaction terms modifying the effect of labor induction on the odds of primary cesarean delivery. The researcher expected to find confounding rather than effect modification and hypothesized in hypothesis number one that client characteristics (including parity, gestation, race/ethnicity, maternal age, medical indication for induction, dystocia, fetal distress, and baby weight) *confound* the effect of labor induction on the odds of primary cesarean delivery. The effect modification identified in this study was somewhat unique to the study findings, particularly given the number of interaction terms identified as significant. Six interaction terms were identified including, dystocia, race and ethnicity, parity, baby weight, medical indication for induction, and gestation.

With the exception of Dublin et al. (2000) that identified significant interaction with parity, prior studies did not identify significant interaction terms.

Several of the studies used methods that might infer effect modification, such as in the Maslow and Sweeney (2000) study which examined women with and without medical indication for induction to determine the effect of elective induction of labor, inferring differences in the effect of labor induction for women with and without medical indication for induction. They also excluded baby weights of greater than 4,000 grams to determine differences that baby weight had on the outcome, once again inferring the researchers expected to find differences in the effect for women delivering larger babies. In the researcher's study, both medical indication and baby weight were identified as significant interaction terms. This has important methodological implications not because one method is better than another, but to highlight the ability of Hosmer and Lemeshow's (2000) methods to include the multiple interaction terms without deploying stratification and exclusion criteria. The method resulted in a flexible final model that controlled for both confounding and effect modification and provided a way to examine the different populations within the study. This model also provided flexibility in comparing other studies that used stratification and exclusion criteria because the model accounted for all effect modifiers that other researchers appeared to address through the stratification and exclusion criteria. Given that the final model included all of the covariates (whether effect modifiers or confounders), the model addressed the various influences of the system and client characteristics.

The unique finding of multiple significant interaction terms in this study may have been due to the large population sample utilized for the study ($n = 160,533$), differences in analysis methods, or perhaps semantics in previously reported studies. However, the researcher concluded that this is an important finding with both clinical and methodological implications for future research investigating the effect of labor induction on the odds of primary cesarean delivery.

These methodological and clinical implications are discussed further in the implications section of Chapter V.

The findings for hypothesis number two indicated that induced nulliparous women had an increased odds of primary cesarean delivery by 1.68 times compared to nulliparous women that were not induced (OR: 1.677; CI: 1.364, 2.063; $p < .001$). Hypothesis number two was stated as follows: “Induction of labor for nulliparous women increase the odds of primary cesarean delivery after controlling for client and system characteristics.” This hypothesis was supported, and was interesting to examine within the context of hypothesis number three because hypothesis number three addresses early gestation.

Hypothesis number three was stated as follows: “Induction of labor for women 40 weeks gestation or less increase the odds of primary cesarean delivery after controlling for system and client characteristics that influence the relationship.” The researcher expected that the trend in early induction of labor (discussed in Chapter I) might be influencing the rise in primary cesarean delivery rates. Hypothesis number three tested that expectation. The researcher’s findings indicated that early gestation did not impact the odds of a primary cesarean delivery when comparing induced women to women who were not induced. Therefore, hypothesis number three was not supported, as the study findings indicated that induction of labor no longer had a significant effect on the odds of primary cesarean, after controlling for 40 weeks gestation or less (OR 1.094; 95% CI: .896, 1.335, $p = .378$) and adjusting for confounders and other effect modifiers. This would indicate that early induction of labor does not increase the odds of a primary cesarean delivery.

However, induction of labor at 40 weeks or less *for nulliparous* women significantly ($p < .001$) increased the odds of primary cesarean delivery by 1.575 times (95% CI: 1.287; 1.928, $p < .001$). So, nulliparity in isolation increased the odds of a cesarean by 1.68 times for induced

nulliparous women compared to nulliparous women that were not induced; and induced nulliparous women less than 40 weeks gestation also have an increased odds, but the odds drop to 1.58. Given the overlap in 95% confidence intervals these differences between odds are not significant differences (see Table 69), but clinically interesting. This would indicate that nulliparity is the predominant factor increasing primary cesarean delivery, regardless of gestation. In conclusion, this study is important because it provides further evidence and understanding of the effect of labor induction on the odds of primary cesarean delivery.

Induction of Labor for Multiparous Women: A Protective Effect for Less than 40 weeks Gestation

Examining the multiparous effect changed the significant effect of labor induction on the odds of primary cesarean delivery after controlling for confounding and other effect modifiers. The effect of labor induction on the odds of primary cesarean delivery was no longer significant using the final model to examine multiparous induced women compared to multiparous women that were not induced ($p = .07$). Additionally, when comparing induced multiparous women greater than 40 weeks gestation compared to multiparous women greater than 40 weeks gestation that were not induced, the final model indicated no significant effect ($p = .253$) on the odds of primary cesarean delivery. However, multiparous induced women *less than 40 weeks gestation* did not have an increased odds of primary cesarean delivery when comparing multiparous women less than 40 weeks gestation that were not induced. In fact, there was a *protective effect* with a coefficient of $-.275$ and an odds ratio of 0.759 (95% CI: $0.610, 0.945$; $p = .01$). This study helps fill a gap in the scientific evidence regarding how earlier induction of labor might be influencing the increase in the primary cesarean delivery rates in the United States. This study's findings indicated that early induction of labor does not appear to be a factor in the increasing primary

cesarean rates, and in fact may assist with decreasing the odds of primary cesarean delivery for multiparous women.

Nulliparous Greater than 40 weeks Gestation

When the odds ratios for nulliparous women greater than 40 weeks gestation were examined using the logistic regression model from the study, the odds were also increased for nulliparous women, with an odds ratio of 1.786 (95% CI: 1.409, 2.202; $p < 0.001$). Once again, the odds for women greater than 40 weeks were not statistically different from nulliparous women 40 weeks gestation or less, as evidenced by the overlap in the 95% confidence intervals for the odds ratios. Additionally, these results adjust for differences in baby weight, dystocia, race and ethnicity, and medical indication for induction by controlling for the effect of the interaction with induction of labor. These findings are highlighted in Table 70 and Figure 33. This would indicate that nulliparous women have an overall increased odds of primary cesarean when induced by between 1.29 and 2.27 times that of women that were not induced, with the degree of risk dependent on the gestation with risk increased beyond 40 weeks gestation. The increased risk although clinically interesting were not significantly different. Therefore, this study concludes that nulliparity is the major factor increasing the odds of a primary cesarean delivery when comparing induced women to women that were not induced.

Table 70

Odds Increased for Nulliparous Women

Isolated Effect	Odds Ratio	Lower ci	Upper ci	p value
Induction of labor	1.165	.948	1.431	NS
Nulliparous	1.6781	1.364	2.063	*
Gestation \leq 40 weeks (37-40)	1.094	0.896	1.335	NS
Nulliparous, Gestation \leq 40 weeks (37-40)	1.575	1.287	1.928	*
Nulliparous, Gestation $>$ 40 weeks (41-42)	1.786	1.409	2.265	*
Multiparous	.0809	0.646	1.013	NS
Multiparous, Gestation \leq 40 weeks (37-40)	0.760	0.610	0.945	*
Multiparous, Gestation $>$ 40 weeks (41-42)	.862	0.667	1.113	NS

Note. NS indicates the effect was not significant $p > .05$; * indicates significant $p \leq .01$.

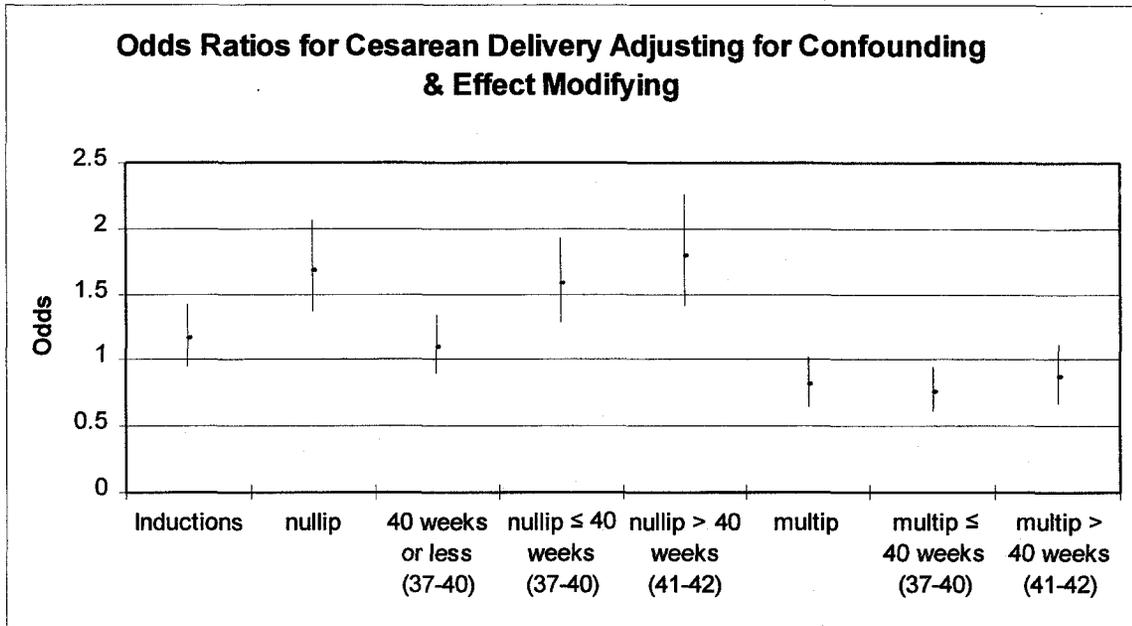


Figure 33. Odds ratios for primary cesarean delivery adjusting for confounders and effect modifiers.

Note. nullip = nulliparity, multip = multiparity.

Teaching Status: A Protective Effect

Hypothesis number four hypothesized that system characteristics would confound the relationship of labor induction on the odds of primary cesarean. In fact, only one system characteristic confounded the relationship, teaching status. Teaching status had a significantly protective effect, with a coefficient in the final model of $-.273$ and an odds ratio of $.761$ (CI: $.726$; $.798$, $p < .000$). This would indicate that teaching hospitals reduce the risk of primary cesarean delivery. There was a total of six teaching institutions in which the study population delivered. Table 71 reflects the study population's distribution in teaching compared to non-teaching institutions. Teachings hospitals had 42.25% of the deliveries with one hospital representing

45.73% of the teaching hospitals' volume. However, over 50% ($n = 36,809$) of the cases within the study population delivered within one of five other teaching institutions.

Table 71

Teaching Status Hospitals

		Teaching Hospital Yes or No	
Teaching Status		Frequency	Percent of Total Population
		No	92702
	Yes	67831	42.25
	Total	160533	100

Teaching Hospitals		Frequency	Percent of Teaching Hospitals
		Hospital A	31022
	Hospital B	7211	10.63
	Hospital C	10669	15.73
	Hospital D	2447	3.61
	Hospital E	5325	7.85
	Hospital F	11157	16.45
	Total	67831	100

The protective effect of teaching hospitals was interesting in light of Oleske, Glandon, Giacomelli, and Hohmann (1991) study examining the influence of teaching status on cesarean delivery rates. Oleske et al.'s study population ($N=130,249$) was from an Illinois hospital discharge database linked with AHA Annual survey data. Although the Oleske et al. study was relatively dated (done in 1991), the Oleske team's results were supported with the current study

findings. The 1991 results indicated that women delivering in hospitals with teaching status are less likely to have a cesarean delivery, after controlling for maternal age, presence of complications, primary payer, and size of the hospital. The results are remarkably similar with reported odds ratio of 0.76 (CI: 0.73, 0.79, $p < .001$). Figure 34 reflects the similar findings of the current study and the Oleske et al. (1991) study.

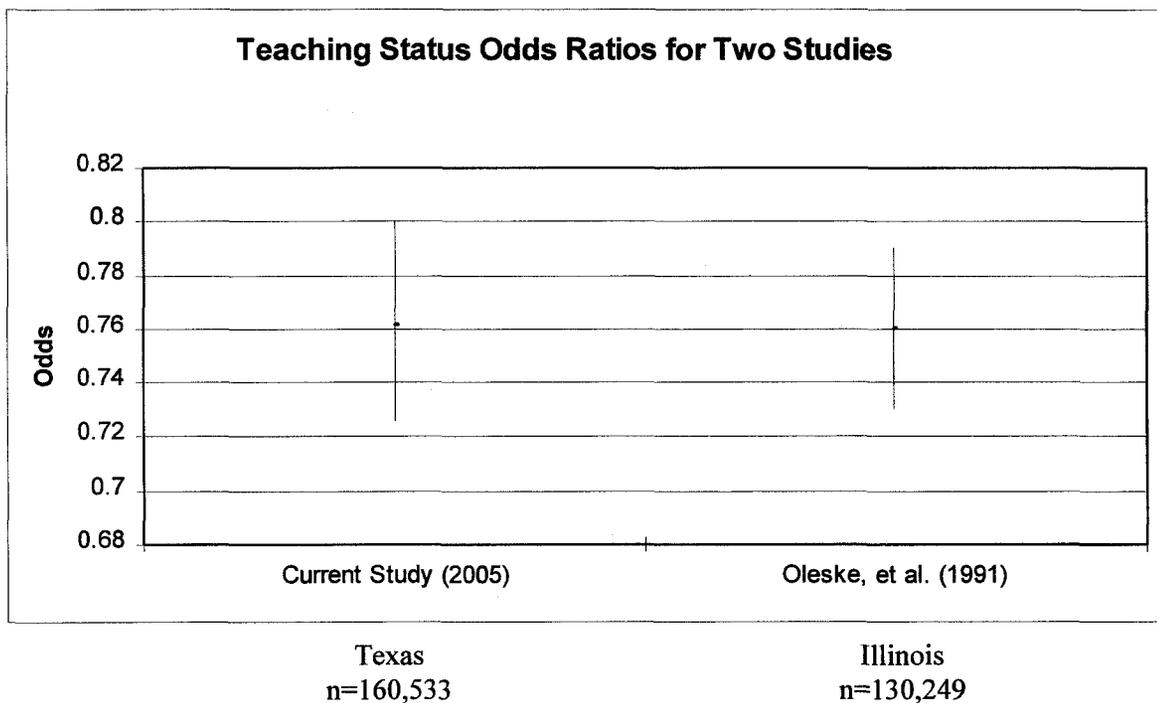


Figure 34. Comparison of the researcher's findings to the Oleske et al. (1991) study findings.

Oleske et al. (1991) concluded that an unresolved issue is how much the increase in cesarean rates is attributable either to physicians' practice styles or to the hospital environment in which care is delivered. They also stated that their results were preliminary and that their results should be tested in other populations and other states. The researcher's findings clearly support the Oleske team's findings.

An additional note regarding teaching status relates to the two Alexander et al. studies (2000, 2001), both of which were done in Parkland Hospital. The obstetrical service for Parkland Hospital is staffed by house officers, and faculty of the Department of Obstetrics and Gynecology at the University of Texas Southwestern Medical School which clearly has a teaching status. Both studies indicated a strict adherence to an induction of labor protocol. The 2000 study examining pregnancy outcomes at 40, 41, and 42 weeks gestation examining the effect of a labor induction protocol for induction of labor at 42 weeks, but not 41 weeks. The 2001 study specifically examined the effect of labor induction on the odds of primary cesarean delivery in post-date pregnancies (per protocol). Clearly, strengths of the Alexander et al. studies are the homogenous patient population within Parkland that supported analysis of an isolated effect of the labor induction protocol. It is interesting to note that the findings of the currently reported study, and the 2001 study done by Alexander et al. have very similar findings with both studies identifying predominantly client characteristics that increase the odds of a primary cesarean delivery, rather than an independent effect of induction labor. In Alexander et al.'s (2000 study), the researchers proposed that a national policy of routine intervention at 41 weeks would affect approximately 500,000 women per year. They concluded that intervention at 41 weeks gestation was unnecessary because of the lack of benefit to mother and baby, and the increased risk of cesarean delivery relating to increased healthcare costs.

The researcher suggests that teaching institutions are more likely to maintain strict adherence to labor induction protocols and that these protocols might be driving the significant results found by Oleske et al. (1991) as well as the reported study. This certainly has clinical implications in that if strict adherence to protocols have a significantly protective effect on risk of primary cesarean delivery, then other community, for-profit and not-for-profit hospitals and their patient populations may benefit from adhering to stricter protocols. One other note of importance,

patient populations within teaching institutions frequently differ with respect to race, ethnicity, comorbidities and payer (Gregory, Korst, & Platt, 2001; Oleske et al., 1991), the fact that both the current study and Oleske et al.'s study adjusted for these factors would indicate that there is something unique contributing to the protective effect. The findings that teaching status protects against a risk of primary cesarean delivery, combined with both the Oleske et al.'s study and Alexander et al.'s study would support consideration of adherence to protocols for induction labor nationally. If national consensus could be generated regarding adherence to labor induction protocols, then this study combined with clinical studies (Alexander et al., 2000, 2001), would indicate that induction labor protocols could impact the increase in primary cesarean rates.

Elective Induction of Labor

The findings of the current study were compared to findings from three studies that specifically examined elective induction of labor. The researcher's findings are important to consider in light of these three studies. All three studies defined elective induction of labor as the absence of a medical indication for induction, using the same or similar definition as this study. The Dublin et al. (2000) and the Maslow and Sweeney (2000) study isolated cases with ICD-9-CM codes indicating a medical indication for induction similar to the reported study (see Appendix C for detailed definition of the ICD-9-CM codes). The Seyb et al. (1999) study used a clinically abstracted database, but the same definition of comorbidities reflecting a medical indication for induction. Maslow and Sweeney also substantiated their data with a medical record chart review. The Maslow and Sweeney (2000) study examined low-risk term (38-41 weeks) pregnancies and the effect of elective induction of labor on cesarean delivery. One of the primary intentions of the study was to identify the cost associated with elective induction of labor. The Maslow and Sweeney (2000) study found that nulliparous women who had been induced were at a two-fold risk to deliver by cesarean delivery compared to those that were not induced. After

controlling for variables including gestational age, birth weight, and maternal age in the nulliparous population, the odds ratio for cesarean delivery for induced women compared to women that were not induced was 2.4 (95% CI: 1.2, 4.9, $p < .05$). When all nulliparous women with infant birth weights over 4,000 grams were excluded, gestational age and elective induction of labor was the only variables that were significant predictors of cesarean delivery ($p < .01$ and $p < .05$, respectively) in the final logistic regression model.

