## Effects of Adverse Birth Events on Maternal Mood, Maternal Functional Status and Infant Care

by

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University of Pittsburgh, 2007

Unplanned, adverse events during labor or delivery may generate a negative response for the mother during the early postpartum period, resulting in disruption of usual functioning and mood. Alterations in maternal mood can lead to a more debilitating condition known as Postpartum Depression. Postpartum Depression negatively affects the quality of life and functional status of mothers and infants. High levels of maternal depressive symptoms are associated with parenting, infant attachment, behavioral problems and cognition (Beck 2002). Little research has been completed exploring the relationship of adverse, unplanned events in labor or delivery and maternal mood, functional status and infant care in the immediate postpartum period. The purpose of this study was to examine the relationship of adverse events in labor or delivery and mood, functional status and infant care at 2-weeks postpartum. The secondary aim was to explore the role of social support as a possible moderator in the relationship between adverse birth events and maternal outcomes. A secondary analysis of data was performed using data collected in a descriptive, longitudinal study examining the effects of antidepressant use during pregnancy. Participants included a convenience sample of 123 women. The main outcome measures included maternal mood, functional status, and infant care at 2-weeks postpartum. Adverse events in labor or delivery did not significantly predict mood (odds ratio =1.34, p=.536), functional status ( $R^2$  change = .001, p=.66), or infant care ( $R^2$ change=.004, p=.48) at 2-weeks postpartum when controlling for depression during pregnancy,

antidepressant use at delivery, education level, age, and parity. Social support had significant effects on mood (p=.02), functional status (p=.014), and infant care (p < .001) but did not moderate the effect of adverse events when predicting mood (odds ratio=1.01, p=.045), functional status ( $R^2$  change=.009, p=.056) and infant care ( $R^2$  change<.001, p=.92). The occurrence of an adverse event in labor or delivery does not appear to predict alterations in mood, functional status, or infant care at 2-weeks postpartum. Although social support does appear to be related to mood, functional status and infant care, it does not appear to moderate the effect of adverse events on the selected outcomes.

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#### PREFACE

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Dylan, Drew, and Joseph. They continue to be the inspiration for everything I do. I hope that by completing this program, they too will be able to see that goals and perseverance do pay off.

#### **1.0 INTRODUCTION**

#### 1.1 PURPOSE

The purpose of this study was to examine the relationship of adverse birth events on maternal outcomes in the early postpartum period. The media often portrays a very idyllic view of the birthing event, with joyful pregnancies, seemingly effortless labor, and uneventful, quick deliveries. However, data regarding birth events are not consistent with this portrayal. Unexpected complications occur in labor or deliveries that are often confusing to the pregnant, laboring woman. In 2005, over 210,000 deliveries were the result of precipitous, prolonged or dysfunctional labor (National Vital Statistics Report, 2006). Breech or atypical fetal presentations accounted for over 170, 000 births, and fetal distress in labor was evident in over 132,000 deliveries in 2005 (National Vital Statistics Report, 2006). Eight percent of all deliveries are diagnosed with dystocia in some form (Algovik, et al, 2004).

paragraph.

Vaginal delivery is the expected mode of delivery, and women are often ill-prepared for circumstances that result in more aggressive intervention. In childbirth classes, women are told that one in four women is likely to have a cesarean delivery (Fawcett, et al, 2005). In spite of this incidence, qualitative analysis of post delivery interviews confirmed that women felt

unprepared for operative delivery and thought that their birth plan or antenatal classes had not prepared them adequately for the birth event (Murphy, et al, 2003).

As noted by Waldenstrom, a woman's dissatisfaction with her birth may affect her emotional well-being and willingness to have another baby (Waldenstrom, et al, 2004). Alterations in maternal mood can go largely unrecognized during the postpartum period. Most people consider the "baby blues" a normal part of childbearing; however, alterations in maternal mood can lead to a more debilitating condition known as Postpartum Depression (PPD).

Prevalence rates of PPD are estimated at 14.5% (Gavin, et al). In other words, approximately one out of seven new mothers experiences depression (Gaynes, et al, 2005). PPD affects 500,000 mothers and infants each year with subsequent recurrence rates in future pregnancies at about 25% ((Wisner, et al, 2002; Wisner, et al, 2004).

Altered maternal mood can have negative effects for mothers including reduced quality of life, reduced functional status, and altered parenting skills (Beck, 2002). If left untreated, altered maternal mood can result in prolonged psychiatric illness and more serious detriment for the entire family. Altered maternal mood can also have negative effects for infants including reduced mother-infant attachment, increased infant behavioral problems, and decreased infant cognition (Beck, 2002). Early screening of altered maternal mood, and treatment of PPD, is critical in reducing potential downstream effects on infant development and future psychiatric illness in children.

This study focused on a variety of negative birth events in contrast to prior studies that have specified either cesarean section or assisted vaginal delivery compared to spontaneous vaginal delivery. The concepts central to this exploration are depicted in the conceptual framework for the study (Figure 1).

## **1.2 CONCEPTUAL FRAMEWORK**

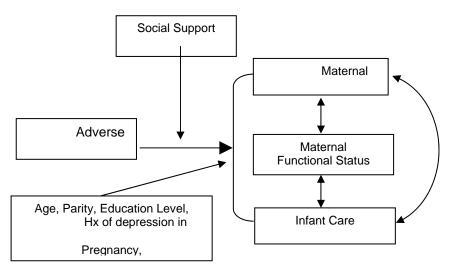


Figure 1. Conceptual Framework for the Study of Adverse Birth Events, Maternal Mood, Maternal Functional Status, and Infant Care

An adverse birth event is likely to precipitate alterations in maternal mood, functional status, and infant care. There is a need to focus on alterations in maternal mood early in the postpartum period beyond what is typically expected. Alterations in maternal mood include depressive symptoms which can include fatigue (beyond what is expected for a new mother), feelings of worthlessness or guilt, diminished ability to concentrate, insomnia, or diminished interest or pleasure (Wisner, et al, 2004). Alterations in functional status after childbirth include the inability to perform tasks at the level of functioning that was exhibited prior to childbirth. Such

activities may include household chores, social and community activities, self-care activities and occupational activities (Fawcett, et al, 1998). Infant care, although not exhibited prior to childbirth, is a primary goal of successful functional status after childbirth. It is possible that women who had negative birth experiences may need to meet their own emotional needs before they can meet those of their infants, or may feel obligated to meet the infant's needs, but not their own (Kennell, et al ,1979).

Previous studies have shown that social support is a moderating factor in postpartum recovery. Social support, defined as a well-intentioned action that is given willingly to a person with whom there is a personal relationship and that produces an immediate or delayed positive response in the recipient, has been studied extensively in pregnancy and parenting (Hupcey, 1998). Receiving social support early in the postpartum period has been linked to better maternal-child interactions and smaller incidence of PPD (Logsdon, et al, 1994). Prior research findings suggest several intervention points for new mothers including adequate social support screening (Soet, et al, 2003).

The acknowledgement that other factors can also greatly impact a mother's birth outcomes were addressed as covariates influencing the maternal response. Maternal age, parity and education level can influence a mother's reaction to her birth. Also, prior history of depression and antidepressant use during delivery were also examined as they could directly contribute to a mother's postpartum mental state.

By taking into account covariates which are thought to influence the maternal outcomes, identifying actual adverse birth events from the medical record, and measuring social support which is believed to moderate the maternal outcomes, this study was able to determine if there is in fact a relationship between unplanned, adverse birth events and specific maternal outcomes.

In this study, both women who have experienced an adverse birth event, as well as women with uncomplicated vaginal deliveries, were investigated in an attempt to determine if there is a significant relationship with maternal mood, functional status and infant care in the early postpartum period.

#### **1.3** SPECIFIC AIMS

The purpose of this study was to examine the relationship of adverse birth events on maternal outcomes in the early postpartum period. More specifically, the primary aim was to examine the relationship between unplanned, adverse birth events during labor or delivery and maternal mood, maternal functional status, and infant care at 2 weeks postpartum. It was hypothesized that unplanned, adverse birth events were associated with altered maternal mood, decreased maternal functional status and decreased comfort in infant care at 2 weeks postpartum.

The secondary aim for this study was to explore if social support was a moderator in the relationship between unplanned, adverse birth events and maternal mood, functional status, and infant care at 2 weeks postpartum. Previous studies have shown that social support is a moderating factor in postpartum recovery. It was hypothesized that social support influenced the maternal response at 2 weeks postpartum to negative birth events.

#### 1.4 **RESEARCH QUESTIONS**

The research questions for this study were as follows:

- 1. Is there a relationship between unplanned, adverse birth events and maternal mood, maternal functional status, and infant care at 2 weeks postpartum?
- 2. Does social support serve as a moderator in the relationship between unplanned, adverse birth events and maternal mood, maternal functional status, and infant care at 2 weeks postpartum?

### **1.5 SIGNIFICANCE OF THE STUDY**

Little research has been completed exploring the relationship of actual adverse, unplanned events in labor or delivery and maternal outcomes, specifically maternal mood, functional status and infant care, in the immediate postpartum period. Much of the literature addresses high-risk pregnancy events, such as preterm labor, that have obvious long-term consequences. However, when the pregnancy has complications, the events in labor or delivery are often expected. When the pregnancy is uncomplicated, adverse events in labor or delivery are often not expected. Understanding the relationship between unplanned, adverse birth events and maternal outcomes should assist providers in making decisions regarding treatment during the immediate postpartum period. By identifying and clarifying the need for such treatments during the immediate postpartum period, healthcare providers can seek to minimize the negative effects of traumatic births and potentially decrease long- term morbidity among postpartum women. In addition to improving patient outcomes, health care costs can be minimized by eliminating the need for further care and evaluation.

#### 2.0 BACKGROUND

### 2.1 MATERNAL CHARACTERISTICS AND ADVERSE BIRTH EVENTS

The purpose of this study was to examine the relationship between unplanned, adverse birth events and maternal outcomes. Adverse birth events in labor or delivery may result in a negative birth experience. Negative birth experiences have been the subject of both quantitative and qualitative research in the past. The birth of a child is a life-altering and memorable event. In fact, women can accurately remember details of their first births even 20 years later (Simpkin, 1992). Not all births are positive experiences. In a prospective, longitudinal study done by Creedy, et al, examining women (n=499) in the third trimester and following them until 4 to 6 weeks postpartum, it was discovered that one in three women (33%) identified a negative birth event and reported the presence of at least three trauma symptoms following the birth of their infant (Creedy, et al, 2000). When research studies have considered the question of negative birth experiences, the general paradigm is to compare emotional reactions to cesarean sections and vaginal births; however, the types and circumstances surrounding a negative birth experience can encompass many different events. In 2004, Waldenstrom completed a longitudinal study investigating the prevalence and risk factors of a negative birth experience in a national sample (Waldenstrom, et al, 2004). In this study, it was found that risk factors for a negative birth experience were related to unexpected medical problems and participants' social background.

There are many examples of unplanned, adverse birth events that can occur during labor or delivery. A prime example of an unplanned, adverse birth event in labor or delivery includes the use of forceps. Forceps are an instrument varying in size and shape but typically encompassing 2 crossing branches, or blades, that are designed for extraction of the fetus while in vertex position (Cunningham, et al, 1993). The practice of using forceps for assisted delivery is losing popularity as new OB/GYNs are not being adequately trained in their use, and vacuum extraction has become the method of choice for assisted vaginal delivery.

A vacuum extractor, also used to assist vaginal delivery, is a device that attaches traction by suction to the fetal scalp. The fetus is then manually extracted from the birth canal by the physician (Cunningham, et al, 1993). Use of forceps to assist with vaginal delivery, as well as the use of a vacuum extractor, is an unplanned, often painful event that may leave the mother in need of significant physical attention following her delivery. Often these procedures are related to prolonged second stage of labor, birth weight and head circumference, and can result in extensive perineal lacerations involving the anal sphincter (Hudelist, et al, 2005). Usually combined with medio-lateral episiotomies, these types of deliveries can result not only in trauma to the mother, but can have grave consequences to the infant's physical well-being as well (Hudelist, et al, 2005). Thus, leaving the mother not only in distress regarding her own emotional and physical trauma, but also in distress because of her infant's status following delivery.

Another type of unplanned, adverse event in labor or delivery is the need for an unplanned caesarean section. Typical reasons cited for an unplanned cesarean section during labor are as follows:

• Failure to progress (FTP) in labor (insufficient cervical dilatation and effacement);

- Cephalo-pelvic disproportion (CPD) meaning the fetal head does not fit in through the mother's pelvis;
- Failure to descend (FTD) into the birth canal (inadequate station). (Cunningham, et al, 1993).

A prolonged stage of labor may be also interpreted as an unplanned, adverse event. There are three stages of labor. The first stage is defined as the commencement of uterine contractions having sufficient frequency, intensity and duration to bring about cervical changes and ends when the cervix is fully dilated (Cunningham, et al, 1993). The second stage begins when dilatation is complete and ends with delivery of the fetus. During this stage, the mother is usually 'pushing'. The third stage begins immediately after the delivery of the fetus and ends with the delivery of the placenta and fetal membranes (Cunningham, et al, 1993).

The average duration of the first stage of labor is about 8 hours for nulliparous women and 5 hours for multiparous women (Cunningham, et al, 1993). In this study, prolonged first stage of labor was defined as exceeding 20 hours for nulliparous women and exceeding 14 hours in multiparous women. The median duration of the second stage of labor in nulliparous women was 50 minutes and 20 minutes for multiparous women (Cunningham, et al, 1993). Prolonged second stage of labor was defined as exceeding 2 hours in nulliparous women and 1.5 hours in multiparous women.

As opposed to prolonged labor, women can also suffer negative effects from precipitate labor. Precipitate delivery is defined as extremely rapid labor and delivery and usually is the result of abnormally low resistance of the soft parts of the birth canal accompanied by abnormally strong contractions (Cunningham, et al, 1993). Occasionally, precipitate delivery is the result of absence of painful sensations and thus a lack of awareness of vigorous labor

(Cunningham, et al, 1993). In either case, the presence of an intense, unexpected labor process can be considered an adverse labor event. For this study, precipitate delivery was defined as labor and delivery occurring in less than 3 hours.

Significant blood loss or extensive perineal lacerations are other types of unplanned, adverse events. Significant blood loss after the third stage of labor has been historically defined as 500 cubic centimeters or more, although this figure is probably low considering clinicians do not have accurate ability to quantify blood loss (Cunningham, et al, 1993).

The concept of significant perineal lacerations can be reserved for third and fourth degree vaginal lacerations. These more serious types of lacerations are often associated with an episiotomy, and less significant (first and second degree) lacerations (Cunningham, et al, 1993). Third degree lacerations extend through the skin, mucous membrane and perineal body, and involve the anal sphincter. Fourth degree lacerations are distinguished by a third degree tear that extends through the rectal mucosa to expose the lumen of the rectum (Cunningham, et al, 1993). Tears of the urethra are also likely to occur with fourth degree lacerations and may bleed profusely. Repair of third and fourth degree lacerations is complicated by the irregular lines of tissue cleavage. Issues with healing and post-operative pain are often more significant with these types of lacerations (Cunningham, et al, 1993).

Placental abruption is another example of an unplanned, adverse event. Placental abruption is defined as the separation of the placenta from its site of implantation before the delivery of the fetus. Bleeding from placental abruption lies between the placental membranes and the uterus and then escapes through the cervix causing an external hemorrhage (Cunningham, et al, 1993). Occasionally, the bleeding remains internal between the placental

membranes and the uterus, causing an internal hemorrhage and more serious consequences (Cunningham, et al, 1993).