The Seyb et al. (1999) study also looked at elective induction of labor for nulliparous women for the purpose of quantifying the risk. This study used a clinical database collected by the researchers for the purpose of conducting this cohort study. The Seyb et al. (1999) study focused on a very specific patient population in a major urban hospital serving predominantly private obstetric practices. The study cohort was all term, nulliparous women with vertex, singleton pregnancies that delivered during an 8-month period. This study was different in that the researchers stratified by three groups. The study population was 1,561 women, divided into three groups: (a) spontaneous labor, (b) elective induction of labor, and (c) medical induction of labor. The Seyb et al. (1999) study reported an odds for elective induction of labor for nulliparous women of 1.89 (95% CI: 1.12, 3.18).

The current study reports an odds ratio for nulliparous women controlling for the modifying effect of medical indication for induction of 1.678 (95% CI: 1.364, 2.063, $p < 0.001$). This was not significantly different from either the Maslow and Sweeney (2000), or the Seyb et al. (1999) findings given the overlap in confidence intervals. The Maslow and Sweeney study had fairly wide confidence intervals (1.2; 4.9), reflective of the relatively small sample size ($n = 1,135$). An important note regarding the Maslow and Sweeney (2000) study was the data validity checks that were done. The study data were substantiated by chart review. Additionally, the researchers used clinical data derived from the obstetrical log books. Therefore, Maslow and

Sweeney's (2000) study validated their data through use of medical record abstract and the obstetrical log book.

In order to compare the Maslow and Sweeney (2000), Dublin et al. (2000), and Seyb et al. (1999) results to the researcher's study results, the researcher isolated cases without medical indication for induction. When cases that did not have a medical indication for induction noted were examined using the final logistic regression model (adjusting for no medical indication for induction, other effect modifiers and confounders), the odds of a primary cesarean delivery were very similar to the results of both Maslow and Sweeney's and Seyb et al.'s studies. Table 72 reflects the results of all three studies examining elective induction of labor defined as the absence of a medical indication for induction. Table 72 reflects the statistical similarities, evidenced by overlap in the 95% Confidence Intervals for the Maslow and Sweeney, the Seyb et al., and the researcher's currently reported study results.

Table 72

Odds of Primary Cesarean Delivery for Nulliparous Women Examining Elective Induction of Labor

Study	Year	OR	95% Confidence Intervals	
			Lower	Upper
Maslow and Sweeney	2000	1.89	1.12	3.18
Seyb et al.	1999	2.4	1.2	4.9
Current Study	2005	1.85	1.49	2.29

The Maslow and Sweeney exclusion criteria are interesting to note compared to the researcher's study. The researcher's study included all birth weights greater than 1,000 grams, but adjusted for interaction across the different birth weights to examine the modified effect. The

current study findings for odds of a primary cesarean delivery comparing induced women without a medical indication for induction to women that were not induced are very similar to the Maslow and Sweeney findings with odds of 1.85 and 1.89, respectively (see Table 72). Maslow and Sweeney indicated they tested for interaction with inclusion criteria of $p < .01$. However, the researchers apparently did not find significant interaction given they did not report any interaction terms in the final model provided. The sample size may have impacted the researcher's power to identify significant interaction with $n = 1,135$. The researchers excluded 4,000 gram birth weight babies, suggesting that the researchers believed that the results would be, and in fact were, different, when isolating the births excluding the 4,000 gram births. They also stated that their study lacked a sufficient number of cases to examine the effect of babies over 4,500 grams. The researcher would conclude that sample size in this study and perhaps others, impacted the researcher's ability to identify significant interaction. However, they controlled for interaction by exclusion criteria and stratification for several of the covariates that the researcher's study found to be significant interaction terms including, parity, baby weight, and medical indication for induction. This would indicate that despite differences in methods, the study findings corroborate.

Dublin et al.(2000) examined the phenomenon of elective induction of labor using a database similar to the one reported here that included Washington state birth certificate and hospital discharge data. They used a different statistical method for analysis; however, Dublin et al.'s conclusion was similar to the reported study, in that findings indicated that induction of labor was associated with an increased likelihood of cesarean delivery for nulliparous women, but not for multiparous women.

The Dublin research team used stratified analysis to examine confounding or interaction for: gestation, maternal age (< 20, 20-34, and ≥ 35 years), race and ethnicity, urban or rural maternal address, payer, birth year, birth weight (2,500 grams; 2,500-3,999 grams; and $\geq 4,000$

grams) and hospital level (including nursery level, number of births per year, and urban or rural location). The Dublin et al. study used the Mantel-Haenszel pooled estimator of relative risks to calculate adjusted relative risks and 95% confidence intervals. If the adjustment for a covariate altered the relative risk for an outcome by greater than or equal to 10%, the covariate was considered to be a confounder. Similar criteria were used in the reported study to establish confounding. If the change in effect of labor induction on the risk of primary cesarean delivery altered by more than 10%, the variable was identified as a confounder. The Breslow-Day test for homogeneity was used to identify possible interactions. The Dublin group found interaction as reported by a significant Breslow-Day test ($p = .001$) for parity and induction. However, interestingly, they report that stratification did not alter the relationship between induction of labor and the risk of cesarean delivery (Breslow-Day test for homogeneity $p = .80$). The differences in results might be reflective of both sample size issues, and different methods for controlling for confounding and effect modification. With the Breslow-Day test of homogeneity a researcher can test the hypothesis that the odds ratio between X and Y is the same at each level of Z. The Breslow-Day test is a test of homogenous association between $2 \times 2 \times K$ tables (Agresti, 1996).

Hosmer and Lemeshow compare logistic regression to stratified analysis for 2×2 tables, as used by Dublin et al. (2000). The stratification method originates from traditional epidemiologic studies with the essential objective of the 2×2 analysis to determine whether the odds ratios are constant or homogenous over the strata. If the odds are constant then the stratified odds ratio estimator (Mantel-Haenszel) is computed. Hosmer and Lemeshow (2000) indicated that logistic regression modeling provides a faster and more effective way to obtain a stratified odds ratio estimator and to assess the assumption of homogeneity of odds across strata, given that the stratified method would require multiple layers of stratified tables. In fact, it was difficult to

follow Dublin et al.'s techniques because they failed to illustrate most of the models in the reported study. Clearly the stratified method suggests an alternative approach for examining the effect of labor induction on primary cesarean delivery, and according to Hosmer and Lemeshow (2000) generates similar results. However, it is difficult to ascertain from the reported results of Dublin et al. why their results may have differed from the findings reported here of additional effect modifiers. This may be a reflection of their smaller sample size, $n = 12,534$. However, the researchers report having done an a priori power analysis to ascertain the size of the sample required to examine the effect of labor induction on cesarean delivery. The researchers selected a random sample from the 387,942 singleton births in Washington state from 1989 through 1993. The researchers noted that 12,534 cases were sufficient to measure an effect of labor induction on the risk of primary cesarean delivery based on their a priori power analysis and a pilot study done.

Another important aspect of the Dublin et al. (2000) study was that the researchers reported adjusted relative risk ratios rather than odds. According to Zhang and Yu (1998), relative risk has become one of the standard measures in biomedical research. Relative risk indicates the multiple of risk of the outcome in one group compared with another group and is usually expressed as the risk ratio in cohort studies and clinical trials. They further indicate that when the risk ratio cannot be obtained directly (such as in a case-control study), the odds ratio is calculated and often interpreted as if it were the risk ratio. Subsequently, the term relative risk commonly refers to either the risk ratio or the odds ratio. Zhang and Yu (1998) caution that only under certain conditions should the odds ratio approximate the risk ratio and that interpreting a relative risk as an odds is appropriate approximation when the incidence of an outcome of interest in the study population is low ($< 10\%$). However, the more frequent the outcome becomes, the more the odds ratio will overestimate the risk ratio when it is more than 1 or underestimate the risk ratio when it is less than 1.

Converting odds ratios to relative risk ratios. The Dublin et al. (2000) study reports adjusted relative risk using the Mantel-Haenszel pooled estimator; therefore, comparability required that the researcher convert the odds ratios reported by the logistic regression method used to relative risk ratio, using a formula suggested for this purpose by Zhang and Yu (1998). Table 73 reports the results comparing the current study findings to the Dublin et al. study results transforming the odds ratios from the current study to relative risk ratios. Both studies indicated a significantly increased risk of primary cesarean delivery for nulliparous women that are electively induced. The current study reports an increased risk of 68%; whereas the Dublin et al. study reports an increased risk of 77%. These findings are not significantly different as evidenced by the overlap in the 95% confidence intervals for both study findings. For multiparous women both studies reflect an insignificant effect of labor induction on the risk of primary cesarean delivery evidenced by the lower and upper 95% confidence intervals containing one in both study results. This indicated that the risk ratio could be one for both studies and no significantly increased risk for induced women compared to women that were not induced (Rothman & Greenland, 1998).

Table 73

Relative Risk Comparing Current Study Results to Dublin et al. (2000) Results

Isolated Effect	Odds Ratio	95% Confidence Interval		RR	95% Confidence Interval		*P ₀
		lower ci	upper ci		Lower ci	Upper ci	
Current Study Results							
Nulliparous	1.85	1.49	2.29	1.68	1.41	1.98	0.12
Multiparous	0.89	0.71	1.12	0.89	0.72	1.12	0.03
Dublin et al. (2000) Study							
Nulliparous				1.77	1.50	2.08	0.09
Multiparous				1.07	0.81	1.39	0.04

Note. *P₀ is the incidence of the primary cesarean outcome of interest in the nonexposed group. Relative Risk calculated as $RR = OR / (1 - P) + (P * OR)$. OR reflects odds ratio.

Johnson et al. (2003) also examined the risk of cesarean delivery after induction of labor at term in nulliparous women. The Johnson et al. (2003) study specifically examined favorability of the cervix to labor for nulliparous women. The study did not examine multiparous women. A favorable cervix was defined as a bishop score of ≥ 5 . The study population was 19,993 births within the Providence Service Area giving birth in one of the Providence Health System hospitals. The data for 7,282 deliveries were abstracted by a trained abstractor for births from 1997 through 1999 for nulliparous women with singleton pregnancies, 37 to 43 weeks gestation. The study results from the Johnson et al. (2003) study also supports that induction of labor for nulliparous women increases the risk of a primary cesarean. Their study findings indicate the risk was increased by 77% (RR 1.77, 95% CI: 1.46, 2.11). This is higher than the reported study, although not statistically higher, as evidenced by the overlap in confidence intervals when comparing the two study results (current study: RR 1.68, 95% CI: 1.41, 1.98, $p < .001$). The researchers indicated they addressed interaction and found no significant interaction terms. Gestational age was included as a continuous variable with no indication that the researchers examined the linearity of the logit for the variable. It is interesting to note that despite the methodological differences to the reported study, the findings were statistically similar with respect to nulliparous women.

Comparing the current study findings with the Dublin et al. and Johnson et al. with regards to relative risk of primary cesarean delivery for nulliparous women, all three studies found that nulliparous women have significantly increased risk of cesarean delivery when induced compared to women that were not induced. Table 74 reflects comparative information on the three studies. The Dublin et al. (2000) and Johnson et al. (2003) had remarkably similar results with a relative risk ratio of 1.77 for both studies when examining induced nulliparous

women compared to nulliparous women that were not induced. The current study supports the findings of both these clinical investigations. It is noteworthy that both these studies used clinically abstracted data with adherence to data validity checks. The current study using hospital discharge data and birth certificate data with total agreement aligns with these study results.

Table 74

Relative Risk Comparing Current Study Results to Dublin et al. (2000) and Johnson et al. (2003)

Isolated Effect	Odds ratio	95% Confidence Interval		RR	95% Confidence Interval		*I ₀
		Lower ci	Upper ci		Lower ci	Upper ci	
Current Study Results							
Current Study Results	1.678	1.364	2.063	1.55	1.31	1.83	0.12
Dublin et al. (2000) Study				1.77	1.50	2.08	0.09
Johnson et al. (2003) Study				1.77	1.46	2.11	

Note. *I₀ is the incidence of the primary cesarean outcome of interest in the nonexposed group. Relative Risk calculated as $RR = OR / (1 - I) + (I * OR)$

The Heffner et al. (2003) study has remarkably similar results to the reported study for nulliparous women, but disagrees on findings for multiparous women. The research team also used a clinically abstracted database from Beth Israel Deaconess Medical Center and Brigham and Women's Hospital in Boston. The sample size was 14,409 women giving birth at one of the teaching institutions. The researchers' findings indicate that induction of labor, older maternal age, and gestational age over 40 weeks were associated with an increase in cesarean deliveries. The study results report that nulliparous women who were induced had an increased odds of cesarean delivery by 1.70 times that of nulliparous women going into spontaneous labor (OR 1.70, 95% CI: 1.48, 1.95, $p < .01$). They also reported that induced multiparous women had an increased odds of a cesarean delivery by 1.49 times that of multiparous women going into spontaneous delivery (OR 1.49; 95% CI: 1.10, 2.00, $p < .05$). Table 75 reflects the comparison of the current study to the Heffner team's research.

Table 75

Odds of Primary Cesarean Delivery Comparing Current Study to Three Studies

Nulliparous Women					
Study	Year	OR	95% Confidence Intervals		P value
			lower	upper	
Hefner et al.	2003	1.70	1.48	1.95	<0.01
Current study	2005	1.68	1.36	2.06	<0.001
Multiparous Women					
Hefner et al.	2003	1.49	1.1	2.00	<.01
Current Study	2005	0.81	0.65	1.01	0.07

The Heffner team (2003) indicated they addressed interaction, but the results do not reflect inclusion of any interaction terms, suggesting that they did not find significant interaction. Because the researchers elected to stratify by parity, creating separate models for nulliparous and multiparous women, this may indicate they either suspected differences, or they found interaction with parity and induction of labor and elected to address the interaction by stratification and the creation of separate models for each cohort. The investigators also reported odds ratios across gestational ages and discuss the differences pointing out that odds are dependent on gestational age. The current study results found that the beta coefficients for the various gestational ages were statistically similar except for gestational ages 40 weeks or less compared to greater than 40 weeks and that interaction was present for induction of labor by gestation 40 weeks or less.

Once again, despite methodological differences, the Hefner et al. study results also align with the results in the currently reported study after addressing interaction within the context of the logistic regression model (with an increased odds ratio for nulliparous women of 1.68 (95% CI: 1.36, 2.06, $p < .001$). However, the multiparous results are very different given that induction of labor with multiparous women no longer reflected a significant impact in the reported study after taking into account all interaction terms ($p = .07$) in the current study. However, Hefner et al. reported significantly increased odds with induction of labor for multiparous women.

The differences in the Hefner et al. study and the currently reported study may be indicative of the lack of interaction terms. The fact that these researchers did not find significant interaction on terms other than perhaps parity could be driven by differences in the sample sizes with the Hefner et al. study having a smaller sample ($n = 14,409$) than the researcher's study sample of $n = 160,533$. Although 14,000 cases are not usually considered small, the researcher concludes that given the number of significant interaction terms in the current study (six interaction terms), a sample of 14,000 may not be sufficient to obtain significant interaction

effects. Given the very large sample size the researcher had relatively small differences were likely detected, yet the researcher concludes that some of the difference in the Hefner et al. study results and the current study may be indicative of the interaction. Hosmer and Lemeshow (2000) caution that failure to address interaction results in a lack of ability to accurately interpret the odds ratios in a model that does not include the interaction terms.

Another interesting aspect of the Hefner et al. study in light of the currently reported study was that the study results were from teaching institutions with clearly identified labor induction protocols, as with the Alexander et al. (2001) study. Additionally, the study strengths (as with Alexander et al.'s) included having used a clinically abstracted database collected by trained abstractors. The Hefner et al. labor induction protocol was distinctly different compared to the Parkland labor induction protocol. The Beth Israel Deaconess Medical Center and Brigham and Women's Hospital in Boston (as reported by Hefner et al.) indicated that their guidelines proscribe elective induction of labor before the 39th week, and they conclude that any induction of labor done prior to the 39th week within their study were likely to reflect medical necessity. Given this notation, the reader would assume that their protocol allows elective induction of labor post 39 weeks gestation. It is difficult to ascertain how the early induction of labor protocol or the failure to address the interaction by either stratification or other methods (for anything other than parity), might have impacted the differences found by the Hefner et al. study compared to the currently reported study.

In the 2001 Alexander et al. study, the researchers examined the effect of labor induction on primary cesarean delivery controlling for client characteristics of maternal age, race, parity, gestational age, cervical dilation, and epidural anesthesia. The findings from the reported study and the Alexander et al. study are also similar. The study findings indicated that induction of labor does not have an independent effect of increasing the odds of primary cesarean delivery

which corroborates with the finding of Alexander et al. (2001). Alexander et al.'s study found that an increased odds of primary cesarean delivery was attributable to client characteristics including nulliparity, gestational age, undilated cervix, and epidural anesthesia rather than induction of labor per se. The study findings comparing the Alexander et al. (2001) study and the current study findings are reflected in Table 75. The odds ratio for induction of labor in the Alexander et al. (2001) study indicated that the odds was 1.10 (95% CI: 0.90, 1.2). The confidence intervals for both studies, reflected in Table 76 contain 1.0, indicating there is no significant effect of labor induction on primary cesarean delivery once confounding client characteristics are taken into account. A difference between the current study and the Alexander et al. study is the researcher's identification of effect modification rather than confounding with several of the covariates identified as confounders in the Alexander et al. (2001) study (parity, race and ethnicity, and gestational age).