The presence of fetal distress as evidenced by fetal heart rate monitoring is another type of adverse event in labor. Often very subjective to interpretation and difficult to diagnose, fetal distress is a diagnosis based on fetal heart rate patterns. Often terms 'reassuring' and 'nonreassuring' heart rate are used instead to eliminate some of the uncertainty in the diagnosis (Cunningham, et al, 1993). Fetal heart rate patterns are dynamic and can change rapidly (Cunningham, et al, 1993). The patterns are usually termed fetal distress when the physician can no longer assuage doubts about the condition of the fetus, and is no longer confident that the fetus is not being compromised (Cunningham, et al, 1993). A variety of interventions can occur in labor once it is believed fetal well-being is being compromised, and emergency cesarean section or assisted vaginal delivery may result (Cunningham, et al, 1993).

Another type of adverse event can involve issues with the amniotic fluid in labor. Amniofusion is a therapy designed to improve symptoms of fetal distress by infusing warm saline via an intrauterine pressure catheter into the uterus (Cunningham, et al, 1993). Fetal distress in this case could have been caused by meconium-staining, compressed cord, or oligohydramnios – a decreased amount of amniotic fluid. Amniofusion has been gaining in popularity as the rates of fetal scalp blood sampling are steadily declining. Meconium-staining are about 12 -20 percent of all pregnancies (Cunningham, et al, 1993). Neonatal morbidity and mortality can be associated with meconium-staining as a result of fetal aspiration (Cunningham, et al, 1993). Requirement of an amniofusion in labor or meconium-staining of the amniotic fluid can be considered adverse, unplanned events that occur in labor.

Preeclampsia that first presents in labor is another example of an adverse event in labor. Pregnancy-induced hypertension can be categorized as preeclampsia when there is the development of hypertension plus proteinuria, and/ or edema in the mother (Cunningham, et al, 1993). In some cases, signs of preeclampsia do not present until the women is in labor and subsequently require aggressive intervention, and possibly emergent delivery to alleviate the symptoms and decrease potentially dangerous maternal and neonatal effects.

Another example of an adverse event is the occurrence of a cord prolapse in labor. Umbilical cord prolapse is a serious complication that is facilitated by an imperfect adaptation between the presenting fetal part and the mother's pelvic inlet causing the cord to prolapse through the birth canal (Cunningham, et al, 1993). Sometimes it is a result of artificial rupture of the amniotic membranes in labor, or a fetal breech presentation (Cunningham, et al, 1993). Failure to deliver the fetus quickly can result in fetal demise.

The final example of an unplanned, adverse event is a shoulder dystocia during the second stage of labor. Shoulder dystocia occurs in less than 2% of all deliveries and severity varies by definition (Cunningham, et al, 1993). Caused by macrosomia, or an increase in fetal body size in relation to the fetal head size, it occurs when the head delivers, but the body remains inside the birth canal. There are various procedures to remedy the crisis. The occurrence of a shoulder dystocia often results in significant fetal morbidity and mortality, especially if not intervened correctly (Cunningham, et al, 1993).

Although I have mentioned the most common types of unplanned events in labor, there are many, more obscure events that can occur. Most adverse events are not mutually exclusive, thus a woman may have more than one event. For instance, prolonged second stage of labor

could result in the need for a vacuum extraction. Another example could be preeclampsia that first presents in labor and necessitates the need for an unplanned, cesarean section.

Term infants are often required to go to the neonatal intensive care unit (NICU) following an unplanned, adverse birth event. Most women probably believe that if all of their prenatal screening procedures were unremarkable, and they made it past 37 weeks gestation, their infants will be fine. The emotional effects of a term infant needing to get specialized care following a delivery event can be detrimental to a mother's well-being and can impact her ability and willingness to adequately care for her needs (Waldenstrom, et al, 2004).

The consequences of an adverse birth event can be evident across the continuum of physical to mental health. The progress of recognizing the impact of adverse birth events has led to explorations of the physical effects and method of delivery. Lydon-Rochelle, Holt and Martin assessed the association between method of delivery and the general health status, sexual, bowel and urinary functioning of primiparous women as measured at 7 weeks postpartum (Lydon-Rochelle, et al, 2001). At 7 weeks postpartum, women who had cesarean or assisted vaginal deliveries reported significantly lower postpartum general health status scores than women with unassisted vaginal deliveries reported significantly lower postpart sort vacuum extraction). Additionally, women with assisted vaginal deliveries reported significantly worse sexual, bowel and urinary functioning. The results suggest that more careful attention to the postpartum general health and sexual functioning of women with cesarean and assisted vaginal deliveries may be merited.

Similar conclusions regarding method of delivery were found in subsequent studies. Murphy, Pope, Frost, and Liebling completed a qualitative study (n=27 women) and determined that operative delivery had a noticeable impact on women's views about future pregnancy and delivery (Murphy, et al, 2003). Three important conclusions were reached by the investigators of this study: (1) antenatal variables did not contribute to the development of acute or chronic trauma symptoms, (2) women who experienced both a high level of obstetric intervention and dissatisfaction with their intrapartum care were more likely to develop trauma symptoms than women who received a high level of obstetric intervention or women who perceived their care to be inadequate, and (3) Posttraumatic Stress Disorder (PTSD) is evident in women after a childbirth experience that include intrusive obstetric intervention during labor and delivery, and the care provided to women in labor.

Continuing with research in the area of method of delivery and physical effects, Hudelist, et al, examined risk factors for third and fourth degree perineal tears in patients having either a spontaneous vaginal delivery or an assisted vaginal delivery with forceps combined with a medio-lateral episiotomy (Hudelist, et al, 2005). Their retrospective, case-control study of 5,377 women revealed that nulliparity, prolonged first and second stage of labor, high birth weight, and type of delivery were identified as risk factors for perineal trauma. When the risk factors were entered into a multivariate regression model, high birth weight and episiotomy in conjunction with forceps proved to be the most significant risk factors for trauma. Perineal trauma sustained as a result of unplanned events, such as assisted vaginal birth, proved to have a significant effect on women in the postpartum period; thus, potentially interfering with their postpartum functional status.

Similarly, Lydon-Rochellle, et al, studied the association of method of delivery, including unplanned cesarean section and assisted vaginal delivery, and the rate of maternal rehospitalization in a retrospective cohort study (n=256,795) (Lydon-Rochelle, et al, 2000). Compared with women who had spontaneous vaginal deliveries, women with cesarean sections and assisted vaginal delivery were significantly more likely to be rehospitalized. It can be

inferred from their findings that rehospitalization could have potential negative effects on both the mother's functional status and general mental well-being.

Research has shown that women who had emergency cesarean sections in labor following complete cervical dilatation were more likely to have intra-operative trauma and neonatal asphyxia (Allen, et al, 2005). Although there is a body of literature regarding outcomes with elective cesarean sections, Allen's, et al, study supports the suggestion that emergency cesarean delivery, particularly when complete cervical dilatation has occurred, has significant effects on maternal morbidity.

Gardella, et al, also completed a retrospective, cohort study examining the effects of sequential use of vacuum and forceps for assisted vaginal delivery on both neonatal and maternal outcomes (Gardella, et al, 2001). Their study compared 3,741 women who had both vacuum and forceps assistance in their deliveries with 11, 223 women with spontaneous vaginal deliveries. They found that the risk of using both instruments greatly increased the risk of neonatal and maternal outcomes, such as neonatal intracranial hemorrhage, nenonatal brachial plexus injury, neonatal facial nerve damage, maternal perineal trauma, hematoma and postpartum hemorrhage. The findings from their study suggest a synergistic interaction effect of multiple instrument use during a single delivery; thus, reinforcing the premise that multiple unplanned events in delivery could be even more detrimental than a single unplanned event.

Similar to physical effects as a result of labor and delivery events, many researchers have also studied mental health effects of unplanned, adverse events. Koo, et al, completed a retrospective cohort study examining the risk of alterations in maternal mood after emergency delivery (Koo, et al, 2003). Using the Edinburgh Postnatal Depression Scale (EPDS) as their measure and chi square statistical analysis between groups, they found that at 6 weeks postpartum, when compared with women having non-emergency deliveries (n=191), women having emergency delivery (n=55) had about twice the risk of developing depressive symptoms. The main finding of their study suggested that women who underwent an emergency delivery have an increased risk for developing PPD and that postnatal follow up of these women could be beneficial in screening for alterations in mood.

In contrast, Patel, et al, found that in their prospective cohort study (n=14,663), women who planned a spontaneous vaginal delivery and required an emergency delivery, whether it be a cesarean section or assisted vaginal delivery, were not significantly at increased risk for postnatal depression at 8 weeks postpartum when compared to women with spontaneous vaginal deliveries (Patel, et al, 2005). Similarly, they found that elective cesarean section did not increase the risk for PPD; thus, emphasizing the importance of women's ability to make informed decisions regarding the association of mode of delivery and PPD.

Opposed to studying maternal outcomes following mode of delivery, van de Pol, et al, studied psychosocial factors as predictors of mode of delivery on a group of 354 healthy nulliparous women (van de Pol, et al, 2006). They found that the only significant predictors of operative delivery after spontaneous onset of labor are high birth weight, non-occiput anterior presentation, advanced gestational age, and fetal distress during labor. Their findings confirm that certain psychosocial traits, such as level of social support, depressive symptoms in pregnancy, and specific personality traits in pregnancy, in pregnancy although they can affect postpartum outcomes, do not predict or protect against assisted vaginal delivery or emergency cesarean section.

Similarly, Wu, et al, studied whether or not mood disturbances in pregnancy were associated with higher frequency of cesarean or assisted vaginal delivery (Wu, et al, 2002). Of

their study of 264 women, there was no statistically significant difference between the rate of cesarean section or assisted vaginal delivery in women with and without elevated depression scores in pregnancy.

Womens' perceptions, rather than the actual medical acknowledgement of an adverse event, may impact a women's response to the event. For example, if a new mother has a prolonged second stage of labor that results in a vacuum extraction, her labor would be considered as having an adverse event as defined in this study. However, for the first time mother, this may appear normal and part of the labor and delivery process. In this study, we are not considering the mother's perception of her labor and delivery, but rather just the presence of one or more adverse, unplanned events as recorded on the woman's medical record.

Beck (2004), following her phenomenologic study investigating women's experiences of birth trauma, concluded that birth trauma "lies in the eyes of the beholder" meaning that mothers often viewed their birth as traumatic, whereas physicians viewed the birth as routine, and viceversa. Such findings, although limited in scope, may warrant future studies including the mother's perception of her labor and delivery to determine if there is a relationship between the mother's perception and the actual events experienced, as well as to determine if there is a relationship between the mother's perception and the specified maternal outcomes.

Similarly, there may be psychosocial or physical health circumstances that influence the maternal response to an adverse birth event. For instance, infertility may be one of those circumstances in which the feelings of elation in finally achieving a pregnancy that results in the delivery of the highly desired infant may surpass the definition of any aspect of the birth as adverse. In this study, evaluation of certain circumstances, such as infertility, was not being

considered; therefore potentially minimizing, or in some cases exaggerating, the effect of the adverse birth event.

Given the available research evidence, the following factors merit acknowledgement as significant risk factors for alterations in maternal outcomes, particularly mood in the early postpartum period: presence of prenatal depression symptoms which may or may not require antidepressant use up until delivery, inadequate social support, very young mothers, and lower socio-economic status (Horowitz & Goodman, 2004). As a result, those factors have been selected to serve as covariates influencing the maternal outcomes identified for this study.

Research regarding history of depression both pre-pregnancy and prenatally will be discussed further in the next section. Both factors have been the strongest predictors to date regarding development of mood alterations in the postpartum period. Due to the large amounts of literature supporting social support's influential role in maternal outcomes, it seemed probable that it would serve as a moderator in the relationship between birth events and maternal outcomes. In addition, when considering the outcome of infant care particularly, parity seemed to be a likely covariate. Having had a child previously, women should be more knowledgeable regarding infant care, and perhaps more aware of their expected functional status and more prepared to function in their required roles. Education level, the measure used in this study, has often been representative of socio-economic status in research. Finally, maternal age was selected as a covariate not only because of support from the literature noting differences with younger mothers, but because of the assumption that women in their late teens may not have had the same life experience preparing them for the life changes that are expected to occur with the birth of a child. There are noted differences between maturity levels of women in their early 20s

as opposed to women in their mid-30s. Therefore, maternal age was selected as covariate influencing the maternal mood, functional status and infant care in the early postpartum period.

#### 2.2 SOCIAL SUPPORT

A significant body of research has demonstrated that social support is facilitative of well-being during major life transitions and periods of acute stress (Cohen & Wills, 1985). Childbirth should be considered a major life transition and as such it can be assumed that social support is potentially influential in developing maternal outcomes following delivery. Historically, social support, a multi-faceted and widely studied concept, has been difficult to define, conceptualize and measure (Hupcey, 1998). There are many definitions for social support in the literature, although many of them tend to be vague and simplistic. There are various models of social support and many different approaches used for examining the concept (Hupcey, 1998). Social support has been measured in a variety of ways including perceived support, adequacy of support network, and satisfaction with support (Logsdon & Winders, 2003).

Sources of social support desired in childbirth have been studied. Although prior research has found that the source of support differed based on age, socio-economic status and ethnicity, the partner (baby's father) was an important part of emotional, informational, and instrumental support (McVeigh, 2000). Similarly, support given by health care providers and delivery attendants has been shown to be influential.

Social support in labor and postpartum has been studied in conjunction with maternal mood, functional status and infant care. Social support has also been studied with the broader

concept of mothering and has been found to cushion the experience of moving into the motherhood role and critical for maternal role adaptation (McVeigh, 2000). In a prospective, longitudinal study completed by McVeigh examining the relationship between satisfaction with social support and functional status after childbirth, it was reported that satisfaction from support from one's partner was significantly correlated with infant care at 6 weeks postpartum, self-care at 3 months, and community activities at 6 months (McVeigh, 2000). Similarly, Cooper, et al, completed a descriptive, cross-sectional study on 147 South-African women and found that social support provided by the partner was significantly increased in the non-depressed women (Cooper, et al, 1999).

Previous studies have shown that social support is a major factor in postpartum recovery and is strongly linked to alterations in maternal mood. Receiving social support early in the postpartum period has been linked to smaller incidence of postpartum depression (Olshansky & Sereika, 2005). A study completed by Coffman, et al, examined relationships in mothers of distressed and normal newborns (Coffman, et al, 1999). The results of their study provided support for a proposed model of social support indicating that close support and met expectations of support were related to both maternal postpartum mood and positive maternal attitude toward the infant. In fact, they found that maternal mood actually mediated the attitudes toward infants thus reinforcing prior research suggesting that maternal mood contributes to disturbances in the mother-infant relationship, and that postpartum social support has implications for both maternal and child well-being.

Klaus' continued program of research on mother-infant relationships supports the notion that social support ante-and post partum improves the psychological health of the mother with associated parental benefits which result in stronger mother-infant ties (Klaus, 1998).

## 2.3 MATERNAL MOOD

There have been many studies focused on alterations in maternal mood. For instance, alterations in mood have been associated with immediate postpartum screening in an effort to wane long-term detrimental effects. Recent focus in research in the area of maternal mood has been on Posttraumatic Stress Disorder (PTSD) following an adverse birth event. Typically these studies focused on later periods during the postpartum recovery where symptoms of PTSD, such as nightmares and flashbacks, become more evident and more debilitating.

PTSD was first recognized as a distinct diagnosis based on a traumatic life event in the Diagnostic and Statistical Manual –III (DSM-III) (Bailham & Joseph, 2003). Initially, PTSD was defined as something outside the range of human experience, leading to the confusion by clinicians regarding inclusion of childbirth to the definition. Recently childbirth has been recognized as a possible event that can trigger PTSD, and has since been acknowledged as such in the DSM-IV 1994 edition (Bailham & Joseph, 2003). Several unique features of PTSD following childbirth include sexual avoidance, mother-infant attachment problems, difficulty breastfeeding, difficulty bonding, and related parenting problem (Bailham & Joseph, 2003).