Table 76

Odds of Primary Cesarean Delivery Comparing Current Study to Alexander et al. (2001) Study

Study	Year	Overall Effect of labor induction			
		OR	95% Confidence Intervals		
			Lower	Upper	
Alexander et al.	2001	1.10	0.90	1.2	not significant
Current Study	2005	1.16	0.95	1.4	p=.15

Note. Neither study reports statistically significant results for induction of labor independently because the odds ratio confidence intervals contain 1.

Although the reported study could not control for undilated cervix and epidural anesthesia, due to the constraints of the data available (as was done with the Alexander et al. study and the Johnson et al. study), the researcher examined the effect of early gestation on

induction of labor and the odds of primary cesarean delivery. The researcher found that induction of labor at 40 weeks or less for nulliparous women significantly ($p < .001$) increased the odds of primary cesarean delivery by an odds of 1.575 (95% CI: 1.287; 1.928, $p < .001$) times that of nulliparous women 40 weeks or less that were not induced. However, given the overall effect induction of labor for nulliparous women was 1.68 (95% CI: 1.36, 2.06; $p < .001$) times that of nulliparous women that were not induced after controlling for the interaction effect of 40 weeks or less gestational age, the increased odds appear to be driven by nulliparity predominantly rather than gestation of less than 40 weeks gestation. This appears to be the case because there is not a statistical difference between the effect of nulliparity for 40 weeks or less and the effect of nulliparity after controlling for the interaction effect evidenced by the overlap in the 95% confidence intervals.

Alexander et al. (2001) indicated their research was limited by the size of the study population. Additionally, the study population was a homogenous population from one institution with a large proportion of Hispanics creating additional questions as the generalizability of the study beyond the study sample. Yet, as stated previously, the strengths of the Alexander et al. study are the controlled environment with specific protocols for induction of labor, as well as consistent practicing physicians within the hospital. The Alexander et al. study also used a clinically abstracted dataset collected by trained abstractors, as was the case with the Hefner et al. (2003) study and the Johnson et al. (2003) study. Given the current study findings substantiate the findings of the Alexander team's study results, the Johnson et al. and to a slightly lesser degree the Hefner et al. study results, the strengths of the combined studies provide compelling evidence that induction of labor increase the odds of primary cesarean delivery for nulliparous women. The combined study findings indicate that induction of labor increases the risk of primary cesarean delivery under certain conditions and that client characteristics should be taken into account when

considering a patient's risk for cesarean, particularly for nulliparous women. These findings align with the health outcomes model. The studies all substantiate that variables intrinsic to the patient rather than the intervention of labor induction acting alone, result in an increased primary cesarean delivery with induced deliveries for nulliparous women.

Conflicting Evidence

A recent study that presented conflicting evidence indicating that induction of labor may *reduce the risk* of cesarean delivery was the meta analysis done by Sanchez-Ramos et al. (2003) examining 16 randomized controlled trials. The Sanchez-Ramos et al. study refutes the causal relationship between induction of labor and cesarean birth for women whose gestational age exceeds 41 weeks, reporting that induction of labor was not associated with an increase in cesarean delivery. In fact, the study results indicate a protective effect for induction of labor with an odds ratio of 0.88 (95% CI: 0.78, 0.99). This analysis provides some evidence that induction of labor may not increase the odds of cesarean delivery rate. However, it is problematic in light of the study findings, because the current study findings are in conflict with the Sanchez-Ramos team's findings under certain client conditions, such as nulliparity.

The Sanchez-Ramos et al. (2003) researchers indicate their systematic review of randomized trials comparing labor induction with expectant management of labor (spontaneous labor) reflects a significantly decreased odds by approximately 12%. The current study findings are in conflict with the reported results of the Sanchez-Ramos team because the current study reports that induction of labor does not significantly impact primary cesarean delivery for women 41 to 42 weeks gestation, once confounders and effect modification are addressed within a logistic regression model. The Sanchez-Ramos et al. (2003) researchers reported having compared women allocated to expectant labor to those women who underwent labor induction.

They reported that labor induction decreased the odds of a cesarean delivery by 12% (OR 0.88, 95% CI: 0.78, 0.99).

The researcher suggests that a meta analysis comparing nulliparous women might be warranted to clarify the differences found by other researchers regarding the importance of parity. The researcher proposes that the Sanchez-Ramos et al. (2003) study results may be influenced by the interaction effect of parity. The findings of this study and other findings (Alexander et al., 2000, 2001; Dublin et al., 2000; Hefner et al., 2003; Johnson et al., 2003) have indicated that induced nulliparous women have increased odds of primary cesarean delivery when compared to induced multiparous women. In fact, the current findings reflect an odds ratio for multiparous women induced compared to women that were not induced of 0.86 (95% CI: .667, 1.13), but the effect is no longer significantly impacting the outcome of primary cesarean delivery ($p = 0.25$). It also is interesting to note that the current study results indicated that multiparous women comparing induced women to women that were not induced prior to 40 weeks gestation had a significantly decreased odds of primary cesarean by 1.24 times that of women that were not induced and 40 weeks gestation or less (OR .76; 95% CI .610, .945, $p = .01$). These findings are interestingly similar results to the Sanchez-Ramos team's results. Yet, the Sanchez-Ramos et al. (2003) study specifically examined post-term women (women who reach or exceeded 41 weeks gestation). Therefore, the Sanchez-Ramos et al. (2003) study results are troubling in light of the current study results because the findings appear to conflict. Certainly, the clinical approach of randomized trials would suggest more clinically credible data within the studies, but the researcher would question if there were enough combined cases to measure the effect, particularly in light of the interaction identified in the current study findings. The Sanchez-Ramos et al. meta-analysis had a total of 6,588 subjects enrolled in the 16 trials. The present researcher suggests this

is too few cases to adequately examine the issues, particularly given that several of the trials had very few cases.

This conflicting evidence is very important given that Sanchez-Ramos et al. (2003) concluded with a suggestion for a policy of labor induction at 41 weeks gestation for otherwise uncomplicated singleton pregnancies, indicating that the policy would reduce the cesarean delivery rate without compromising perinatal outcomes. This recommendation suggests a policy in contrast to the Alexander et al. (2000) recommendation that induction of labor intervention at 41 weeks gestation is unnecessary and results in an increased risk of cesarean. The current study findings would support Alexander et al.'s recommendation, rather than the Sanchez-Ramos et al. recommendation.

Implications

A clearer understanding of the effect of labor induction on the odds of primary cesarean delivery is important to clarify in light of the increasing induction of labor rates and primary cesarean delivery rates. Additionally, it is important to understand how the different effects of the various system and client characteristics impact the effect through either confounding or effect modification because the effect often depends on many factors. The predominant scientific evidence supported that induction of labor increases the odds of primary cesarean delivery particularly for nulliparous women. Yet, the Sanchez-Ramos et al. study presented enough evidence to potentially confuse the issue. The findings within the body of historical scientific evidence have not always made clear under what conditions induction of labor increases or reduces the odds of a primary cesarean delivery. This study provides a modeling method that allowed the researcher to compare and contrast numerous studies, given the researcher included all interaction and confounding variables and controlled for the effect with final model interpretation. Additionally, the robust sample size providing size and scope using secondary data

analysis provided sufficient power to identify significant effect modification that may provide some evidence of why study findings on the effect of labor induction on the odds of primary cesarean delivery conflict, such as with the various study findings on multiparous women.

A sample size adequate to identify the complex interrelationships between induction of labor on the odds of primary cesarean delivery, and client and system characteristics that modify or confound the relationship was an important aspect of the study. The synopsis of the literature in Appendix D demonstrates the various studies, some of which clearly examined interaction and some that did not report having done so often had sample size issues. The studies examined, with the exception of Hefner et al. (2003), Johnson et al. (2003), and Maslow and Sweeney (2000) did not clearly mention controlling for or examining effect modification or interaction. Note that two of the studies were more recent 2003 studies (Hefner et al. and Johnson et al.). However, several of the studies stratified by various factors. For example, Coonrad et al. (2000) made no mention of any methods they may have used to examine or control for interaction, yet draw conclusions that imply interaction with ethnicity and hospital ownership differences. Alexander et al., in their 2000 study, indicated that success of labor induction (vaginal delivery) increased as gestational age increased, suggesting that gestational age may be a proxy to readiness of the cervix and that across gestational ages there are differences in the effect of labor induction on primary cesarean delivery.

In light of the study findings and the findings of other studies that examined induction of labor on the odds of primary cesarean delivery, the researcher concludes that the findings within the various studies may have identified interaction with the various factors, but the researcher did not differentiate between a confounder and an effect modifier. Hosmer and Lemeshow's (2000) techniques for risk modeling clearly delineate differences in a variable that confounds a relationship and one that modifies the effect. With effect modification if a researcher or clinician

describes a certain variable as having an effect on a given relationship with “it depends,” then the variable is not considered a confounder but is considered instead an effect modifier in which interaction is occurring between the given variable and the relationship (Lemeshow, 2004).

The researcher concludes that much of the confusion reflected in the scientific literature regarding the effect of labor induction on the odds of primary cesarean delivery may be a reflection of failing to address interaction appropriately and sample size issues. Many of the studies report conflicting information regarding whether induction of labor increases the odds of primary cesarean delivery, such as the differences between the Sanchez-Ramos et al. (2003) study results and the Alexander et al. (2000, 2001) study results, and the Hefner et al. (2003) results on multiparous women.

Secondary Data Analysis

Data from hospital discharge records and birth certificates provided a large enough dataset to measure the effect of labor induction on the odds of primary cesarean delivery, controlling for client and system characteristics that modify or confound the effect. Using the cases with total agreement provided valid data that also appear to corroborate many studies that employed expensive methods to clinically abstract medical records. Given the number of studies which used clinically abstracted and expensive data collection methods that agreed with this researcher’s findings, including Alexander et al. (2001), Hefner et al. (2003), Johnson et al. (2003), the researcher concludes that one important implication of the study results is that secondary data analysis of cases with agreement on one or more data set can be used to cost effectively examine induction of labor on the odds of primary cesarean delivery. Had the results differed substantially from several of the clinically abstracted data studies, it might have called into question the validity of using hospital discharge data and birth certificate data to examine

obstetrical outcomes. But, in fact, the overwhelming evidence, particularly for nulliparous women, was substantiated.

Implications of Interaction Identified

Implications include evidence to indicate under what circumstances women having an induction of labor compared to women that do not have an induction of labor increase their odds of a cesarean delivery. This information is particularly useful given the recent bioethical position statement by ACOG that a woman has a right to elect a cesarean delivery. A woman that might not have “elected” a cesarean may not be aware that under certain circumstances she is increasing her odds of an operative delivery. The issue is one of informed consent. However, given the literature on the topic and the confusion within the body of scientific literature on the effect of labor induction on the odds of primary cesarean delivery, a practicing obstetrician would be correct in telling a woman that the scientific literature has been unclear on this issue. The researcher believes that the lack of clarity is based partly on the interaction evidenced within this study and the confusion in interpreting the scientific evidence in the face of the interaction. The prior studies using straight forward methods and failing to address the interaction or having too few cases to measure the interaction effect may have confused the issue. Alexander et al. (2001) study methods addressed two of the effect modifying client characteristics identified in this study (parity and gestation). Their findings indicated that the covariates rather than induction of labor independently increases the odds of a primary cesarean, which is essentially inferring similar findings, but not speaking specifically to the effect modification in terms of interaction.

Alexander’s team reported a 40% increase in the number of primary cesarean deliveries in induced women compared to women that went into spontaneous labor. However, this increase was attributed to client characteristics of nulliparity, gestational age, undilated cervix and epidural anesthesia rather than labor induction per se. The covariates were identified as confounders. In

their earlier study the researchers used stratification methods (Alexander et al., 2000) to isolate the effect of labor induction on the odds of primary cesarean delivery and to examine cesarean birth rates by cervical dilatation in women who entered spontaneous labor before induction of labor, compared with those who underwent induction of labor at 42 weeks gestation. This preliminary analysis was followed by analysis using logistic regression to control for population differences.

This lack of clarity on interaction may be a semantics issue, but it may lead other researchers to inappropriately interpret odds ratios from logistic regression if they fail to address interaction using logistic regression. Additionally, clinicians may misinterpret the findings without further clarity of the effect modification present between induction of labor and other conditions a woman may bring to the delivery. Hosmer and Lemeshow (2000) clearly differentiate the differences between confounding and interaction stating that interaction is not confounding, and that it is important to differentiate the difference because a researcher cannot interpret odds ratios and beta coefficients appropriately if the interaction is not identified and addressed with either stratification methods or appropriate logistic regression methods. This study contributes to a clearer understanding of the effect of labor induction on the odds of primary cesarean delivery with important implications. The interaction identified in this study impact two areas, the clinical implications and the methodological implications.

Clinical implications. The clinical implications for this study involve two areas: (a) implications for clinical decision making about induction of labor, and (b) implications for patient's relating to informed consent. With the controversy in the scientific literature surrounding induction of labor and the effect of labor induction on primary cesarean delivery, a practitioner may or may not inform a woman that under certain circumstances a decision to electively induce labor might significantly increase her odds of primary cesarean delivery. This

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5 FED. TAX NO.		6 ICD-9-CM PROCEDURE CODE		7 COV.D.	8 HC.D.	9 C.D.	10 L.R.D.	11	
12 PATIENT NAME				13 PATIENT ADDRESS					
14 BIRTH DATE	15 SEX	16 MS	21 D HR	22 STAT	23 MEDICAL RECORD NO.		31		
38									
a									
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42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATES	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49		
1							1		
2							2		
3							3		
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63 TREATMENT AUTHORIZATION CODES		64 ESC	65 EMPLOYER NAME		66 EMPLOYER LOCATION				
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I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

issue is particularly important in light of ACOG's recent bioethical position statement on a woman's right to elect to have a cesarean delivery. If a woman has the right to elect to cesarean, then she also has the right to be informed that a decision to induce (under certain circumstances) may increase her odds for a cesarean. She, in fact, may elect to be induced with the increased odds. However, it is important to inform a woman of what the ultimate implications for an elective procedure may be.

The study findings are important to these ethical issues with implications for medical decisions, because the findings indicate that a woman may not be fully knowledgeable of the implications when choosing an elective induction of labor because the literature has been unclear on when and under what conditions a decision to induce might increase the odds. However, with these study findings and the support of other study findings that indicate early induction of labor (≤ 40 weeks gestation) for nulliparous women increased the odds of a primary cesarean delivery by 1.58 times compared to nulliparous women delivering early that were not induced. Yet, if a nulliparous woman waits and is induced after 40 weeks, the odds of a primary cesarean delivery for an induced labor was 1.79 times that of a non-induced delivery. It is important to note that these odds are not statistically different when examining the 95% confidence intervals surrounding the two odds ratios (95% CI: 1.29, 1.93; 1.41, 2.27, respectively). However, knowing those odds, a nulliparous woman can make an informed decision regarding an elective induction of labor with the assistance of her physician regarding risk to her and the baby, and other factors that influence the decision. This study clearly indicated as have other studies (Alexander et al., 2001; Hefner et al., 2003; Johnson et al., 2003), that nulliparous women had an increased odds of a primary cesarean delivery. The issue of informed consent for multiparous women regarding the risk of primary cesarean with induction of labor has been particularly confusing, with some studies indicating multiparous women increased their odds of a primary cesarean (Hefner et al.,

2003) with an induction of labor and others (Dublin et al., 2000) indicating they do not. This researcher found that induction of labor for multiparous women no longer had a statistical impact on the odds of a primary cesarean delivery ($p > .05$). However, multiparous women induced at 40 weeks or less gestation had a protective effect reducing the odds by .76 times that of multiparous women 40 weeks or less that were not induced.

Nursing implications for the study findings relate to patient education, patient advocacy, and clinical practice. Perinatal educators often provide information and education to pregnant women that impact decisions regarding induction of labor. It is important that perinatal educators have correct information to advise patients during childbirth preparation classes. The evidence regarding the effect of induction of labor on the odds of a primary cesarean delivery has been in conflict. This study provides further evidence that will support perinatal educators appropriately informing women of their risk of primary cesarean delivery in the event the woman elects an induction of labor.

Nursing implications for clinical practice relate to the importance of evidenced based nursing practice. Nurses play an important role in obstetrics advising and educating patients on decisions regarding child birth preparation and advocating on behalf of women during the laboring process. Nurses are the direct care giver supporting laboring women and in that role have considerable autonomy (Cesario, 2004). Nurses often assist patients with decisions on such things as whether or not to elect to have an induction of labor or an augmentation of labor. Additionally, the obstetrical labor and delivery nurse is the primary decision maker in the bedside care of the laboring woman influencing the primary care provider in labor management decisions (Cesario, 2004). It is important that obstetrical nurses understand the scientific evidence related to inductions and primary cesarean delivery to properly support and advise patients and primary care providers. It is important that obstetrical nurses and obstetrical primary care providers

recognize that under certain circumstances relating to client or system characteristics women may have increased odds of a primary cesarean delivery with induction of labor.

There are many other factors that physicians, nurses and patients take into account when electing or advising an induction of labor, including things such as size of baby, cervical readiness, and patient issues such as family situations or distance from the hospital. This discussion is an over-simplification of complex clinical decision making and the patient's right to informed consent, but the example illustrates the potential clinical application for the study findings. Given the lack of clarity that characterizes the current literature, a physician may or may not be informing a woman that an elective induction of labor may increase the odds of a primary cesarean delivery.

Methodological implications. A major methodological implication of this study is the importance of the logistic regression methods suggested by Hosmer and Lemeshow (2000) and utilized in this study. The researcher believes that these methods and the large dataset provided the ability to adequately examine the effect of labor induction on the odds of primary cesarean delivery, in light of the effect modification and confounding identified. This section discusses methodological implications.