A number of risk factors have evolved from the literature for PTSD following difficult childbirth including type of delivery. It has been suggested that emergency cesarean section is likely to be associated with postpartum emotional difficulties (Bailham & Joseph, 2003). Instrumental delivery may also be a significant risk factor for PTSD. Social support has been found to be an important protective factor in PTSD-prone populations, and interventions

involving the provision of support appear to be effective in promoting mental health following childbirth (Bailham and Joseph, 2003). Similarly, in a review of evidence for PTSD after birth, Susan Ayers confirmed that the research suggests that a history of psychiatric problems, mode of delivery, and low social support during labor put women at increased risk of postnatal PTSD (Ayers, 2004)

Theoretical models of PTSD acknowledge the role of individual differences and the influence of psychosocial factors which can explain why some women experience PTSD and others do not. There is some noted overlap in symptoms between PTSD and PPD. However, it is believed that these are distinct disorders and it is possible that women present with one without the other.

Creedy, Shochet, and Horsfall studied psychological health following an adverse birth event (Creedy, et al, 2000). Twenty-eight women (5.6%) met DSM-IV criteria for acute Posttraumatic Stress Disorder. The level of obstetric intervention experienced during childbirth (beta = 0.351, p < 0.0001) and the perception of inadequate intrapartum care (beta = 0.319, p < 0.0001) during labor were consistently associated with the development of acute trauma symptoms exhibited with PTSD.

Continuing with the focus on PTSD, Cheryl Beck used descriptive phenomenology to explore the essence of mother's experiences of PTSD after childbirth (Beck, 2004). This study examining the lives of mothers with Posttraumatic Stress Disorder attributable to childbirth provides an additional impetus to increase research efforts in this area.

Alterations in maternal mood can lead to a more debilitating disease known as Postpartum Depression (PPD). PPD is a serious health condition in child-bearing women affecting 500,000 women and infants each year (Wisner, et al, 2002). It is the most common, unrecognized complication of childbirth today. Often criticized as not an actual disease, PPD is the primary outcome variable in many funded research studies. PPD has more recently gained fame and notoriety in the public view via headlines and media attention (e.g., Brooke Shields, Andrea Yates). Affective mood disorders following childbirth range in severity from early postpartum "baby blues" to postpartum psychosis. Along this continuum lies PPD. Despite growing knowledge, PPD screening is not common in the United States.

According to the DSM-IV, PPD is a specifier for Major Depressive Disorder (MDD) and occurs within 4 weeks after delivery (APA, 2000). However, researchers commonly define depression occurring within 3 months postpartum as PPD (Wisner, et al, 2002). To date, there is not a consensus as to whether PPD represents a separate diagnosis or whether it is a variant of MDD, Bi-Polar or minor depression. Symptoms of PPD include feelings of sadness, guilt, inadequacy, tearfulness, hopelessness, listlessness, sleep disturbances, inability to concentrate, and mood lability (Martinez-Schallmoser, Telleen et al. 2003).

The etiology of PPD appears to be multi-factorial and complex (Martinez-Schallmoser, Telleen, et al, 2003). An exact cause of PPD is not known and there is little evidence to support a biological basis (Cooper, 1998). Theories suggest that hormonal changes in pregnancy or thyroid changes may play a role; however, there is not firm evidence to support this (Cooper, 1998).

Psychosocial risk factors and mental health history continue to consistently be linked as the major etiological factors in PPD (Cooper, 1998). Other risk factors for PPD include a depressive symptoms during the pregnancy, young, single, lower socio-economic status, exposure to recent life stress, difficult infant temperament, mode of delivery, infant health at delivery, and absence of social support (Beck, 2002). The strongest risk factors found repeatedly in studies were depressive symptoms during pregnancy (OR 6.78) or a history of depression

before pregnancy (OR 3.82) (Rich-Edwards, Kleinman, et al, 2006). Socio-demographic factors of postpartum women such as acculturation, race, ethnicity and low income have also been studied extensively and linked to PPD (Martinez-Schallmoser, Telleen, et al, 2003). For example, Mexican-American women with increased acculturation in the form of English spoken as the primary language, and increased stress over extended family involvement, have been linked to increase incidence of PPD (Martinez-Schallmoser, Telleen, et al, 2003). Similarly, African-American and Hispanic mothers had the highest prevalence of depressive symptoms compared to non-Hispanic whites explained primarily by low income and poor pregnancy outcome in a study completed by Rich-Edwards ((Rich-Edwards, Kleinman, et al, 2006).

Prevalence rates of PPD vary greatly according to populations studied and instruments used. A meta-analysis of 59 studies reported the overall prevalence of major PPD to be 13% (Dennis, et al, 2004). Put more simply, one out of every 8 women suffers an episode of depression after birth (Peindl, et al, 2004). Women who have suffered one episode of depression after birth have a risk of recurrence in a subsequent birth of about 25% (Wisner, et al, 2004). Although inception rate is greatest in the first 12 weeks, up to 50% of mothers who suffer from PPD will remain depressed at 6 months postpartum (Dennis, et al, 2004). The most serious form of mental illness following childbirth, postpartum psychosis, affects less than 1 % of all new mothers (Dennis, et al, 2004). Around 60%-80% of women who give birth experience a mild form of postpartum depression, known as the baby blues. The baby blues usually occurs within 3-10 days after birth and can last several hours or up to 10 days (Olshansky & Sereika, 2005).

Postpartum Depression negatively affects the quality of life and functional status of mothers and infants. High levels of maternal depressive symptoms have been associated with breastfeeding, infant interaction, infant temperament parenting skills, infant attachment, infant

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behavioural problems and infant cognition (Beck, 2002; Chabrol, Teissedre, et al, 2002; Cooper & Murray, 1998).

In their critical review and analysis of the literature, Grace, Evindar, and Stewart revealed the following general conclusions:

- The strongest cognitive effects of PPD on infants were found at age 18 months;
- The strongest behavioral effects of PPD on infants were found at age 5 years as rated by their school teachers;
- There are significant effects of PPD on latency and intensity of crying;
- Effects are enhanced with parental conflict and lower socio-economic status;
- Child gender appears to be a significant factor with boys suffering from more of the detrimental effects (Grace, et al, 2003)

A large amount of qualitative research has also occurred in an attempt to understand the phenomenon of PPD for the women experiencing the disorder. Mason, et al, studied the lived experience of PPD in a psychiatric population. The subjects in this study described how their past experience affected their thoughts and views of their labor and delivery, and their postpartum experience (Mason, Rice, et al, 2005). Recently, PPD in women with a history of infertility has been studied (Olshansky & Sereika, 2005). Although considered successes in the medical community, infertile women also can suffer from PPD and often are afraid or ashamed to admit their feelings or voice their concerns.

Psychotherapy and more recently drug therapy has been widely used as interventions in research studies as both the treatment and as prevention of PPD. Counseling interventions are gaining more popularity in the immediate period following delivery; however, they are not

proving to be very effective. Counseling interventions longer into the postpartum period have recorded more successes (Chabrol, Teissedre, et al, 2002).

The two most widely studied groups of antidepressants used for PPD are tricyclics and SSRIs. In a study done by Wisner, etal, in 2001, the tricyclic Nortriptyline was found to be no more effective than the placebo in preventing a recurrence or the time to recurrence in women with a history of PPD (Wisner, Perel, et al, 2001). Similarly, in 2004, Wisner, et al, reported that the SSRI sertraline was more effective than the placebo in preventing recurrence and also reported a longer time to recurrence (Wisner, Perel, et al, 2004). Most recently, Wisner, et al, completed a study comparing Sertraline and Nortriptyline and found that psychosocial functioning improved similarly in both groups (Wisner, et al, 2006).

Early screening and treatment of PPD has been a critical focus of the recent literature. In fact, perinatal depression has been identified as a major public health issue by the Agency for Heathcare Research and Quality (AHRQ). Recently, several United States senators have introduced the MOTHERS (Mom's Opportunity to Access Help, Education, Research, and Support for Postpartum Depression) Act to Congress (www.ahrq.gov, 2007). The MOTHERS Act will ensure that new mothers and their families are educated about postpartum depression, screened for symptoms, and provided with essential services for treatment. In addition, the MOTHERS Act will increase research into the causes, diagnoses and treatments for postpartum depression. The MOTHERS Act was introduced in response to a recently passed New Jersey state bill requiring physicians and nurses to educate and screen new mothers on PPD. Research on early identification of risk factors is timely in that it will add to the literature on what is known already, and will contribute to the body of knowledge in which health care providers prepare their screening and education practices.