The decision of what variables to control for when examining the effect of labor induction on the odds of primary cesarean delivery is important; otherwise, a researcher may generate different findings based on the variables a researcher elects to control for within a logistic regression model. Hosmer and Lemeshow (2000) recommended a stepwise selection process, followed by backward elimination to confirm that order of entry did not impact the variables that enter the model. In fact, when the researcher performed the backward elimination, private payer no longer impacted the effect of labor induction on the odds of primary cesarean delivery and was eliminated from the model. Hosmer and Lemeshow caution that the stepwise

methods use statistical grounds for inclusion and researchers should take into account the clinical plausibility of the variables entering the model. Therefore, this process should not be generated by computer without a researcher judiciously controlling the steps.

Without methods suggested by Hosmer and Lemeshow (2000) and the large sample size ($n = 160,533$), interactions may not have been detected. These complex interrelationships are important to understand when examining the effect of labor induction on the odds of primary cesarean delivery, because the effect of labor induction on the odds of primary cesarean delivery depends on factors that are specific to client characteristics.

Historically, studies reporting effects of labor induction on the odds or risk of primary cesarean delivery may have been obscured by effect modification of multiple factors. Several studies identified the client characteristics as confounders. It may be that some of these studies did not differentiate between effect modification (interaction) and confounding. Several of the studies indicated that they tested interaction terms and found no significant interaction. The researcher believes that this may have been a reflection of sample size issues insufficient to measure the interaction effects. If there are clearly differences with the impact of labor induction on the odds of primary cesarean delivery across multiple strata, then the researcher (according to Hosmer & Lemeshow, 2000) should address the interaction term if it is significant at $p \leq .01$. Clearly, an important methodological implication is the needed sample size to measure significance of the interactions. Therefore, the two major methodological implications are: (a) studies examining induction of labor and primary cesarean delivery should anticipate interaction in multiple client characteristics, and (b) sample size considerations a priori should address interactions with induction of labor and the following terms: gestation, dystocia, parity, baby weight, race, and ethnicity. Studies that fail to address both of these issues run a risk of reporting odds ratios that have been influenced by interaction.

Recommendations for Further Study

After examining the data integrity of both data sources for agreement on induction of labor and primary cesarean delivery, the researcher elected to take a conservative approach to analysis and select cases with total agreement on the two key variables of interest. The researcher examined four preliminary models from the different data scenarios: (a) agreement on induction of labor by both data sources, (b) agreement on primary cesarean delivery, (c) agreement on induction of labor *or* primary cesarean delivery, and (d) agreement on *both* induction of labor *and* primary cesarean delivery. This preliminary analysis examined whether or not it made a difference in the study results depending on the data methods used for determining induction of labor and primary cesarean delivery. The findings indicated that deciding how to identify induction of labor and primary cesarean delivery may make a difference in risk modeling the effect of labor induction on the odds of primary cesarean delivery based on slight differences noted in the direction of some covariates. An example of one difference detected that might have impacted the overall results was the change in the direction of the beta coefficients for fetal distress and urban hospitals; however, this effect was a very small effect change on the crude modeling of labor induction on the odds of primary cesarean delivery. The present researcher believes that the overall differences in the methods were difficult to fully ascertain without complete modeling techniques on all four approaches. However, the researcher also believes that the total agreement approach was the most valid method to get to the effect of labor induction on the odds of primary cesarean delivery. Given that the study findings corroborate with other clinical studies (Alexander et al., 2000, 2001; Hefner et al., 2003), supports the researcher's decision regarding the correct methods to identify induction of labor and primary cesarean delivery.

This approach was supported by a study done by DiGiuseppe et al. (2001) to create models to risk adjust cesarean delivery rates. DiGiuseppe et al. used abstracted medical record data in comparison to birth certificate data, with DiGiuseppe's team determining that the data source does not make a significant difference in results for predictive risk modeling when testing the discrimination of each of the models against one another. However, their study indicated that the model with variables using only variables with better agreement ($> .60$ Kappa Scores) reflected results more in line with the abstracted medical records model. The researcher's findings aligned with several clinical studies (Alexander et al., 2001; Hefner et al., 2003, Johnson et al., 2003) that utilized clinically abstracted data from medical records, suggesting that the total agreement method for identifying induction of labor and primary cesarean delivery is an effective alternative to expensive abstraction data collection methods.

The researcher suggests a follow-up study testing all four data selection approaches with the full modeling approach recommended by Hosmer and Lemeshow (2000) to control for confounding and effect modification. The researcher acknowledges that to fully test the hypothesis of no difference in the model results a follow-up study is warranted. This is an important follow-up study because many studies do not have both data sources available to validate the correct identification of labor induction and primary cesarean delivery. Additionally, in the United States vital statistics are based on birth certificate data and many national studies are based on the National Inpatient Hospital Sample. Therefore, studies to substantiate the validity of using one data source or the other to examine outcomes is an important follow-up study.

State and National Studies

Currently, Texas does not have readily available merged data on birth certificate and hospital discharge data for use by researchers. However, pending legislative changes may improve the ability for researchers to obtain this dataset for the entire state. The researcher

recommends that in the event the entire state of Texas' combined dataset of birth certificate data merged with hospital discharge data becomes available, the study findings should be corroborated with a sample from the larger Texas database, given that the data were isolated to a region within Texas, may have some regional practice bias that impacted the study findings. It also follows that this study should be done in states other than Texas or with a national dataset to substantiate findings. However, currently there is not a dataset available with national hospital discharge data merged with birth certificate data. Substantiating study findings with other regions of the nation is particularly important for obstetrical outcomes given regional trends in obstetrical outcomes may be different.

Use of the Health Outcomes Model

The reported study was an example of how the Health Outcomes model can be applied to practical research to examining healthcare outcomes. This application has implications for other studies particularly given that most if not all outcomes measured have complex confounding and effect modification that a researcher might anticipate; an example of other studies where both the methods and application of this model might be applied would be surgical site infections. There are many complex relationships impacting surgical site infections just as there were with the examination of labor induction and primary cesarean delivery, including both client and system characteristics that confound the measurement of accurate surgical site infections. The practical application of this model to assist researchers in evaluating outcomes for obstetrical outcomes, as well as other healthcare outcomes, is important to consider for future studies examining healthcare outcomes and interventions which may positively impact the outcomes.

Three- and Four-way Interaction

This researcher did not address potential three-way and four-way interactions. Addressing three-way and four-way interaction is suggested as further follow-up to this study

with methodological research to expand the modeling and interpretation methods to include potential three- and four-way interactions. Given the two-way interaction revealed in this study, and other studies that isolated with exclusion criteria more than one factor, significant three- and four-way interaction may be present with induction of labor and dystocia, race and ethnicity, parity, baby weight, and gestation. Methods described by Lemeshow (2004) do not address three- and four-way interaction and would require special work with Lemeshow and his biostatistics team, or other researchers with expertise in addressing three- and four-way interaction.

The confounding of the covariates within this study design warrant further investigation. It is likely that some of the client and system characteristics were confounding one another. The researcher expects that private payer did not enter the model because other variables within the study population explained the payer differences, such as race and ethnicity and the teaching status. It is likely that a large proportion of the indigent are isolated to the teaching institutions within this region. Additionally, hospital ownership suggests a similar scenario. The public hospitals also are typically the teaching institutions. Therefore, the teaching effect was so strong within the study that it explained all the variance that may otherwise have been explained by the other hospital characteristics such as ownership and private payer. These confounding relationships warrant further investigation in subsequent studies, as these characteristics may have access to care implications.

This study excluded cases that were questionably an induction of labor or primary cesarean delivery by using cases with total agreement on both the birth certificate and the hospital discharge data. This exclusion appeared to eliminate cases with premature rupture of membranes. The Johnson et al. (2003) study had inclusion criteria which included the cases with premature rupture of membranes in the spontaneous labor group, yet some consider these cases an induction of labor when the woman fails to progress. The ambiguity of these cases, which may relate to the

debate on the definition of spontaneous onset of labor, warrants investigation. This subset of cases can be identified in coding data and to examine the odds of primary cesarean delivery and any effect the designation of “induction of labor” may have had on the overall odds of primary cesarean delivery. In this case, the researcher believes it is likely that with this unique subset of cases induction of labor is likely to have a protective effect.

Patient Safety and Neonatal Outcome Studies

Neonatal outcomes were not included in the study. A recommended follow-up to this study is to match the neonatal record with the mother’s obstetrical delivery record with similar methods for matching described in this study. The effect of labor induction on neonatal outcomes should be examined, controlling for primary cesarean delivery to determine if, in fact, we are protecting the neonate with the primary cesarean delivery. The elective induction of labor may be precipitating further neonatal and obstetrical problems. Therefore, the researcher recommends including the medical indication for induction within the study design to control for elective induction of labor compared to induction of labor with a medical indication for induction.

A study examining obstetrical patient safety issues also should be done to determine if the increases in labor induction rates are precipitating additional obstetrical problems. The Agency for Healthcare Research and Quality (2002) recently has released the AHRQ Patient Safety Indicators. The indicators include seven measures addressing obstetrical delivery including: (a) cases of birth trauma, injury to neonate, per 1,000 liveborn births; (b) cases of obstetric trauma (4th degree lacerations, other obstetric lacerations) per 1,000 instrument-assisted vaginal deliveries; (c) cases of obstetric trauma (4th degree lacerations, other obstetric lacerations) per 1,000 vaginal deliveries without instrument assistance; (d) cases of obstetric trauma (4th degree lacerations, other obstetric lacerations) per 1,000 Cesarean deliveries; (e) cases of obstetric trauma (3rd and 4th degree lacerations, other obstetric lacerations) per 1,000

instrument-assisted vaginal deliveries; (f) cases of obstetric trauma (3rd and 4th degree lacerations, other obstetric lacerations) per 1,000 vaginal deliveries without instrument assistance; (g) cases of obstetric trauma (3rd and 4th degree lacerations, other obstetric lacerations) per 1,000 Cesarean deliveries (AHRQ, 2005, pp. 21-22).

Economic Impact Studies

With the importance of controlling healthcare costs in the United States, the Maslow and Sweeney's (2000) findings provided evidence indicating that there may be an economic impact to elective induction of labor. The present researcher suggests that economic impact of protocols evaluating early induction of labor compared to later induction of labor, as well as, spontaneous labor compared to induction of labor should be further explored in future studies. Given the purpose of this study was not to examine economic impact, the researcher suggests that further analysis should be done examining the cost of electing an induction of labor.

Expanded Dataset with Clinical Data

The prospective study done by Xenakis et al. (1997) investigated 597 women with maternal or fetal indications for induction assessing the success rates and labor characteristics associated with induced labor using an integrative protocol for labor induction including: prostaglandin use, amniotomy, and oxytocin. Success was defined as a successful vaginal delivery versus a failed induction resulting in a cesarean delivery. In this prospective study, patients were categorized into three groups at admission, according to the woman's cervical findings on pelvic exam using the Bishop scores (Xenakis et al., 1997). Bishop scores are calculated based on criteria for dilatation of the cervix, effacement, station of the fetus, consistency of the cervix, and position of the fetal head. These factors determine a score that indicates how ready the woman is for spontaneous onset of labor (Bishop, 1964). In the Xenakis et al. (1997), the Bishop score groupings were 0-3, 4-6, and > 7. Cervical priming with

prostaglandin 2 (PGE₂) was done when Bishop scores were under 7, oxytocin was begun with a Bishop score of 7, and amniotomy done as soon as feasible. The study outcomes examined included: prostaglandin priming duration, time from oxytocin to 4 cm dilation, time from 4 cm dilation to active labor, and from complete dilation to delivery.

The present researcher recommends expanding the current study to examine the added clinical data that would include Bishop score criteria for dilatation of the cervix, effacement, station of the fetus, consistency of the cervix, and position of the fetal head. One of the assumptions by the researcher was that increases in early induction of labor may be precipitating the increase in primary cesarean delivery. However, this assumption was not validated with hypothesis testing. If cervical readiness could have been identified and controlled for by using the Bishop score criteria within the study design, the researcher believes that the early inductions with unfavorable Bishop scores would have significantly increased the odds of primary cesarean delivery compared to women induced early with favorable Bishop scores.

Limitations to the Research Study

In recommending further study, the researcher identified some of the barriers and limitations to this study in light of the results and recommendations. Exclusions of repeat cesarean deliveries introduced a systematic bias with multiparous women in the study. Because the study excluded repeat cesareans, there was a study design bias created by this exclusion. Additionally, during the 4-year study period it is likely that some of the multiparous women included in the study had delivered one or more successful deliveries vaginally; therefore, these women would have had more than one delivery potentially represented in the sample. These deliveries represent a bias in the direction of multiparous women and successful vaginal delivery. It is unknown to what degree this might have impacted the study results and other studies with multiparous women reviewed in the literature review. Of all the studies reviewed, Alexander et

al. (2000) was the only study that addressed this potential bias. Alexander et al. selected a random sample from the repeat multiparous deliveries. In the reported study, the present researcher could not have controlled for this limitation without impacting the DFWHC methods for matching and preparing data for analysis. Since the data were masked for confidentiality prior to delivery to the researcher, the only way the multiple deliveries could be identified is with the DFWHC creating a variable to indicate multiple births by each women (for example, birth 1, birth 2, etc.). This requirement would have created an additional requirement for the DFWHC to match more than one birth episode in the study period by one woman. For future studies controlling for parity, the researcher recommends addressing this issue with the same approach deployed by Alexander et al. (2001). Additionally, researchers that can control the matching criteria might consider including criteria to match multiple births for multiparous women to identify those women who had more than one delivery represented in the data.

An additional bias introduced with the inclusion of multiparous women and the exclusion of prior history of cesarean delivery introduces a multifactorial issue with the relationship of parity, induction of labor, and primary cesarean delivery. Figure 35 illustrates an inherent potential bias towards multiparous women having a successful induction of labor (meaning vaginal delivery) when isolating the primary cesarean population. The bias relates to the exclusion of all women with a prior cesarean delivery. By excluding women with a prior cesarean delivery, the only multiparous women remaining in the study population are women who are likely to be predisposed to a successful vaginal delivery because these women have successfully delivered one or more pregnancies vaginally before the current delivery. This is inherent in the very nature of a multiparous woman that has not had a previous cesarean delivery.

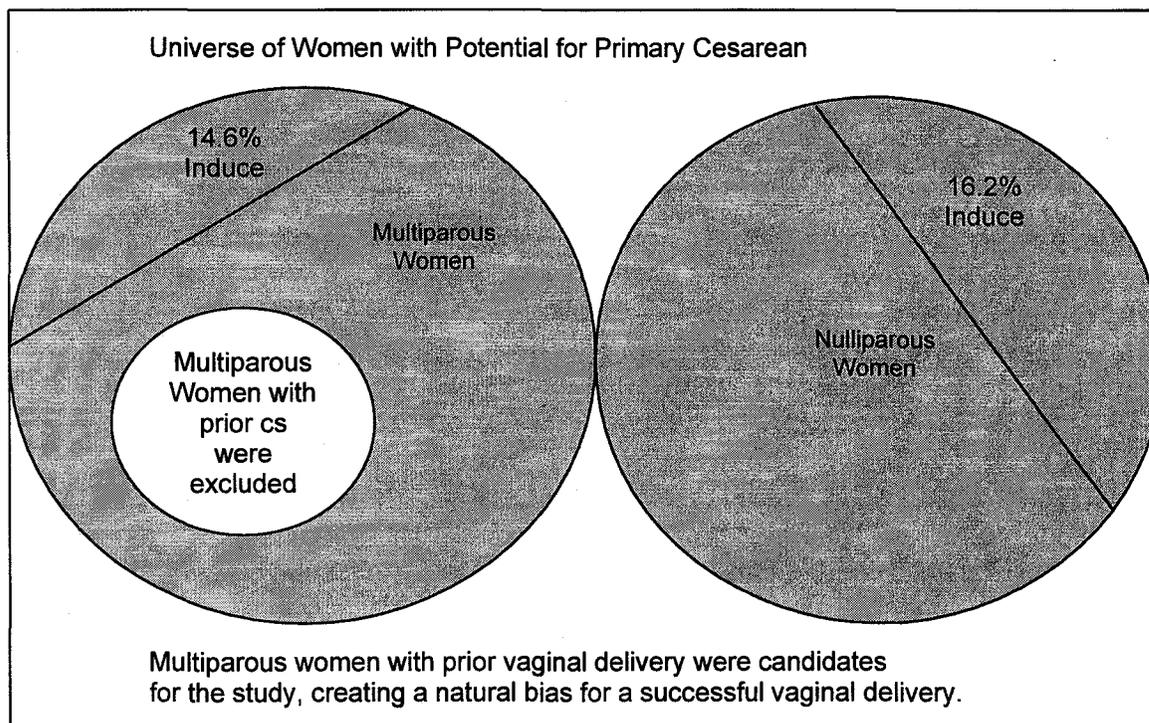


Figure 35. Inherent bias with multifactorial relationship of labor induction, parity and primary cesarean delivery.

Note. Gray area denotes the universe of women with potential for primary cesarean delivery.

One of the most important limitations to the study was the ability to access clinical data that influence the effect of labor induction on the odds of primary cesarean delivery. Two important variables that this study failed to address due to the limitations of the data are epidural anesthesia and cervical readiness measured by the Bishop score. Cervical readiness is an important factor reflecting success of labor induction. Studies (Alexander et al., 2000, 2001; Johnson et al., 2003) have indicated the importance of cervical readiness and timing on epidural anesthesia for examining induction of labor and primary cesarean delivery. One assumption made via the study findings was that early induction of labor was an adequate marker for cervical readiness. This assumption may have been weak and subsequent studies are needed to validate

whether or not this assumption was accurate. It is likely that the early induction of labor could have been biased with a high proportion of women that had cervixes ripe for induction of labor, or that the use of cervical ripening agents may improve the success of labor inductions. Without the cervical status, the researcher could not control for what the effect of labor induction would be with and without cervical readiness for labor.

However, the Johnson et al. (2003) study did look at the cervical readiness, defined as greater than or equal to 5 cm dilatation. The Johnson et al. (2003) study examined the effect of labor induction on the risk of primary cesarean delivery with stratification by cervical readiness or no cervical readiness (< 5 cm dilatation). Their study results for the effect of labor induction on the risk of primary cesarean delivery for nulliparous women aligned with the results on the researchers findings with the risk of primary cesarean delivery of 1.77 (95% CI: 1.46, 2.11) and 1.55 (95% CI: 1.31, 1.83), respectively. The researcher suspects that if the cervical readiness data were available the findings would further align with the Johnson et al. (2003) study to indicate that lack of cervical readiness increases the risk of primary cesarean delivery by two-fold (RR 3.0; 95% CI: 2.38, 3.73).

Using electronic data sources in retrospective analysis prevents randomization, and as such cannot be used to confirm causal connection between exposure (induction of labor) and outcome (primary cesarean delivery). However, given that many of the randomized clinical trials cited in the Sanchez-Ramos et al. meta-analysis did not have adequate sample size to control for interaction and the individual studies were limited in their ability to control for multiple covariates that influence the effect of labor induction on primary cesarean delivery, the combination of clinical studies such as Alexander et al. (2000; 2001), Johnson et al. (2003), and Hefner et al. (2003) create compelling supporting evidence that nulliparity significantly influences an increased odds of primary cesarean delivery as does increasing gestational ages.

Summary

In summary, this study helps to clarify the effect of labor induction on the odds of primary cesarean delivery. It is important to better understand how induction of labor may be increasing the primary cesarean delivery rates. It also is important to understand whether the increased cesareans provide better or worse outcomes for the mother and baby. With a better understanding of the effect of labor induction on primary cesarean delivery a next step is to qualify whether or not the increased labor inductions are safe for both the mother and the baby to assist with addressing safe effective obstetrical deliveries. This study provides a foundation upon which future studies can utilize similar methods to examine patient safety indicators for the neonate and the mother to determine how the increases in labor inductions may be impacting outcomes and whether or not the increased odds of a primary cesarean delivery has a positive or negative effect on other measures of quality (such as neonatal mortality and the obstetrical AHRQ Patient Safety Indicators). This study provides evidence that under certain circumstances induction of labor increases the odds of a primary cesarean delivery, but the study does not examine what the effect may be on the neonate, and other outcomes relating to safe delivery (such as third and fourth degree tears).

The two IOM reports calling for immediate action to fundamentally change the United States healthcare delivery system in order to address patient safety and quality concerns indicate the complexities inherent in the delivery system precipitate many of the patient safety issues that arise (Kohn et al., 2000). Labor management and the multifactorial relationships affecting a safe delivery for the mother and neonate are important to understand in order to determine when and what may be the best mode of delivery for the mother and neonate. The study done by Gould et al. (2004) indicates that neonatal morbidity increases in neonates born of low-risk women who deliver in either low cesarean rate hospitals or high rate for cesarean hospitals. These researchers

encourage further studies to develop methods to adjust for the complexities inherent in obstetrical delivery to assess quality of care in the hospitals that could impact the outcome, such as examination of intrapartum care.

The researcher's methods and modified Quality Health Outcomes model utilized in this study provide a foundation to address practice pattern variation (intervention), the hospital's contribution (system characteristics), and to control for maternal and neonatal risk (client characteristics). The logistic regression analysis methods could be utilized to further examine the effect of labor induction on both the maternal and neonatal outcome adjusting for differences of the client and hospital, potentially including such things as intrapartum care differences. Further studies are important to fully understand what constitutes quality of care as it relates to the effect of labor induction on the delivery outcome, as well as other variables that influence the outcome.

The study has bioethical implications relating to informed consent, because it is important for women to recognize that nulliparous women have an increased odds of primary cesarean after induction of labor and an elected induction of labor may increase the odds of a primary cesarean delivery. This study, combined with evidence from clinical studies, may assist clinicians in protocol development or practice decision making, recognizing that under certain circumstances odds of a cesarean delivery are increased.

Additionally, this study utilized administrative data in lieu of an expensive process of abstracting clinical data. Secondary data analysis of readily available electronic data has provided a cost efficient method for this study. The combined data set of hospital discharge data, birth certificate data, AHA survey data and DFWHC NICU Survey data (2002), although challenging to use, have implications for future research in obstetrical outcomes.

One additional finding of this study that is important to note was the agreement analysis. Secondary data may have data integrity issues that can be resolved with more than one source of

information to validate the data. This study utilized cases with both data sources (hospital discharge data and birth certificate data) in agreement on whether an induction of labor and primary cesarean delivery was done. With total agreement the findings of the study align with several studies utilizing expensive abstraction methods to obtain clinical data (Alexander et al., 2001; Johnson et al., 2003; Maslow & Sweeney, 2000; Seyb et al., 1999). These readily available electronic data sources, combined with methods developed by AHRQ to examine obstetrical patient safety, provide a cost-effective method to further investigate obstetrical outcomes using large databases to control for the complex relationships inherent in obstetrical delivery.

Secondary data analysis of administrative data provided an advantage of having a large volume of demographically diverse cases thus addressing issues of generalizability and sample size limitations which have hampered other studies on obstetrical outcomes (Alexander et al., 1999, 2001; Maslow & Sweeney, 2000; Rogers et al., 1997; Seyb et al., 1999). This study supported the use of secondary data analysis as a viable and advantageous alternative, providing a heterogeneous and large sample of cases at a lower cost for analysis of obstetrical outcomes to assist with providing a better understanding of how induction of labor effects the odds of primary cesarean delivery.

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Appendix A

Correspondence from the Center for Disease Control National

Center for Health Statistics Issuing Approval to

Use Figure 2

**Correspondence from the Center for Disease Control National Center for Health Statistics
Issuing Approval to Use Figure 2**

As all of the information we provide is public information you may freely use our figures and data. It would be appreciated if you would include a small reference that you obtained the data through our organization. Thank you.

-----Original Message-----

From: Moore, Ericka Y. On Behalf Of NCHS QUERY
Sent: Thursday, January 08, 2004 2:55 PM
To: NCHSED
Subject: FW: Data posted to form 1 of
<http://www.cdc.gov/nchs/mail/mail.htm>

-----Original Message-----

From: [REDACTED]
Sent: Thursday, January 08, 2004 11:50 AM
To: NCHS QUERY
Subject: Data posted to form 1 of <http://www.cdc.gov/nchs/mail/mail.htm>

name: Susan McBride
title: Vice President
organization: Dallas Fort Worth Hospital Council
phone: [REDACTED]
email:
Remote Name: [REDACTED]

address:

[REDACTED]
Irving Tx 75062

comments:

Dear CDC National Vital Statistics Staff,

My name is Susan McBride. I am a graduate student at Texas Woman's University and am currently writing my dissertation for a doctoral degree in nursing. I am writing you to request permission to place a copy of Figure 5, (Rates of induction of labor by length of gestation in weeks: United States, 1989-2000) contained in Martin, J., Hamilton, B., Ventura, S., Menacher, F. and Park, M., Births: Final data for 2000. National vital statistics reports: Vol 50 No. 5. Hyattsville, Maryland: 1-101, into my dissertation.

I am examining the effect of inductions on primary cesarean delivery in my dissertation. The figure will only be used for the purpose of my dissertation work. Thank you for your assistance with this issue. I look forward to hearing back from you.

Sincerely,
Susan McBride, RN, MS, PhD(C)

Appendix B

Permission to Use Health Outcome Model

**Permission from Sigma Theta Tau International to Use
Health Outcomes Model**

Please consider this our permission you use our copyrighted material (figure 2, Quality Health Outcomes Model, referenced in your request) in your dissertation. No substantive changes to the material may be made without written permission from the authors.

Melody Jones
Editorial Assistant
Journal of Nursing Scholarship
Sigma Theta Tau International
550 W. North Street
Indianapolis, IN 46202



-----Original Message-----

From: Susan McBride [REDACTED]
Sent: Monday, January 12, 2004 5:12 PM
To: Melody Jones
Subject: Fwd: Re: Permission to use model

JNS Publication Office
Sigma Theta Tau International
550 West North
Indianapolis, IN 46202

Dear Sir or Madam:

My name is Susan McBride. I am a graduate student at Texas Woman's University and am currently writing my dissertation. I am writing you to request permission to place a copy of Figure 2 in Mitchell, Ferketich, and Jennings article published in the first quarter of 1998. I am using the Quality Health Outcomes Model as the conceptual framework and would request that I be able to copy the Quality Health Outcomes Model figure to illustrate the model in my dissertation. The figure will only be used for the purpose of my dissertation work. I have

already requested and received permission from Pamela Mitchell and colleagues as the primary author and have attached the email documenting her consent. Thank you for your help with this issue. I look forward to hearing back from you.

Sincerely,

Susan McBride, RN, MS, PhD (C)

[REDACTED]
[REDACTED]

Permissions from Mitchell on behalf of Mitchell, Ferkitich & Jennings
To use the Health Outcomes Model

Dear Ms. McBride:

On behalf of my colleagues, I am pleased that you are finding the Quality Health Outcomes Model useful. The copyright for the figure as it appears in Image is held by Sigma Theta Tau International. You may forward this email as verification that the authors are supportive of your request to reproduce the figure.

Send your request for permission to Melody Jones via email:

[REDACTED]

Best wishes in your study.

Pam Mitchell

Pamela H. Mitchell, Elizabeth S. Soule Professor,
Associate Dean for Research, School of Nursing, &
Adjunct Professor, Department of Health Services, SPHCM
Director, Center for Health Sciences Interprofessional Education
Box 357265, University of Washington
[REDACTED]

On Fri, 9 Jan 2004, Susan McBride wrote:

Dr. Mitchell,
I am a doctoral student at Texas Woman's University and am in the process of dissertation. My research is on examining the effect of inductions on primary cesarean delivery using a 4 year data set of 41 hospitals in Texas (approximately 250,000 cases) of merged hospital discharge data, birth certificate data and AHA survey data. I am using the Quality Health Outcomes Model as the conceptual framework for my study and would like to request that I be able to copy the

Quality Health Outcomes Model figure to illustrate the model in my dissertation published in the following article:

Mitchell, P., Ferketich, S., & Jennings, B. (1998). Quality health outcomes model. *Image Journal of Nursing Scholarship*, 30 (1), 43-46.

I have been in healthcare outcomes management for over a decade and believe your model is excellent for examining clinical issues in healthcare. I would appreciate your approval to utilize your diagram for my study.

Sincerely,

Susan McBride, RN, MS
VP of the DFW Hospital Council Data Initiative

Appendix C

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk

Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress

Risk Factor with ICD-9-CM Codes Detailed Definitions

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

MeasId	MeasName	Diagn/Proc	Definition	Fifth Digit Meaning	Source	Values	High Risk for CS Factor	Medical Indication for Induction	Dystocia Failure to Progress	Fetal Distress
AbnUtCer	Abnormalities of the uterus and cervix	654.31-654.32, 654.41-654.42, 654.61-654.62, 654.71-654.72, 654.81-654.82, 654.91-654.92								
		654.31	Retroverted & incarcerated gravid uterus	delivered with or without mention of antepartum complication						
		654.32	Retroverted & incarcerated gravid uterus	delivered with mention of postpartum complications						
		654.41	Other abnormalites in shape or position of gravid uterus & of neighboring structures (Cystocele, pelvic floor repair, pendulous abdomen, prolapse of gravid uterus, rectocele, rigid pelvic floor)	delivered with or without mention of antepartum complication						
		654.42	Other abnormalites in shape or position of gravid uterus & of neighboring structures (Cystocele, pelvic floor repair, pendulous abdomen, prolapse of gravid uterus, rectocele, rigid pelvic floor)	delivered with mention of postpartum complications						
		654.61	Other congenital or acquired abnormalities of cervix	delivered with or without mention of antepartum complication						
		654.62	Other congenital or acquired abnormalities of cervix	delivered with mention of postpartum complications						
		654.71	Congenital or acquired abnormality of vagina (previous surgery to vagina, septate vagina, stenosis of vagina, stricture of vagina, tumor of vagina)	delivered with or without mention of antepartum complication						
		654.72	Congenital or acquired abnormality of vagina (previous surgery to vagina, septate vagina, stenosis of vagina, stricture of vagina, tumor of vagina)	delivered with mention of postpartum complications						
		654.81	Congenital or acquired abnormality of vulva (fibrosis of perineum, persistent hymen, previous surgery to perineum or vulva, rigid perineum, tumor of vulva)	delivered with or without mention of antepartum complication						

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

Measur	MeasName	Diag/Proc	Definition	Final Digit Meaning	Source	Y-axis	High Risk for CS Factor	Medical Indications for Induction	Desirable Failure to Progress	Fetal Distress
		654.82	Congenital or acquired abnormality of vulva (fibrosis of perineum, persistent hymen, previous surgery to perineum or vulva, rigid perineum, tumor of vulva)	delivered with mention of postpartum complications delivered with or without mention of ante partum complication						
		654.91	Other and unspecified uterine scar							
		654.92	Other and unspecified uterine scar							
		641.21	Premature separation of placenta (ablatio placentae, abruptio placentae, accidental ante partum hemorrhage, couvelaire uterus, detachment of placenta (premature), premature separation of normally implanted placenta)	delivered with or without mention of ante partum complication	DX	0,1	X			
Abruptio	Placenta abruptio	641.21								
AntiHemOB	Placental hemorrhages; hemorrhage w/coag defects	641.31, 641.81, 641.91			DX	0,1	X			
		641.31	Ante partum hemorrhage associated with coagulation defects (ante partum or intrapartum hemorrhage associated with: fibrinogenemia, hyperfibrinolysis, hypofibrinogenemia)	delivered with or without mention of ante partum complication						
		641.81	Other ante partum hemorrhage (hemorrhage: ante partum NOS, intrapartum NOS, of pregnancy NON)	delivered with or without mention of ante partum complication						
		641.91	Unspecified ante partum hemorrhage (hemorrhage: ante partum NOS, intrapartum NOS, of pregnancy NON)	delivered with or without mention of ante partum complication						
UnstaleLie	Unstable Lie of Fetus	652.01	Unstable Lie	Delivered	DX	0,1	X			
BreechOB	Breech presentation without version	652.21	Breech Presentation without mention of version (breech delivery (assisted) (spontaneous) NOS, buttocks presentation, complete breech, frank breech)	delivered with or without mention of ante partum complication	DX	0,1	X			
CPDbonpe	Disproportion or obstruction/abnormality of bony pelvis, fetal and outlet contraction	653.11, 653.21, 653.31, 653.01, 660.11	Disproportion In Pregnancy, Labor, And Delivery for obstruction of bony pelvis	Delivered	DX	0,1	X			

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

MeasId	MeasName	Diagn/Prnc	Definition	Fifth Digit Meaning	Source	Values	High Risk for CS Factor	Medical Indication for Induction	Dystocia Failure to Progress	Fetal Distress
		653.01	Major Abnormality Of Bony Pelvis, Not Further Specified	Delivered						
		653.11	Generally Contracted Pelvis In Pregnancy, Labor, And Delivery	Delivered						
		653.21	Contracted pelvis NOS	Delivered						
		653.21	Inlet Contraction Of Pelvis In Pregnancy, Labor, And Delivery Inlet contraction (pelvis)	Delivered						
		653.31	Outlet Contraction Of Pelvis In Pregnancy, Labor, And Delivery Inlet contraction (pelvis)	Delivered						
		660.11	Obstruction By Bony Pelvis During Labor	Delivered						
Previa	Placenta previa w and w/o hemorrhage	641.01, 641.11			DX	0,1	X			
		641.01	Placenta Previa Without Hemorrhage (Low implantation of placenta) (Placenta previa noted: during pregnancy, before labor (and delivered by cesarean delivery)) without hemorrhage	Delivered						
		641.11	Hemorrhage From Placenta Previa (Low-lying placenta) (Placenta previa: incomplete, marginal, partial, total) NOS or with hemorrhage (intrapartum)	Delivered						
PriorCSOB	History of prior cesarean	654.20-654.23			DX	0,1	X			
		654.20	Previous Cesarean Delivery Complicating Pregnancy, Childbirth, Or The Puerperium	Unspecified As To Episode Of Care						
		654.21	Uterine scar from previous cesarean delivery	Delivered						
CHFOB	Congestive Heart Failure	428-428.9			DX	0,1	X			
		428	Congestive Heart Failure, Congestive heart disease, Right heart failure (secondary to left heart failure)	Unspecified						
		428.1	Left Heart Failure (Acute edema of lung) (Acute pulmonary edema) with heart disease NOS or heart failure; Cardiac asthma; Left ventricular failure							
		428.2	Systolic Heart Failure							
		428.3	Diastolic Heart Failure							