# 2.4 FUNCTIONAL STATUS

Alterations in functional status after childbirth have been linked to social support, infant care, maternal mood and physical trauma following delivery. Functional status after childbirth is a multidimensional construct. Theoretical basis for the concept of functional status can be partly attributed to the role function adaptive models of Roy's Adaptation Model (McVeigh, 2000). Functional status is thought to be achieved when women assume their motherhood role responsibilities and also reorganize their lives around their infant (McVeigh, 2000). Alterations in functional status include the inability to perform tasks at the level of functioning that was exhibited prior to childbirth. Such activities may include household chores, social and community activities, self-care activities and occupational activities (Fawcett, 1988). Midwifery and related nursing research have indicated that full functional status after childbirth can take up to 6 months postpartum and typically longer then the 6 weeks allotted for recovery (McVeigh, 2000).

Many factors are thought to affect functional status and role adaptation following childbirth including maternal age and parity. Most differences seem to disappear by 3 month postpartum but are evident in the early postpartum period (McVeigh, 2000).

#### 2.5 INFANT CARE

Infant care in the postpartum period has been studied extensively and much is known regarding the importance of the mother-infant relationship. Infant care, although not exhibited prior to childbirth, is a primary goal of successful functional status after childbirth. Shin, Park, and Kim studied predictors of maternal sensitivity during the early postpartum period (Shin, et al, 2006). Maternal sensitivity is defined as a mother's ability to perceive and interpret her infant's signals and communication and then respond appropriately. It is a major factor in successful mother-infant attachment. Through the mother-infant relationship, the mother is able to provide an environment that is appropriate and beneficial to the infant's growth and development. Cooper, et al, completed a descriptive, cross-sectional study on 147 South-African women and found that maternal sensitivity was significantly decreased in the depressed women as opposed to the non-depressed women (Cooper, et al, 1999).

Prior studies have shown that social support influences the maternal sensitivity (Broom, 1994; Kivijarvi, et al 2004). Similarly in Shin's, et al, study, social support has been found to be a predictor of adequate maternal sensitivity; thus suggesting that social support is influential in successful provision of infant care (Shin, et al, 2006).

In 1987, Zekowski, O'Hara and Willis studied the effects of maternal mood on the mother-infant interaction (Zekowski, 1987). Their results found that the infants were sensitive to the mother's depressed mood and were less responsive to their mothers than were the controls.

Their study of 30 mother-infant dyads added to the literature regarding what is known about the infant response to mother's mood.

Infant care is an important outcome when considering the effects of an unplanned, adverse labor or delivery event. It is possible that women who had negative birth experiences may need to meet their own emotional needs before they can meet those of their infants, or may feel obligated to meet the infant's needs, but not their own (Kennell, et al,1979).

## 2.6 SIGNIFICANCE OF THE EARLY POSTPARTUM PERIOD

The postpartum period has been recognized as a time for increased vulnerability for depression but the diagnostic criteria for PPD, particularly time of onset, have been frequently debated. Given the timely subject of screening in the early postpartum period, the 2 week time point was selected as the time point of interest for this study. Potential debate as to whether perinatal depression arising in pregnancy or very early postpartum differs from late onset depression, although there is little evidence to support this (Stowe, et al, 2004). For example, in a study completed by Stowe, et al, they found that there were 2 distinct time points for onset of depression, including depression occurring during pregnancy and depression beginning later than 6 weeks postpartum (Stowe, et al, 2004).

In a recent study, Heneghan, et al, suggested that pediatricians take a role in screening for depression in the mothers of new infants (Heneghan, et al, 2000). Practical, legal and ethical issues may come into play regarding the pediatrician's role in assessing mothers' mental health. Researchers and clinicians are beginning to recommend that PPD screening occur at the neonatal

visit, often occurring at 2 weeks postpartum. Given that PPD is amenable to treatment, specifically psychotherapy and pharmacotherapy, early screening and detection could result in quicker onset of treatment and decreased morbidity for the mother and infant.

Preliminary research suggests the predictive power of maternal mood in the immediate postpartum period (2 weeks) in the development of PPD (Dennis, et al, 2004). Significant positive correlations have been found on measures of depressive symptomatology found at 2 weeks and time points later in the postpartum period, such as 6 weeks. Dennis, et al, used the Edinburgh Postnatal Depression Scale to assess depressive symptomatology on a sample of 166 women at 1 week postpartum (Dennis, et al, 2004). They found that almost 30% of new mothers in their sample exhibited depressive symptomatology at 1 week postpartum, implying that women can experience some form of mental distress in the immediate postpartum period.

#### 2.7 SUMMARY

There are many types of unplanned, adverse events that can occur during childbirth that can result in a negative birth experience for the mother. The literature lends support that adverse birth events, particularly unplanned cesarean sections or assisted vaginal births, can have detrimental physical and mental health effects for the mother. Certain characteristics of the mother, such as depression during pregnancy, education level or socio-economic status of the mother, maternal age, and parity, can also affect maternal outcomes. In order to better understand the relationship between adverse birth events and the specified outcomes, these characteristics were statistically controlled for in this study.

Social support has been an extensively studied construct in many examples of life transitions. Childbirth is such a transition. Research has shown that the amount and adequacy of social support has positively influenced maternal outcomes following childbirth. As such, social support was selected for use as a moderator for this study due to the assumed influential effects it may have on the outcome variables.

Maternal mood, functional status, and infant care are all critical components to a mother's mental and physical health following childbirth. The literature suggests that all three of these outcomes can be influenced by a multitude of factors. It would appear logical to assume that an unplanned, adverse birth event could influence one or all of these outcomes. The early postpartum period, specifically 2 weeks, has not been extensively studied with regard to the effects of adverse birth events on maternal mood, functional status and infant care. The 2 week time point can be viewed as a potentially critical time for postpartum screening for both maternal and infant wellness. As focus continues to heighten on the high incidence of undiscovered alterations in maternal mood and their potentially deadly results, early identification and its associated predictors appeared to be an important and timely subject for investigation.

#### 3.0 METHODS

#### 3.1 DESIGN

In order to examine the relationship between adverse birth events and maternal mood, functional status and infant care, a secondary analysis of data from Antidepressant Use During Pregnancy (ADUP; MH R01 60335, PI, Dr. Katherine Wisner) was performed. This ongoing study enrolls women for the investigation of anti-depressant use in pregnancy.

Secondary data analysis was an appropriate and cost effective approach for examining these relationships. The secondary data analysis and parent study, ADUP, shared variables of interest, specifically the identification of the actual labor and delivery events and the identification of multiple, specific maternal outcomes. The parent study possessed recent, stable data for addressing the secondary study's aims.

Antidepressant Use During Pregnancy (ADUP; MH R01 60335) was developed from recommendations by the American Psychiatric Association (APA) Committee on Research on Psychiatric Treatments and its reports on treatment of major depressive disorder (MDD) during pregnancy. The objective of ADUP is to study if the antidepressants to which a pregnant woman is exposed: treat MDD, affects infant development, and serves as an additional drug exposure to the infant. More specifically, the APA work group identified areas in which data are needed: 1) whether minor physical anomalies occur with greater frequency in drug-exposed infants, 2) if maternal weight gain and infant birth weight are compromised by drug exposure, 3) assessment of longer-term behavioral teratogenicity in offspring, and, 4) management strategies to reduce neonatal toxicity. The serotonin reuptake inhibitors (SSRI) are being studied because these agents are first-line treatments for MDD. ADUP is a prospective investigation of the effects of treatment of pregnant women with SSRIs. The mothers and their children are followed at various checkpoints during the period of 24 months post-birth, including 2 weeks postpartum which was this secondary analysis's time point of interest. ADUP study participants also included a large control group of women not being treated for depression, and not using any antidepressant medications. Although birth data are obtained for the parent study using the Peripartum Events Scale (PES), there was no specific plan in the parent study for analysis based on the incidence of a negative birth event.