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

MeasID	MeasName	Diagn/Proc	Definition	Fifth Digit Meaning	Source	Value	High Risk (or CS) Factor	Medical Indication for Induction	Dystocia Failure to Progress	Fetal Distress
		428.4	Combined Systolic and Diastolic Heart Failure 428.9 Heart Failure, Unspecified Cardiac failure NOS; Heart failure NOS; Myocardial failure NOS; Weak heart							
		428.9	Heart Failure, Unspecified Cardiac failure NOS; Heart failure NOS; Myocardial failure NOS; Weak heart							
CngUIAb	Congenital abnormalities of the uterus	654.01-654.02			DX	0,1	X			
		654.01	Congenital abnormalities of uterus (double uterus & uterus bicornis)	delivered with or without mention of antepartum complication						
		654.02	Congenital abnormalities of uterus (double uterus & uterus bicornis)	delivered with mention of postpartum complications						
DelayTwnOB	Delayed delivery of 2nd twin, triplet, etc.	662.31	Delayed delivery of second twin, triplet, etc.	delivered with or without mention of antepartum complication	DX	0,1	X			
DispropOB	Fetal abnormalities causing disproportion	653.61, 653.71			DX	0,1	X			
		653.61	Hydrocephalic Fetus Causing Disproportion	Delivered						
		653.71	Other Fetal Abnormality Causing Disproportion Conjoined twins, Fetal: ascites, hydrops, myelomeningocele, sacral teratoma, tumor	Delivered						
EarlyDelOB	Delivery before 37 weeks gestation	644.21	Early Onset Of Delivery before 37 weeks of gestation	Delivered, With Or Without Mention Of Antepartum Condition	DX	0,1	X			
TransvseOB	Transverse or oblique lie	652.31	Transverse or Oblique Presentation, Oblique Lie, Transverse Lie	Delivered	DX	0,1	X			
FaceBrowOB	Face or brow presentation of fetus	652.41	Face Or Brow Presentation Of Fetus Mentum presentation	Delivered	DX	0,1	X			
FetDeathOB	Fetal or intrauterine death	656.41	Intrauterine Death Affecting Management Of Mother Fetal death: NOS, after completion of 22 weeks' gestation, late; Missed delivery	Delivered	DX	0,1	X			
FetMalpOB	Obstruction caused by malposition of fetus	660.01	Obstruction Caused By Malposition Of Fetus At Onset Of Labor Any condition classifiable to 652 causing obstruction during labor	Delivered	DX	0,1	X			

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

Maternal	MeasName	Diagnoses	Definition	Fifth Digit Meaning	Source	Values	High Risk In CS Factor	Medical Indications for Induction	Dystocia Failure to Progress	Fetal Distress
FIMHemOB	Fetal maternal hemorrhage	656.01	Fetal-maternal Hemorrhage Affecting Management Of Mother	Delivered	DX	0.1	X			
HerpesOB	Genital herpes	054.10-054.12	Leakage (microscopic) of fetal blood into maternal circulation	Delivered	DX	0.1	X			
		054.10	Genital Herpes Unspecified							
		054.11	Genital Herpes Vulvovaginitis							
		054.12	Herpetic Ulceration Of Vul							
IncCervix	Cervical incompetence (presence of Shirodkar suture)	654.51-654.52	Herpetic Ulceration Of Vul		DX	0.1	X			
		654.51	Cervical Incompetence Complicating Pregnancy, Childbirth, Or The Puerperium	With Delivery With Mention Of Postpartum Complication						
		654.52	Presence of Shirodkar suture with or without mention of cervical incompetence	With Delivery With Mention Of Postpartum Complication						
LockedTwoOB	Locked Twins	660.51	Locked Twins	With Delivery	DX	0.1	X			
MalPosOB	Prolapsed arm; other malposition / malpresentation	652.71, 652.81, 652.91	Locked Twins		DX	0.1	X			
		652.71	Prolapsed Arm Of Fetus	Delivered						
		652.81	Other Specified Malposition Or Malpresentation Of Fetus	Delivered						
		952.91	Compound presentation	Delivered						
		652.91	Unspecified Malposition Or Malpresentation Of Fetus	Delivered						
MultiMalpOB	Multigestation with malpresentation	652.61	Multiple Gestation with malpresentation of the one fetus or more	Delivered	DX	0.1	X			
		651.01 = 2, 651.11 = 3, 651.21 = 4, 651.31 = 2, 651.41 = 3, 651.51 = 4, 651.61 = 1, 651.81 = 1, 651.91 = 1								
		651.01	Twin Pregnancy	Delivered						
		651.11	Triplet Pregnancy	Delivered						
		651.21	Quadruplet Pregnancy	Delivered						
		651.31	Triplet Pregnancy With Fetal Loss And Retention Of One Or More Fetus(es)	Delivered						
		651.41	Quadruplet Pregnancy With Fetal Loss And Retention Of One Or More Fetus(es)	Delivered						
		651.51	Loss And Retention Of One Or More Fetus(es)	Delivered						
		651.61	Other Multiple Pregnancy With Fetal Loss	Delivered						

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

MeasId	MeasName	Diagn/Proc	Definition	Fifth Digit Meaning	Source	Values	High Risk for CS Factor	Medical Indication for Induction	Dystocia Failure to Progress	Fetal Distress
		651.81	Other Specified Multiple Gestation	Delivered						
		651.91	Unspecified Multiple Gestation	Delivered						
Myomectomy	Myomectomy	68.29	Other excision or destruction of lesion of uterus, Uterine Myomectomy		PX	0,1	X			
HPVOB	Human papilloma virus	79.4	Human Papillomavirus In Conditions Classified Elsewhere And Of Unspecified Site		DX	0,1	X			
OligoOB	Oligohydramnios	658.01	Oligohydramnios without mention of rupture of membranes	Delivered	DX	0,1	X			
obfemabn	Congenital Abnormality Of Organs And Soft Tissues Of Pelvis	654.01-654.02			DX	0,1	X			
		654.01	Congenital Abnormalities Of Uterus Complicating Pregnancy, Childbirth, Or The Puerperium Double uterus; Uterus bicornis	Delivered						
		654.02		Delivered, With Mention Of Postpartum Complication						
RuptUtrsOB	Rupture of uterus during labor	665.11	Rupture Of Uterus, With Delivery	Delivered	DX	0,1	X			
UterTumor	Tumors of the uterus	654.11-654.12	Rupture of uterus NOS		DX	0,1	X			
		654.11	Tumors Of Body Of Uterus Complicating Pregnancy, Childbirth, Or The Puerperium Uterine fibroids	Delivered						
		654.12		Delivered, With Mention Of Postpartum Complication						
UmbCordOB	Prolapsed cord; other cord problems w/compression	663.01, 663.11, 663.21			DX	0,1	X			
		663.01	Prolapse Of Cord Complicating Labor And Delivery Presentation of cord	Delivered						
		663.11	Cord Around Neck, With Compression, Complicating Labor And Delivery Cord tightly around neck	Delivered						
		663.21	Other And Unspecified Cord Entanglement, With Compression, Complicating Labor And Delivery Entanglement of cords of twins in mono-amniotic sac; Knot in cord (with compression)	Delivered						
ValvDisOB	Valvular disease of mother	395.0-395.9, 397-398.99			DX	0,1	X			

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

MeasId	MeasName	Diagn/Proc	Definition	Birth Order Meaning	Source	Value	High Risk for CS Factor	Medical Indication for Induction	Dystocia Failure to Progress	Fetal Distress
PreEchTN	Pre-eclampsia with pre-existing HTN	642.71-642.72						X		
		642.71	Pre-eclampsia Or Eclampsia Superimposed On Pre-existing Hypertension Conditions classifiable to 642.4-642.6, with conditions classifiable to 642.0-642.2	Antepartum complication with delivery						
		642.72		With Delivery, With Mention Of Postpartum Complication						
PregHTN	Transient HTN of pregnancy	642.31-642.32						X		
		642.31	Transient Hypertension Of Pregnancy Gestational hypertension; Transient hypertension so described, in pregnancy, childbirth, or the puerperium	Antepartum complication with delivery						
		642.32		With Delivery, With Mention Of Postpartum Complication						
RenalDisOB	Unspecified renal disease w/o HTN	646.21-646.22						X		
		646.21	Unspecified Renal Disease In Pregnancy, Without Mention Of Hypertension (Albuminuria) (Nephropathy NOS) (Renal disease NOS) (Uremia) (Gestational proteinuria) in pregnancy or the puerperium, without mention of hypertension	Delivered						
		646.22		With Mention Of Postpartum Complication						
SevPreEc	Severe eclampsia	642.51-642.52						X		
		642.51	Severe Pre-eclampsia Hypertension in pregnancy, childbirth, or the puerperium, not specified as pre-existing, with either albuminuria or edema, or both, specified as severe; Pre-eclampsia, severe; Toxemia (pre-eclampic), severe	Antepartum complication with delivery						
		642.52		With Delivery, With Mention Of Postpartum Complication						
SGAOB	SGA; poor fetal growth	656.51	Poor Fetal Growth, Affecting Management of Mother, "Light-for-dates", "Placental Insufficiency", "Small for Dates"	Delivered				X		

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

MeasID	MeasName	Diagn/Proc	Definition	Fifth Digit Meaning	Source	Value	High Risk for CS Factor	Medical Indication for Induction	Dystocia Failure to Progress	Fetal Distress
DiabPregOB	Diabetes Mellitus	648.01-648.02								
		648.01	Diabetes Mellitus (conditions classifiable to 250) excludes gestational diabetes	delivered with or without mention of antepartum complication						
		648.02	Diabetes Mellitus (conditions classifiable to 250) excludes gestational diabetes	delivered with mention of postpartum complications						
gestdiab	Gestational Diabetes	648.81-648.82		648.81-648.82						
		648.81	Abnormal glucose tolerance conditions (gestational diabetes)	delivered with or without mention of antepartum complication						
		648.82	Abnormal glucose tolerance conditions (gestational diabetes)	delivered with mention of postpartum complications						
EclampOB	Eclampsia	642.61-642.62								
		642.61	Eclampsia Complicating Pregnancy, Childbirth Or The Puerperium Toxemia: eclamptic, with convulsions	Delivered, With Mention Of Antepartum Complication						
		642.62	Eclampsia Complicating Pregnancy, Childbirth Or The Puerperium Toxemia: eclamptic, with convulsions	Delivered, With Mention Of Postpartum Complication						
HrtMurm	Heart murmur	785.2	Undiagnosed Cardiac Murmurs							
		642.01-642.02, 642.11-642.12, 642.21-642.22, 642.91-642.92	Heart murmur NOS							
HTNOB	Essential HTN, other forms of hypertension									
		642.01	Benign Essential Hypertension Complicating Pregnancy, Childbirth, And The Puerperium specified as complicating or as a reason for obstetric care during pregnancy, childbirth, or the puerperium	Antepartum complication with delivery						
		642.02		With Delivery, With Mention Of Postpartum Complication						
		642.11	Hypertension Secondary To Renal Disease, Complicating Pregnancy, Childbirth, And The Puerperium Hypertension secondary to renal disease, specified as complicating or as a reason for obstetric care during pregnancy, childbirth, or the puerperium	Antepartum complication with delivery						
		642.12		With Delivery, With Mention Of Postpartum Complication						

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

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Measid	MeasName	Diagn/Proc	Definition	Final Diag Meaning	Source	Values	High Risk for CS Factor	Medical Indication for Induction	Dystocia Failure to Progress	Fetal Distress
		642.21	Other Pre-existing Hypertension Complicating Pregnancy, Childbirth, And The Puerperium (Malignant hypertension) specified as complicating or as a reason for obstetric care during pregnancy, childbirth, or the puerperium	Antepartum complication with delivery						
		642.22		With Delivery, With Mention Of Postpartum Complication						
		642.91	Unspecified Hypertension Complicating Pregnancy, Childbirth, Or The Puerperium Hypertension NOS, without mention of albuminuria or edema complicating pregnancy, childbirth, or the puerperium	Antepartum complication with delivery						
		462.92		With Delivery, With Mention Of Postpartum Complication						
InfectOB	Septicemia during labor, infected amniotic cavity	658.41, 659.31			DX	0,1		X		
		658.41	Infection Of Amniotic Cavity	Delivered						
		659.31	Delayed Delivery After Artificial Rupture Of Membranes	Delivered						
MembRuptOB	Premature or prolonged rupture of membranes	658.11, 658.21			DX	0,1		X		
		658.11	Premature Rupture Of Membranes Rupture of amniotic sac less than 24 hours prior to the onset of labor	Delivered						
		658.21	Delayed Delivery After Spontaneous Or Unspecified Rupture Of Membranes Prolonged rupture of membranes NOS; Rupture of amniotic sac 24 hours or more prior to the onset of labor	Delivered						
MildEclOB	Mild/unspec pre-eclampsia	642.41-642.42			DX	0,1		X		
		642.41	Mild Or Unspecified Pre-eclampsia Hypertension in pregnancy, childbirth, or the puerperium, not specified as pre-existing, with either albuminuria or edema, or both, mild or unspecified; Pre-eclampsia: NOS, mild; Toxemia (pre-eclamptic): NOS, mild	Antepartum complication with delivery						

Risk Factor Exclusion Criteria, Medical Indications for Induction Risk Factor, Dystocia/Failure to Progress Risk Factor, Fetal Distress Risk Factor with ICD-9-CM Codes Detailed Definitions

MeasId	MeasName	Diagn/Proc	Definition	Fifth Digit Meaning	Source	Value	High Risk for CS Factor	Medical Indication for Induction	Dystocia Failure to Progress	Fetal Distress
		642.42		With Delivery, With Mention Of Postpartum Complication						
CPD	Cephalopelvic Disproportion	653.51	Unusually Large Fetus Causing Disproportion, Disproportion of fetal origin with normally formed fetus; Fetal disproportion NOS	Delivered					X	
Prolabor	Prolonged Labor	662.01, 662.11, 662.21	Prolonged first stage of labor	Delivered	DX	0,1			X	
			Unspecified type prolonged labor	Delivered						
			Prolonged second stage of labor	Delivered						
ShoulderOB	Obstruction of labor by shoulder dystocia	660.41	Shoulder (girdle) Dystocia	With Delivery	DX	0,1			X	
TrnvArstOB	Deep transverse arrest and persistent OP position	660.31			DX	0,1			X	
HiHeadOB	Head high at term (increased risk with first baby)	652.51			DX	0,1			X	
oblipcer	Obstruction By Abnormal Pelvic Soft Tissues During Labor Prolapse of anterior lip of cervix	660.21	Obstruction By Abnormal Pelvic Soft Tissues During Labor, Prolapse of anterior lip of cervix; Any condition classifiable to 654 causing obstruction during labor Prolapse of anterior lip of cervix Any condition classifiable to 654 causing obstruction during labor	Delivered	DX	0,1			X	
abforlab	Abnormal Forces Of Labor	661.01, 661.11, 661.21, 661.41		Delivered	DX	0,1			X	
		661.01	Primary Uterine Inertia, Failure of cervical dilation; Hypotonic uterine dysfunction primary; Prolonged latent phase of labor							
		661.11	Secondary Uterine Inertia, Arrested active phase of labor; Hypotonic uterine dysfunction, secondary							
		661.21	Other And Unspecified Uterine Inertia, Atony of uterus; Desultory labor; Irregular labor; Poor contractions; Slow slope active phase of labor							
		661.41	Hypertonic, Incoordinate, Or Prolonged Uterine Contractions, Hypertonic, Incoordinate, Or Prolonged Uterine Contractions							
FetDstrsOB	Fetal distress	656.31	Fetal Distress Affecting Management Of Mother Fetal metabolic acidemia	Delivered	DX	0,1				X

Appendix D

Synopsis of the Induction Literature

Synopsis of the Induction Literature

<i>Notable Studies on Induction of Labor</i>							
Author (s)	Objective	Year	Data Source (s)	Sample	Design & Methodology	Conclusions	Notable Information
Coonrod, D., Bay, C., & Kishi, G.	To describe labor induction risk factors and consequence among women with term singleton gestations, vertex presentation.	2000	Birth certificate Data	1997 Arizona Births 75,786, post exclusions n=65,607	Retrospective study using stratification & Logistic regression, Risk Modeling approach to analysis.	Large variation in labor induction were noted across maternal ethnicity & hospital ownership.	Do not mention any methods to examine or control for interaction, yet conclusion of across ethnicity and hospital ownership difference infer effect modification. Confounding defined as any confounder with > 10% change in the induction coefficient. Stratification appears to have been used to address effect modification.
Alexander, J., Bloom, S. & McIntire, D.	To compare the effects of induction with the effects of cesarean delivery without induction on neonatal outcomes in pregnancies complicated by severe preeclampsia and delivery of very low birth weight infants.	1999	Chart Abstraction	278 singleton live-born infants who weighted 750-1500 grams, delivered because of severe preeclampsia	Retrospective study design, Stratification t test, Mann-Whitney U test, Chi Square & Fisher Exact for differences, Logistic regression to adjust for differences.	Induction of labor in cases of severe preeclampsia is not harmful to very low birth weight infants.	Success of labor induction (vaginal delivery) increased as gestational age increased, suggesting that gestational age may be a proxy to readiness of the cervix.