## 3.2 SAMPLE

Participants consisted of 123 women with postpartum data available for analysis from the parent study. Inclusion criteria for ADUP are age 18 years or older, pregnant, at least 20 weeks gestation at time of entry, English-speaking, and able to provide informed consent. Exclusion criteria are active substance abuse within the past 6 months and no obstetrical care. Data from consented participants in the parent study were included in this secondary analysis if the following instruments were completed after the 2 week postpartum visit: Peripartum

Events Scale (PES), Postpartum Support Questionnaire (PSQ), Edinburgh Postnatal Depression Scale (EPDS), Inventory of Functional Status After Childbirth (IFSAC), and Infant Care Survey (ICS). Participants were excluded from this study if their scheduled 2 week postpartum visit exceeded a timeframe of 4 weeks postpartum. If a participant had more than one child entered into ADUP, the first sibling was routinely included in the study and the second sibling was eliminated in order to maintain the independence of subjects.

Listwise deletion was selected to handle missing data after it was statistically determined that the groups containing complete data sets and the groups with missing data did not differ in terms of demographic characteristics and mean variable scores. Also, a listwise deletion method still allowed sufficient power to test the study hypotheses.

Given the fixed sample size of 123, the minimum detectable effect size in terms of  $R^2$  was estimated using PASS (version 2005, NCSS, Kaysville, UT). Because prior studies did not use the same covariates when estimating the effects of the addition of an adverse event in labor or delivery on maternal outcomes, a range of  $R^2$  values attributed to the covariates was used for predicting power. For the primary aim, a sample size of 123 had 80% power to detect a change in  $R^2$  ranging from .045 to .054 attributed to the addition of the adverse events indicator variable. This estimation included controlling for all covariates, with an estimated  $R^2$  ranging from .1 to .25, when using an F-test from a hierarchical regression model with a significance level of .05

For the secondary aim, a sample size of 123 had sufficient power (at least 80%) to detect a change in the  $R^2$  statistic ranging from .045 to .06 attributed to the interaction term for social support with the adverse birth event indicator variable when using an F-test with a hierarchical regression model and a significance level of .05. This model also assumed controlling for the main effect terms for social support as well as all covariates.

#### 3.3 VARIABLES

The variables for this study included: adverse birth event, social support, maternal age, parity, education level, history of depression in pregnancy, antidepressant use at delivery, maternal mood, maternal functional status, and infant care. The independent variable of interest was the presence or absence of an adverse birth event. Social support was measured as a moderating variable. The presence of social support may influence a woman's response to an adverse birth event as expressed in mood, functional status and infant care. The dependent variables in this study were maternal mood, maternal functional status, and infant care. The covariates that were expected to influence the outcome variables were maternal age, years of education, parity, antidepressant use at delivery, and depression in pregnancy.

#### 3.4 MEASURES

The measures proposed for this study were selected from those available through ADUP and were consistent with the framework for this study. All instruments were well established with moderate to strong psychometric properties. The covariates were collected from a series of interviews and demographic questionnaires developed for ADUP. Interviews and questionnaires were administered by the ADUP investigators during the participants' initial visit upon entry into the parent study. Data were retrieved, coded, and entered into SPSS by members of the ADUP data analysis team lead by the project director, Barbara Hanusa, Ph.D.

The presence of an adverse birth event was the independent variable for this study. Subjects having an adverse birth event were identified by positive responses and comments in certain categories of the Peripartum Events Scale (PES). The PES is a 14-item scale developed to quantify stressful events related to delivery (O'Hara, 1986). Data were entered onto the PES for the parent study via a retrospective medical record review by obstetrical content experts, specifically an OB/GYN physician and a labor and delivery nurse. For intended use, increased scores, or responses, on the PES indicate increased stressful events related to the delivery. The total PES score that was obtained for the parent study was not used for this study.

Specific categories on the PES that were reviewed were: precipitous labor, secondary arrest of labor, other traumatic or life threatening events such as abruption or cord prolapse, midforceps or vaginal breech delivery, vacuum extraction, primigravida labor longer than 20 hours, multigravida labor greater than 14 hours, primigravida second stage longer than 2 hours, multigravida longer than 11/2 hours, abnormal FHR, abnormal contractions, fetal blood sampling, abnormal fetal monitoring, significant lacerations, or term infant to NICU–unplanned. In addition to a yes/no response on the PES, all categories had an additional field for comments. For this secondary analysis, a careful review of the above listed categories and their corresponding comments was completed on all women identified as having complete data as defined for this investigation. A judgment was determined as to whether or not the birth had an unplanned, adverse event. All judgments were validated by a second obstetrical content expert. After consensus on identification of the occurrence of an adverse event between both reviewers, participants were coded either [0] indicating no adverse event, or [1] indicating the occurrence of

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an adverse, unplanned event(s) in labor or delivery. A participant could be identified as having more than one adverse event as events were not mutually exclusive. After the participants were identified as having an adverse, unplanned event(s), they were entered into new categories of events that were created for grouping analysis in this study (Table 1).

# Table 1. Adverse, Unplanned Events Identified from the Peripartum Events Scale

#### Vacuum extraction

Cesarean Section due to failure to progress, cephalo-pelvic disproportion, or failure to descend

Significant lacerations or blood loss

Term infant to NICU – Unplanned

Emergency Cesarean Section due to placenta abruption or fetal distress

Prolonged second stage of labor

Forceps delivery

Amniofusion for meconium or abnormal fetal heart rate monitoring

Precipitous delivery

Prolonged first stage of labor

Development of preeclampsia in labor

Cord prolapsed

Shoulder dystocia

Other

Social support, the moderating variable, was measured by the Postpartum Support Questionnaire (PSQ). The PSQ is a self-report, 34-item likert-scale used to measure postpartum social support in four categories (informational, material, emotional, and comparison). Each of the 34 items has a response format with 8 options (from *not important* to *very important* and from *no support* to *a lot of support*). In addition to a total score, categories can be summed separately for importance and support ratings, and each category total score can range from 0 to 238 with a possible overall score of 952. Higher scores on the PSQ indicate higher levels of postpartum social support. In five studies of postpartum women, Cronbach's alpha scores have ranged from .88 to .95. Test-retest reliability and concurrent validity have been established (Logsdon, et al, 1996). All 34 items (and all categories) were included for analysis in this study.

Maternal mood, the first outcome variable, was measured by the Edinburgh Postnatal Depression Scale (EPDS). The EPDS is a widely used, 10-item self-report likert-scale used for the detection of postnatal depression. Each item receives a score of 0 ("No, never") to 3 ("Yes, most of the time"), with the higher numbers representing increased severity of a particular symptom (Cox, et al, 1987). The total score was determined by adding all item scores, thus the range of total score is 0 to 30. Boyd, et al, (2005) completed a brief review of all postpartum depression screening instruments and found that across all studies, the EPDS had internal consistency estimates ranging from .73-.87 and test-retest reliability ranging from .53-.74 (time points ranging from 3 to 12 weeks) (Boyd, et al, 2005). A recommended cut-off point of 9/10 has been suggested to increase sensitivity for the purposes of community screening (Dennis, et al, 2004).

Postpartum functional status of the mothers, the second outcome variable, was measured by the Inventory of Functional Status after Childbirth (IFSAC). The IFSAC is a self-report, 36-

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item, likert-scale designed to measure functional status after childbirth. Items are rated on 4point scales, arranged in 5 subscales encompassing the five dimensions of social aspects of recovery (infant care, household activities, social and community activities, self-care activities and occupational activities) (Fawcett, et al, 1988). A subscale mean was determined for each of the five subscales based on the items answered within that subscale. The total IFSAC score was determined in the same manner, using all items that are answered. The possible range can be expanded due to presence of other children in the home, employment, or attending school (44 additional points, 16 additional points, and 20 additional points respectively). All possible categories were used in this study. The higher the score on the IFSAC or subscales indicates greater functional status. The possible range of total score is 0-212. Prior psychometric testing has found that test-retest reliability was greater than 0.82 for all subscales, except the occupational activities subscale, due to the small number of women from the study sample who had returned to work at the time of the psychometric property testing (Fawcett, et al, 1988).