Synopsis of the Induction Literature

<p>Joseph, K., Young, D., Dodds, L., O'Connell, C., Allen, V., Chandra, S., & Allen, A.</p>	<p>To estimate the contribution of changes in maternal characteristics (age, parity, prepregnancy weight, weight gain in pregnancy, smoking status) and obstetric practice (induction, epidural, & midpelvic forceps delivery & delivery by an obstetrician) to recent increases in primary cesarean delivery.</p>	<p>2003</p>	<p>Nova Scotian Atlee Perinatal Database (>150 variables) reported by delivery hospitals on all births in Nova Scotian province of Canada.</p>	<p>127,564 (1988-2000) births in Nova Scotia Canada</p>	<p>Retrospective study design, with Logistic regression & Poisson regression reporting prevalence rates overtime.</p>	<p>Recent increases in primary cesarean delivery rates in Nova Scotia are a consequence of changes in both maternal characteristics & practice pattern changes, including increases in induction of labor.*</p>	<p>Attributed a component of the increased primary cesarean delivery rate in Nova Scotia to the increase in inductions on term and postterm deliveries.</p>
<p>Heinberg, E., Wood, R., & Chambers, R.</p>	<p>To determine whether the elective medical initiation of labor places the multiparous woman at increased risk for cesarean.</p>	<p>2002</p>	<p>Chart Abstraction</p>	<p>304 case control pairs drawn from 6114 total births from Oschner Clinic in New Orleans from July 1994 to March 2000.</p>	<p>Retrospective matched pair, case-control study, matching on age, parity, gestational age and staff obstetrician for multiparous women undergoing elective induction of labor versus a matched pair undergoing spontaneous labor.</p>	<p>Elective induction of labor compared to spontaneous onset of labor does not predispose a woman to cesarean delivery.**</p>	<p>28% induction rate reported for the study period confirmed by chart review, excluded women with history of prior cesarean delivery and included singleton births, 37-41 3/4ths weeks gestation.</p>

Synopsis of the Induction Literature

<p>Rogers, R., Gilson, G., Anthony, C., Izquierdo, L., Curet, L., & Qualls, C.</p>	<p>To evaluate whether active management of labor lowers cesarean rates, shortens the length of labor, and overcomes any negative effects of epidural analgesia on nulliparous labor.</p>	<p>1997</p>	<p>405 low risk nulliparous women delivering at a New Mexico tertiary facility serving predominantly indigent patients. Study period was from August 1992 to April 1996.</p>	<p>Randomized prospective study design, no report of statistical methods, although p values are reported.</p>	<p>Patients undergoing active management of labor had shortened labors and were more likely to be delivered within 12 hours, differences that persisted despite the use of epidural analgesics. There was a trend towards a reduced rate of cesarean reported, although not significantly different.</p>	<p>Low cell size, randomized trial was a strength of the study.</p>
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Synopsis of the Induction Literature

<p>Alexander, J., McIntire, D., & Leveno, K.</p>	<p>To determine the effects of induction on cesarean delivery in post-date pregnancies.</p>	<p>2001</p>	<p>Chart Abstraction</p>	<p>1325 women with pregnancies 41 to 41 3/4ths weeks gestation were prospectively enrolled in the study.</p>	<p>Prospective observational study. Statistical analysis was done using Mantel Haenszel Chi Square for trend, Student t test, and multiple logistic regression used to control for cervical dilatation, gestational age nulliparity, and epidural analgesia</p>	<p>Risk factors intrinsic (including undilated cervix, epidural analgesia, more advanced gestational age, and nulliparity) to the patient rather than induction are the cause of excess cesarean in women with prolonged pregnancies. **</p>	<p>Excluded women with risk for cesarean delivery. Power analysis performed to determine how many patients would be required to show no effect of labor induction on cesarean delivery with a beta of .8 & an alpha of .05, approximately 5200 patients would be required. Strength of the study was uniformity of practice management. Gestation was entered into the logistic regression equation as a continuous integral variable in weeks gestation. No notation of interaction terms tested.</p>
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Synopsis of the Induction Literature

Hefner, L., Elkin, E., & Fretts, R.	To quantify the impact of labor induction and maternal age on cesarean delivery rates in nulliparous and multiparous women between 36 and 42 weeks gestation.	2003	Birth Record Database for Beth Israel Deaconess Medical Center and Brigham & Women's Hospital in Boston	14,409 women delivering at one of the two hospitals from 1998 through 1999.	Retrospective cohort study using stratification and logistic regression. The Cochran-Mantel Haenszel statistics were calculated to test the association between labor induction and each indication for cesarean delivery, stratified by gestational age.	Induction of labor, older maternal age, and gestational age over 40 weeks each independently increase the risk for cesarean delivery.*	Nulliparous and Multiparous women were stratified into different models. Interaction terms were tested and retained if significant at $p \leq .05$ or if they had an impact on other coefficients in the model.
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Synopsis of the Induction Literature

<p>Dublin, S., Lydon-Rochelle, M., Kaplan, R., Watts, D., & Critchlow, C.</p>	<p>To examine associations between induction of labor and maternal & neonatal outcomes among women without an identified indication for induction.</p>	<p>2000</p>	<p>Linked Birth Certificate and Hospital Discharge Data in Washington.</p>	<p>Randomly selected sample from Washington State births from 1989 to 1993 n=12,534.</p>	<p>Population based cohort study</p>	<p>Among women who lacked an identified indication for induction of labor, induction was associated with increased likelihood of cesarean delivery for nulliparous women but not multiparous women and "modest" increase in instrumental delivery and dystocia for all women.*</p>	<p>Power analysis reported indicating 12,534 cases was sufficient to test the hypothesis regarding an association between induction of labor and mode of delivery as cesarean or instrumental delivery. Induction identified if either data source indicated induction. Of the 2886 women induced 1313 were identified from BC data, 540 from HDD and 1033 from both. Confounding defined as any covariate that changed the induction coefficient > 10%.</p>
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Synopsis of the Induction Literature

<p>Johnson, D., Davis, N., Brown, A.</p>	<p>To evaluate the effect of induction on the route of delivery in nulliparous women laboring at term in a community hospital system.</p>	<p>2003</p>	<p>Prospective Data Collection by Trained perinatal data coordinator.</p>	<p>7,282 deliveries in nulliparous women delivering from April 1997 to Oct 1999 in one of three Providence hospitals in the Portland area of the U.S.</p>	<p>Prospective observational study design, analysis included t tests and chi square analysis for demographic differences, and logistic regression for examining the relationship of inductions on primary cesarean delivery.</p>	<p>Induction of labor in nulliparous women is associated with a significant increase of risk for primary cesarean delivery, particularly for women with unfavorable cervix.*</p>	<p>Confounders identified were: maternal age > or = to 35 years, male sex, birth weight > or equal to 4000 grams, baby's gestational age in weeks. No significant interaction terms were identified.</p>
<p>Sanchez-Ramos, L., Bernstein, S., Kaunitz, A.</p>	<p>To systematically review and summarize the medical literature regarding the effects of expectant management of labor and labor induction on mode of delivery and perinatal outcomes in patients with suspected fetal macrosomia.</p>	<p>2002</p>	<p>Literature Review for articles examining macrosomia with observational studies and randomized trials included in the study. The researchers abstracted data from the literature.</p>	<p>11 studies met study criteria with a total of 3751 subjects represented.</p>	<p>Metanalysis of studies examining macrosomia and induction.</p>	<p>Based on observational studies labor induction for suspected macrosomia increases the risk of cesarean without improving outcomes, however, the two randomized trials examined did not support these findings, and were limited by sample size.</p>	<p>The articles reviewed ranged in date from 1991 to 1997 with the two randomized trials being 1997. One would question whether these findings would hold with the differences in obstetrics.</p>

Synopsis of the Induction Literature

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<p>Maslow, A. & Sweeny, A.</p>	<p>To determine the effects of induction on the risk of cesarean delivery in a low risk cohort, and to evaluate cost of elective inductions.</p>	<p>2000</p>	<p>Hospital Discharge Data</p>	<p>1810 women delivering live born infants from June 1997 to Jan 1998 in St Joseph's Medical Center.</p>	<p>Retrospective exploratory study design with t tests and chi square analysis done for demographic differences and logistic regression used to create a model with risk factors for cesarean delivery.</p>	<p>Elective induction of labor significantly increases the risk of cesarean delivery for nulliparous women and increases the predelivery time and cost associated with the delivery.*</p>	<p>No mention of tests for interaction, yet the researchers report different models for all women, parity = 0 and parity 1 or greater. They also report different modeling findings when nulliparous women with infants having birth weights greater than 4000 grams are excluding. This leads to a conclusion that the researchers either anticipated interaction or did some type of analysis that lead to this exclusion. This exclusion resulted in a model with gestation and elective induction as the only significant predictors of cesarean delivery.</p>
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Synopsis of the Induction Literature

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<p>Alexander, J., McIntire, D., & Leveno, K.</p>	<p>To assess pregnancy outcomes at 40, 41, and 42 weeks gestation when labor induction is done routinely at 42 but not 41 weeks.</p>	<p>2000</p>	<p>Prospective Data Collection by Trained perinatal data abstractors.</p>	<p>56,317 deliveries at Parkland Hospital in Dallas delivering from 1988 to 1998.</p>	<p>Prospective observational study design, analysis included chi square analysis to compare proportions, and analysis of variance was used for continuous variables for differences between the different gestational groups.</p>	<p>Routine labor induction at 41 weeks likely increases the labor complications and operative delivery with out significantly improving neonatal outcomes.*</p>	<p>A strength of the study was a consistent labor induction protocol implemented by Parkland Hospital, thereby controlling for practice pattern variation.</p>
<p>Yeast, J., Jones, A., & Poskin, M.</p>	<p>To study the increasing risk of induction in a community hospital.</p>	<p>1999</p>	<p>Prospective Data Collection for perinatal database.</p>	<p>18,055 singleton pregnancies delivering from 1990 to 1997 in a community hospital in Kansas City.</p>	<p>Prospective observational study. Statistical analysis was done using t test and chi square analysis for demographic differences and logistic regression to examine risk factors for cesarean delivery.</p>	<p>The use of induction has significantly increased in the community hospital with no significant impact on cesarean delivery.**</p>	<p>The study reports nulliparity and elective induction increase the risk of cesarean delivery (odds ratio 1.75, no CI reported)</p>

Synopsis of the Induction Literature

Seyb, S., Berka, R., Socol, M., Dooley, S.	To quantify the risk of cesarean delivery associated with elective induction in nulliparous women.	1999	Prospective Data Collection.	1,516 nulliparous women divided into one of three groups: spontaneous labor, elective induction, medical indication for induction..	Prospective exploratory cohort study using analysis of variance for differences among groups, chi square, and chi square for trend. Stepwise logistic regression was used to create a risk model for cesarean delivery.	Elective induction is associated with a significantly increased risk of cesarean delivery in nulliparous women.*	The study reports a pilot study for the purpose of performing a power calculation . The needed sample size to detect a two fold difference in the cesarean rate (alpha .05) and power of 80% was calculated as 1220 deliveries for the spontaneous delivery group and 122 in the elective induction group.
Sanchez-Ramos, Olivier, F., Delke, I., Kaunitz, A.	To compare labor induction with expectant labor management for patients who reach or exceed 41 weeks gestation.	2003	Computerized databases, references in published studies on randomized controlled trials.	16 studies met study criteria.	Metanalysis of randomized controlled trials examining postterm induction and primary cesarean delivery.	Labor induction at 41 weeks gestation for uncomplicated singleton pregnancies reduces cesarean delivery rates without compromising neonatal outcomes.**	Study results indicates that induction for 41 weeks or greater decreases the odds of cesarean delivery by 12% (OR .88; 95% CI 0.78, 0.99)
* Study findings indicated an independent effect of inductions on primary cesarean delivery.							
** Study findings did not find an independent effect of inductions on increased risk of cesarean delivery.							

Appendix E

Example of State of Texas Certificate of Birth

STATE OF TEXAS CERTIFICATE OF BIRTH BIRTH NUMBER

NEWBORN

1. Name First Middle Last 2. Date of Birth 3. Sex

4a. Place of Birth - County 4b. City or Town (If outside city limits, give precinct no.) 5. Time of Birth 6a. Plurality - Single, Twin, Triplet, etc. 6b. If Plural Birth, Born 1st, 2nd, 3rd, etc.

7a. Place of Birth Clinic / Doctor's Office Licensed Birthing Center Hospital Home Name of Hospital or Birthing Center (If Not Institution, Give Street Address)

Residence Other (Specify):

8a. Attendant's Name and Mailing Address 8b. I solemnly certify that this child was born alive at the place and time and on the date as stated.

Signature and Title Date Signed

9a. MD DO CHM Midwife Other (Specify): 9b. Attendant Facility Administrator / Designee Other (Specify):

MOTHER

10. Name First Middle Maiden Surname 11. Date of Birth 12. Birthplace (State or Foreign Country)

13a. Residence - State 13b. County 13c. City or Town 13d. Street Address or Rural Location

13e. Inside City Limits 14. Mother's Mailing Address (If Same As Residence, Enter Zip Code Only)

Yes No

FATHER

15. Name First Middle Last 16. Date of Birth 17. Birthplace (State or Foreign Country)

REGISTRAR

18a. Registrar's File Number 18b. Date Received by Local Registrar 18c. Signature of Local Registrar

CONFIDENTIAL INFORMATION FOR MEDICAL AND PUBLIC HEALTH USE - THE FOLLOWING INFORMATION WILL NOT BE SHOWN ON CERTIFIED COPIES

19a. Mother Married? Yes No 19b. I consent for my baby's immunization information to be included in the statewide immunization Registry and to share the immunization information with registered providers. Yes No 19c. SSN for your new baby? Yes No 19d. SSN of Mother Yes No 19e. SSN of Father Yes No

20. Signature of Parent - I have reviewed the information above and agree that it is correct.

21. Father's mailing address (If Same as Mother enter 'Same')

MOTHER

22a. Mother 23a. Hispanic Origin, If Yes, Specify (Mexican, Cuban, Puerto Rican, etc.) Yes No 24a. Mother 25a. Mother 25c. Mother

FATHER

22b. Father 23b. Hispanic Origin, If Yes, Specify Yes No 24b. Father 25b. Father 25d. Father

PREGNANCY HISTORY

27. Source of Prenatal Care (check all that apply) Hospital Clinic Public Health Clinic Private Physician Midwife None Unknown Other (specify):

28. Hepatitis B Immunization Given Yes No 30. Birthweight G, or LB, OZ

28a. Now Living 28b. Now Dead 28c. Other (specify):

Number _____ Number _____ Number _____

None None None

31. Date Last Normal Menses Began 32. Clinical Estimate of Gestation (Weeks)

33. Prenatal Care Began During 1st, 2nd, 3rd, etc. month, Specify: 34. Number of Prenatal Visits

35a. HIV Test Done Prenatally Yes No 35c. HIV Test Done at Delivery Yes No 36. Serologic Test Done at Delivery Yes No

37a. Mother Transferred Prior to Delivery No Yes (Specify Facility): 37b. Infant Transferred After Delivery No Yes (Specify Facility): 37c. Hospital Use

38a. MEDICAL RISK FACTORS FOR THIS PREGNANCY (Check all that apply) 1 Anemia (HCL < 30/Hgb. < 10) 2 Cardiac disease 3 Acute or chronic lung disease 4 Diabetes 5 Hydranmios / Oligohydramnios 6 Hemoglobinopathy 7 Hypertension, chronic 8 Hypertension, pregnancy-associated 9 Eclampsia 10 Incompetent cervix 11 Previous infant 4000+ grams 12 Previous preterm or small- for - gestational-age infant 13 Preterm labor 14 Renal disease 15 Blood group isoimmunization 16 Preterm rupture of membranes (< 37 wks.) 17 STD 18 Zidovudine administered during pregnancy 19 NONE 20 Other (specify): 21 UNKNOWN

38b. OTHER RISK FACTORS FOR THIS PREGNANCY (Complete all items) Yes No Tobacco use during pregnancy _____ Average number of cigarettes per day Yes No Alcohol use during pregnancy _____ Average number of drinks per week _____ lb. Weight gained during pregnancy

38c. OBSTETRIC PROCEDURES (Check all that apply) 1 Amniocentesis 2 Electronic fetal monitoring 3 Induction of labor 4 Augmentation of labor 5 Tocolytic 6 Ultrasound 7 NONE 8 Other (specify):

38d. COMPLICATIONS OF LABOR AND/OR DELIVERY (Check all that apply) 1 Febrile (> 100° F. or 38° C.) 2 Meconium, moderate / heavy 3 Premature rupture of membrane (> 12 hours) 4 Abruptio placenta 5 Placenta previa 6 Other excessive bleeding 7 Sutures during labor 8 Precipitous labor (< 3 hours) 9 Prolonged labor (> 20 hours) 10 Dysfunctional labor 11 Breech / Malpresentation 12 Cephalopelvic disproportion 13 Cord prolapse 14 NONE 15 Other (specify):

38e. METHOD OF DELIVERY Check one of 1 - 4. Check 5 and/or 6 if applicable 1 Vaginal 2 Vaginal birth after previous C-section 3 Primary C-section 4 Repeat C-section 5 Forceps 6 Vacuum

38f. ABNORMAL CONDITIONS OF THE NEWBORN (Check all that apply) 1 Anemia (HCL < 38/Hgb. < 13) 2 Fetal alcohol syndrome 3 Hyaline membrane disease / RDS 4 Meconium aspiration syndrome 5 Assisted ventilation < 30 min. 6 Assisted ventilation > 30 min. 7 Seizures 8 Sepsis 9 UABG pH < 7.2 10 NONE 11 Other (specify):

38g. CONGENITAL ANOMALIES OF CHILD (Check all that apply) 1 Anencephalus 2 Spina bifida / Meningocele 3 Hydrocephalus 4 Microcephalus 5 Other central nervous system anomalies _____ (specify) 6 Heart malformations 7 Other circulatory / respiratory anomalies _____ (specify) 8 Rectal atresia / stenosis 9 Tracheo-esophageal fistula / Esophageal atresia 10 Omphalocele / Gastroschisis 11 Other gastrointestinal anomalies _____ (specify) 12 Malformed genitalia 13 Renal agenesis 14 Other urogenital anomalies _____ (specify) 15 Cleft lip / palate 16 Polydactyly / Syndactyly 17 Limb reductions 18 Club foot 19 Diaphragmatic hernia 20 Other musculoskeletal / integumental anomalies _____ (specify) 21 Down's syndrome 22 Other chromosomal anomalies _____ (specify) 23 NONE 24 Other: _____ (specify)

WARNING: THE PENALTY FOR KNOWINGLY MAKING A FALSE STATEMENT IN THIS FORM CAN BE 2-10 YEARS IN PRISON AND A FINE OF UP TO \$5000.

STATE COPY VS-111 REV. 9/99

Appendix F
UB92 Electronic File Format for
Administrative Billing Data

ST 1845 IPLY UB-92

1		2		3 PATIENT CONTROL NO.		4 TYPE OF BILL			
5 FED. TAX NO.		6 ADJUSTMENT PERIOD		7 COVD.	8 N-C.D.	9 C.I.D.	10 L.R.D.	11	
12 PATIENT NAME				13 PATIENT ADDRESS					
14 BIRTHDATE	15 SEX	16 MS	17 ADMISSION DATE	18 DISCHARGE DATE	19 D.H.R.	20 STAT.	21 MEDICAL RECORD NO.	31	
37								A	
38								B	
39								C	
40								a	
41								b	
42								c	
43								d	
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATES	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49		
1								1	
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4								4	
5								5	
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50 PAYER		51 PROVIDER NO.		52 REL. EXPD.	53 ASG. BET.	54 PRIOR PAYMENTS		55 EST. AMOUNT DUE	56
57								A	
58 INSURED'S NAME								B	
59 P. REL.								C	
60 CERT. - SSN - HIC. - ID NO.									
61 GROUP NAME								A	
62 INSURANCE GROUP NO.								B	
63 TREATMENT AUTHORIZATION CODES								C	
64 ESC									
65 EMPLOYER NAME								A	
66 EMPLOYER LOCATION								B	
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UNIFORM BILL:

NOTICE: ANYONE WHO MISREPRESENTS OR FALSIFIES ESSENTIAL INFORMATION REQUESTED BY THIS FORM MAY UPON CONVICTION BE SUBJECT TO FINE AND IMPRISONMENT UNDER FEDERAL AND/OR STATE LAW.

Certifications relevant to the Bill and Information Shown on the Face Hereof: Signatures on the face hereof incorporate the following certifications or verifications where pertinent to this Bill:

1. If third party benefits are indicated as being assigned or in participation status, on the face thereof, appropriate assignments by the insured/beneficiary and signature of patient or parent or legal guardian covering authorization to release information are on file. Determinations as to the release of medical and financial information should be guided by the particular terms of the release forms that were executed by the patient or the patient's legal representative. The hospital agrees to save harmless, indemnify and defend any insurer who makes payment in reliance upon this certification, from and against any claim to the insurance proceeds when in fact no valid assignment of benefits to the hospital was made.
2. If patient occupied a private room or required private nursing for medical necessity, any required certifications are on file.
3. Physician's certifications and re-certifications, if required by contract or Federal regulations, are on file.
4. For Christian Science Sanitoriums, verifications and if necessary re-verifications of the patient's need for sanatorium services are on file.
5. Signature of patient or his/her representative on certifications, authorization to release information, and payment request, as required by Federal law and regulations (42 USC 1935f, 42 CFR 424.36, 10 USC 1071 thru 1086, 32 CFR 199) and, any other applicable contract regulations, is on file.
6. This claim, to the best of my knowledge, is correct and complete and is in conformance with the Civil Rights Act of 1964 as amended. Records adequately disclosing services will be maintained and necessary information will be furnished to such governmental agencies as required by applicable law.
7. For Medicare purposes:

If the patient has indicated that other health insurance or a state medical assistance agency will pay part of his/her medical expenses and he/she wants information about his/her claim released to them upon their request, necessary authorization is on file. The patient's signature on the provider's request to bill Medicare authorizes any holder of medical and non-medical information, including employment status, and whether the person has employer group health insurance, liability, no-fault, workers' compensation, or other insurance which is responsible to pay for the services for which this Medicare claim is made.
8. For Medicaid purposes:

This is to certify that the foregoing information is true, accurate, and complete.
I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State Laws.

9. For CHAMPUS purposes:

This is to certify that:

- (a) the information submitted as part of this claim is true, accurate and complete, and, the services shown on this form were medically indicated and necessary for the health of the patient;
- (b) the patient has represented that by a reported residential address outside a military treatment center catchment area he or she does not live within a catchment area of a U.S. military or U.S. Public Health Service medical facility, or if the patient resides within a catchment area of such a facility, a copy of a Non-Availability Statement (DD Form 1251) is on file, or the physician has certified to a medical emergency in any assistance where a copy of a Non-Availability Statement is not on file;
- (c) the patient or the patient's parent or guardian has responded directly to the provider's request to identify all health insurance coverages, and that all such coverages are identified on the face the claim except those that are exclusively supplemental payments to CHAMPUS-determined benefits;
- (d) the amount billed to CHAMPUS has been billed after all such coverages have been billed and paid, excluding Medicaid, and the amount billed to CHAMPUS is that remaining claimed against CHAMPUS benefits;
- (e) the beneficiary's cost share has not been waived by consent or failure to exercise generally accepted billing and collection efforts; and
- (f) any hospital-based physician under contract, the cost of whose services are allocated in the charges included in this bill, is not an employee or member of the Uniformed Services. For purposes of this certification, an employee of the Uniformed Services is an employee, appointed in civil service (refer to 5 USC 2105), including part-time or intermittent but excluding contract surgeons or other personnel employed by the Uniformed Services through personal service contracts. Similarly, member of the Uniformed Services does not apply to reserve members of the Uniformed Services not on active duty.
- (g) based on the Consolidated Omnibus Budget Reconciliation Act of 1985, all providers participating in Medicare must also participate in CHAMPUS for inpatient hospital services provided pursuant to admissions to hospitals occurring on or after January 1, 1987.
- (h) if CHAMPUS benefits are to be paid in a participating status, I agree to submit this claim to the appropriate CHAMPUS claims processor as a participating provider. I agree to accept the CHAMPUS-determined reasonable charge as the total charge for the medical services or supplies listed on the claim form. I will accept the CHAMPUS-determined reasonable charge even if it is less than the billed amount, and also agree to accept the amount paid by CHAMPUS, combined with the cost-share amount and deductible amount, if any, paid by or on behalf of the patient as full payment for the listed medical services or supplies. I will make no attempt to collect from the patient (or his or her parent or guardian) amounts over the CHAMPUS-determined reasonable charge. CHAMPUS will make any benefits payable directly to me, if I submit this claim as a participating provider.

ESTIMATED CONTRACT BENEFITS

Appendix G

Permission to Use DFWHC Data

August 11, 2004
TWU Institutional Review Board
F [REDACTED]
Denton, Texas 76204

Dear TWU Institutional Review Board,

Susan McBride has been given the authorization from the Dallas Fort Worth Hospital Council (DFWHC) Board of Directors to utilize the DFWHC Discharge Data file and the Birth Certificate research file for her research for dissertation. She may also share the data with the Ohio State University Biostatistics Department, Dr. Stanley Lemeshow and staff support, Amy Lehman.

We understand that the study will examine the effect of inductions on primary cesarean delivery. The study will utilize the Dallas Fort Worth Hospital Council's database containing 41 hospital's merged birth certificate, hospital discharge data, and the American Hospital Association's Annual Hospital Survey data. Prior to release of the data to the researcher, the DFWHC staff will remove all protected personal healthcare information including name, address and social security number of the patient and all physician identifying information. We understand that the name of the hospital will remain in the file in order to examine hospital characteristics for such things as bed size, ownership and teaching status and rural versus urban location. The hospital names will not be used for any written reports or articles relating to the findings of the study.

The Dallas Fort Worth Hospital Council have required a previous review and approval of the Texas Woman's University Institutional Research Review Board prior to release of the research file, and we understand that this study has been approved as an Exempt Review due to the secondary data analysis. We request that the DFWHC be provided with the results of the analysis for use with the Council hospitals should the Council decide that the study results provide value to individual hospitals. The DFWHC staff will provide the research data file to the researcher on a zip disk or CD, which will be returned to the Council once the study, is complete.

Sincerely,

[REDACTED]

John C. Gavras
President/CEO

Appendix H
Permission to Conduct Study



The Graduate School
P.O. Box 425649, Denton, TX 76204-5649
940-898-3415 Fax 940-898-3412

466-13-6435

September 22, 2004

Ms. Susan McBride
[Redacted]
Forth Worth, TX 76118

Dear Ms. McBride:

I have received and approved the prospectus entitled "A Study Examining the Effect of Inductions on Primary Cesarean Delivery" for your Dissertation research project.

Best wishes to you in the research and writing of your project.

Sincerely yours,

[Redacted Signature]

Jennifer L. Martin, Ph.D.
Dean of the Graduate School

ekd

cc: Dr. Patti Hamilton, College of Nursing
Dr. Marcia Hern, Dean, College of Nursing

Think SUCCESS  Think TWU

SUSAN MCBRIDE, RN, MS

OBJECTIVE

As a Clinician with over 20 years of experience in clinical, management, healthcare informatics & outcomes management capacities, my professional objective is to contribute to education, research and development of measuring cost & quality of healthcare services with a focus on healthcare informatics & improving health and clinical outcomes of populations.

EMPLOYMENT

DALLAS FORT WORTH HOSPITAL COUNCIL

Vice President of the DFWHC Data Initiative, 2002-Present The Data Initiative is an Education and Research foundation dedicated to supporting hospitals in quality & patient safety initiatives, and data collection, analysis and reporting of information that supports quality & patient safety. Responsibilities include: coordination of research, education, study design, data collection, reporting and analysis for community-wide initiatives for the Hospital Council representing 70 hospitals in North Central Texas area. Additionally, responsibilities include oversight of the data submission process for 64 hospitals for the Texas state public domain data initiative.

TEXAS HEALTH RESOURCES

Director of Outcomes Management, 1997-2002 Responsibilities include: study design, project management, database management, data collection (abstract & survey), statistical analysis, reporting, and support of the Quality management departments through consulting, education and training. Contributions include:

- 1997-98 Stabilization & Restructure of the Mediquial Atlas Database and its use (move from costly abstracting process to use of administrative Atlas Module). This resulted in reorganization of the department with cost savings of approximately \$50,000.00.
 - Created a mechanism for loading TSI versus SMS data preventing a costly rewrite of the interface between SMS and Atlas (estimate of \$30,000 for HL7 interface)
- Automation of Quality System Indicators creating additional drill down capability to be used by Process Improvement Teams to address potential quality or efficiency issues.
- Designed database for Fast Track Process Improvement using Cognos Power Play that will address both clinical and operational opportunities for improvement.
- Initiated Process Improvement Teams for Data Integrity Issues for C-Section data and Cardiology Cath Lab data.
- Developed "real time" data analysis capabilities using SPSS for Cardiology, Cardiac Surgery, Infection Control, & Surgical Data Outcomes Data—working interactively with SPSS and physicians to manipulate and analyze data in a "real-time" interactive mode.
- Brought programs back into line with Up-to-date Reporting, this includes: System Indicators to the Board, Cardiac Summit data, and

Health Status Questionnaire (HSQ) studies.

- Created physician profiles for cardiology, cardiac surgery, and O.B. Standardized and automated reporting using SPSS syntax.
- Created Risk model using logistic regression for risk of mortality for cardiac surgery program.
- Developed automated methodology for examining infection rates using the new CDC Guidelines for Preventing Surgical Site Infection (1999) and the SurgiServ Clinical data.
- Coordinated the development of Annual Trending Analysis for O.B., Cardiac Surgery, & Cardiology.
- Responsible for the THCIC data submission cleansing and submission process for the state public domain data initiative for all PHS hospitals.
- Coordinate compliance issues for state, federal and accreditation projects, as needed for all THR hospitals.
- Member of the State's Quality Methods Technical Advisor Committee responsible for advising the state on appropriate reporting methods using administrative billing data.
- Brought up a Cardiac Clinical data repository for Outcomes data analysis and Case Management, responsible for technical development and expansion of the program system-wide in 3 THR hospitals.

PRESBYTERIAN HOSPITAL OF DALLAS

Clinical Nurse Specialist Consultant, 1995-1997

- Assisted with reviewing & updating Policy & Procedure for the Operating Room in preparation for online document management
- Developed Perioperative Internship Curriculum & Assisted with the Instruction of the Didactic
- Updated all education and competency training documentation
- Clinical resource nurse for all specialty areas
- Assisted with the Preparation for JCAHO review
- Developed Orientation Programs for RNs, Scrub Technicians, and PSAs
- Represented the OR on various hospital-wide committees
- Initiated critical pathway development for Total Joints

SKJ, CONSULTING

Consultant, 1995-1997

- Consulted with organizations on detailed database development & redesign
- Developed an education program for Johnson & Johnson Central Europe on Infection Control
- Consulted with various payers & providers on negotiations of managed care arrangements & cost containment efforts
- Reviewed & negotiated catastrophic health care events & policy coverage for the consumer

SELECTPLUS, INC. (Acquired by Western Fidelity Insurance in 1992 & by Dun & Bradstreet & EDS in 1993)

Chief Operating Officer, Co-founder 1991-1992

Chief Executive Officer Selectplus, Board of Director Western Fidelity Insurance Company 1992-1993

President-Selectplus, Division of Dun & Bradstreet Healthcare 1993-1995

- Founder of Selectplus, Product Lines developed include:
 1. Detailed, usual & customary cost comparison database that encompassed more than half of the US hospitals

2. *Universal charge master, which created a common language at the line item level for hospitals and managed care entities*
 3. *Resource pathway for measurement of cost and resource utilization from physician-to-physician or facility-to-facility on a line item level*
- Successfully engineered the sale of Selectplus to Dun & Bradstreet Healthcare
 - Maintained position as President of Selectplus, Division over the Selectplus Products Line
 - Served as V.P. of Sales & Marketing directing sales representatives and marketing associates for Dun & Bradstreet Healthcare's Compete Product (an outcome analysis tool for payers, providers, and managed care entities)
 - Assisted with Product Development of Dun & Bradstreet Healthcare's HEDIS Software and Compete 2.0
 - Worked with numerous database sets, examples include: charge master billing data, cost accounting data, clinical data repository data, HEDIS data, UB82/92 data
 - Worked with different Software developed by Mediquel, DBHC, & EDS
 - Experience working with teams utilizing pattern detection tools, fuzzy logic, neural nets, and case tools to build logical models for large clinical databases
 - Served as resource consultant to EDS & customers on data warehouse development teams for HEDIS warehousing & clinical database repositories.

DR. MANUCHER NAZARIAN, MD

Clinical Specialist, RN First Assistant, 1990-1992

- First Assisted in Cardiovascular & Vascular Surgery
- Operated the Cardiopulmonary Bypass Pump
- Assisted with the clinical follow up in the office, hospital, & ICU
- Assisted with patient teaching
- Automated the Billing System in the Physician's office, reviewed appropriate coding for all cardiovascular procedures

HARRIS METHODIST FORT WORTH

Level IV Staff Nurse, 1985-90, PRN 1992-1995.

- Scrubbed and circulated in orthopedics, neurosurgery, general surgery, cardiovascular, ENT, ophthalmology and plastics
- Charge nurse on weekends and holidays
- Education Coordinator: Assisted with development and instruction on Internships, precepted new employees

ARLINGTON MEMORIAL HOSPITAL

Scrub Technician 1980-1982; Staff Nurse, 1982-1985

- Scrubbed and circulated in orthopedics, neurosurgery, general surgery, cardiovascular, ENT, and plastics

EDUCATION

TEXAS WOMAN'S UNIVERSITY

Doctorate Program Nursing 1997-Present

Completed all doctoral level statistical courses with advanced training in multivariate analysis. Competency testing in statistics complete for doctorate in Nursing Science. Research interest is in using advanced informatics capabilities

to design clinical outcomes research. Specifically interested in testing logistic regression versus artificial intelligence/data mining techniques to determine best methods for detecting significant prediction capabilities in large clinical data sets.

Includes the following statistical and advanced analytic methods:

- Stat I, II, III (3 courses)
- Systematic Advanced Inquiry in Nursing
- Clinical Nursing Research Instrumentation Development
- Advanced Statistical Analytic Methods (Statistics Department)
- Advanced Data Mining Techniques with Secondary Data Sources

NEW ENGLAND EPIDEMIOLOGY INSTITUTE SUMMER PROGRAM

June 1998

Completed Logistic Regression Modeling Course taught by Stanley Lemeshow
Completed Course in Epidemiological Methods for Health Care Utilization and Outcomes Research

TEXAS WOMAN'S UNIVERSITY

Master of Science in Nursing, 1995

Major - Clinical Nurse Specialist Track

UNIVERSITY OF TEXAS AT ARLINGTON

Bachelor of Science in Nursing, December 1982

TEXAS A&M UNIVERSITY

Prenursing, 1976-1978

CERTIFICATIONS

Certified, Perioperative Nursing, CNOR, 1989- 1995

PROFESSIONAL AFFILIATIONS

Association of Operating Room Nurses (AORN), Dallas Chapter

Texas Nurse's Association

American Nurse's Association

National League of Nursing

RECENT PUBLICATIONS

Rowton, A. and McBride, S., (2000) Drilling down for performance improvement data. In J. Schilp and R. Gilbreath (Eds), *DataQuest: Finding and using integrated data for performance improvement*. San Francisco: Jossey-Bass Publishing.

McBride, Susan "Outcomes Management, Part I", (1999), Long Term Care Network A Division of Primedia Healthcare, EDA 318-0309.

McBride, Susan "Outcomes Management, Part II", (1999). Long Term Care Network A Division of Primedia Healthcare, EDA 318-0310.

McBride, Susan "The Quest for Quality", (1999). Long Term Care Network A Division of Primedia Healthcare, EDA 318-0345.

Gilder, R., Koch, R. & McBride, S. (1999). "Enhancing perioperative nursing effectiveness through informatics", *AORN Journal*, 1999 May, 69:5, 978, 981-2,

Koch, F., McBride, S., & Gilder, R. (1997) "Nursing Informatics", Infection Control & Sterilization Technology, April.

RECENT PRESENTATIONS

Video Production Satellite Broadcast: "Outcomes Management, Part I", (February, 1999), Long Term Care Network A Division of Primedia Healthcare.

Video Production Satellite Broadcast: "Outcomes Management, Part II", (February, 1999). Long Term Care Network A Division of Primedia Healthcare.

"Complying with JCAHO Requirements for Management of Information, Quality and Patient Outcomes." AORN Congress, San Fransisco, California (April, 1999).

Video Production Satellite Broadcast: "The Quest for Quality", (August, 1999). Long Term Care Network A Division of Primedia Healthcare.

"Complying with JCAHO Requirements for Management of Information, Quality and Patient Outcomes." AORN Perioperative Specialty Conference, San Diego, California, (September, 1999).

Video Production Satellite Broadcast: "The Oryx Initiative": Facilitated and organized a panel discussion on the JCAHO Oryx Core Measures with Texas Hospital Association Director of Quality, JCAHO Vice President over Quality Measurement and Texas-based Physician over Quality for Columbia Hospitals (May, 2000). Produced for the Physician Education Series, Nursing Network & the Long Term Care Network by Primedia Healthcare Productions.