Infant care, the third outcome variable, was measured by the total score of the Infant Care Survey (ICS). The ICS is a self-report, 52-item scale measuring parents' beliefs about their knowledge of and skills with infant care activities relating to health, safety, and diet on a 5-point likert- scale ranging from 1, *a great deal of confidence* to 5, *very little confidence* (Froman, et al 1989). The total score was determined by adding all item scores. Possible range of total score is 52 to 260. Higher scores indicate less confidence regarding infant care activities. Prior studies have found internal consistency estimates for knowledge and skills to be .95 and .96 (Froman, et al, 1989).

# 3.5 DATA MANAGEMENT

Data were entered by the staff at Women's Behavioral Health CARE, Pittsburgh, PA, the project site of the parent study and reviewed by the statistician, Barbara Hanusa, PhD. The data were deidentified by an honest broker at the parent site prior to releasing the data for analysis in this study. Approval to conduct this study was obtained from the University of Pittsburgh IRB. The database system at Women's Behavioral Health CARE resides on a secure server that is behind the University of Pittsburgh Medical Center firewall. Assessments were tracked at the parent site to identify missing forms and generate timely reports of enrollees, where the participants were in the study, and the anticipated time for the next interview. Data were stored by subject identification number. Subject names and contact information were kept in separate databases from the assessments. Paper files, such as consent forms and medical records, were kept in locked file drawers in study coordinators offices.

## 3.6 ANALYSIS

Statistical guidance for the analyses in this proposal was provided by Dr. Susan Sereika, Associate Professor at the School of Nursing and Departments of Biostatistics and Epidemiology in the Graduate School of Public Health. Data was analyzed using SPSS (version 13, SPSS, Inc., Chicago, IL). Detailed descriptive analysis of the data was performed. Continuous variables were analyzed for mean, range, standard deviation, skewness, kurtosis and frequency statistics. Categorical variables were evaluated for distribution using frequency statistics and percentages. If categories resulted in illogical or inconsistent groupings with insufficient frequencies, variables were recoded to present more meaningful groupings. Relationships between discrete categorical variables were examined via a two-way contingency table using the chi-square test of independence, or by using multi-way frequency analysis among three or more discrete variables. Case processing summaries produced in SPSS were also evaluated.

All underlying assumptions required for multiple linear regression techniques were performed including tests for univariate and bivariate normality and sample distributions, distribution of the residuals (estimates of the conceptual model errors), linearity, and homogeneity of error variance. The data collected for each participant were assumed to be independent. Statistical tests (such as Shapiro-Wilkes test for normality and Levene test for homogeneity) as well as graphical and descriptive techniques described in the previous section were employed to examine desired assumptions. Exploratory graphs of the continuous variables included: histograms, normal Q-Q plots, detrended normal Q-Q plots, stem and leaf plots, and scatter plots. Residual plots such as standardized residuals versus predicted values were also examined. Multicollinearity among the predictor variables was also examined via estimates for condition indices, variance decomposition proportions, tolerance, and variance inflation factors.

If the underlying assumptions were violated, data transformations on the continuous variables (such as log or square root) were considered and assessed for use in the analysis. The choice of transformation depended on the degree to which the sample distribution deviated from the normal distribution. Constants were added if the original distribution contained values less

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than one to avoid taking a log, square root, or inverse of zero. All assumptions were re-evaluated following transformation. If transformation of a continuous variable did not appear to be helpful, transformation of the variable into a categorical variable, using clinically meaningful cut-points, was employed as a more suitable remedy.

This exploratory investigation also included the examination of the relationships between outliers and dependent variables, and the independent variable. All outliers were evaluated for validity. A sensitivity analysis excluding the outliers was performed. Outliers were identified via statistical techniques such as frequency statistics, measures of Mahalanobis distance, and examination of z scores, as well as graphical techniques such as bivariate plots between pairs of variables. Once identified, steps were taken statistically to reduce their possible influence.

Patterns of missing data were evaluated. The randomness of missing data between subjects and within a given subject was investigated using available information on subject characteristics as well as Little's MCAR Test to evaluate if data was missing at random. Missing Value Analysis in SPSS was performed in order to ascertain the statistical influence, if any, the missing data had on the variables in this design. Amount and percentage of missing data for each variable was carefully explored. The need for potential imputation techniques was carefully evaluated. Possible imputation techniques might have included mean imputation where the sample mean is used to replace missing data, or regression analysis where missing data are estimated using other variables in the sample as predictors for the missing variable.

The primary specific aim, to examine the relationship between unplanned, adverse birth events during labor or delivery and maternal mood, maternal functional status, and infant care at 2 weeks postpartum, was investigated first. The initial review of the data was an evaluation of the Peripartum Events Scale (PES). An Event Indicator was computed for each subject in SPSS to indicate whether or not the subject had an adverse, unplanned event in labor or delivery [0= No, 1= Yes]. Data for the outcome variables of maternal mood, maternal functional status and infant care were used from measurements taken at the 2 week postpartum visit.

To investigate whether a relationship existed between the adverse birth events and the outcomes of maternal mood, maternal functional status, and infant care, statistical modeling using multiple linear regression analysis was used. The covariates: maternal age, parity, education level, history of depression in pregnancy, and antidepressant use at delivery, was included in the statistical model. The level of statistical significance was set at .05.

Following initial estimates of simple, unadjusted regression, adjusted estimates were obtained by fitting the outcome-specific multiple regression models in a hierarchical manner. Covariates were included in the first block of predictor variables, followed by the adverse event indicator variable in the second predictor variable block. Model summary statistics to evaluate overall fit and prediction capabilities included  $R^2$ , adjusted  $R^2$ , the standard error of the estimate, and PRESS, the sum of the prediction residuals.

For the hierarchical regression, the change in the  $R^2$  statistic with the addition of adverse event indicator variable was computed. The crude and adjusted estimated regression coefficients and their 99% confidence intervals were obtained as effect size estimates for the adverse event indicator variable. Residual analyses were conducted for each model estimated to check for outliers and influential observations and to assess the distributional properties of residuals.

The secondary aim was to explore if social support was a moderator in the relationship between unplanned birth events and maternal mood, functional status, and infant care. Social support was measured using data received from the Postpartum Support Questionnaire (PSQ) completed at the 2 week postpartum visit. An analytic approach similar to that described for the analysis for the primary specific aim was employed. The hierarchical regression models developed for each outcome variable in the primary aim were expanded to also include the main effect for social support (as measured by the PSQ total scale score) in the second block of predictor variables. The third block of predictor variables consisted of an interaction term, computed as the product of the PSQ total scale score with the adverse events indicator variable. To estimate moderation effects for social support on the relationship between the identified outcome variables and adverse birth events, I examined the change in  $R^2$  statistic with the addition of the interaction term for social support with adverse birth events to the main effects linear regression model. The adjusted regression coefficient with confidence interval was also obtained as an effect size estimate. Also exploratory in nature, an interaction term was created and assessed for model influence for all of the covariates listed in the study.

#### 4.0 PILOT STUDY

# 4.1 RELIABILITY AND VALDITY ESTIMATES FOR THE EDINBURGH POSTNATAL DEPRESSION SCALE USED AT 2 WEEKS POSTPARTUM

#### 4.1.1 PURPOSE

The Edinburgh Postnatal Depression Scale (EPDS), is the most widely used screening questionnaire for PPD (Boyd, Le, & Somberg, 2005). Developed by Cox, Holden, and Sagovsky in 1987, the EPDS was designed to assess postpartum symptoms in new mothers. The items measure emotional and cognitive symptoms of PPD. The EPDS is a screening tool and is not designed to diagnose MDD (Dennis, 2004). The EPDS has been used internationally and has well-documented reliability and validity in multiple languages (Dennis, 2004). The EPDS is typically selected for use due to its ease of use, uncomplicated interpretation, and high maternal acceptance (Dennis, 2004). The purpose of this study was to analyze the reliability and validity estimates of the EPDS at measures taken at 2 weeks postpartum. Although previous psychometric studies have been conducted on this instrument, this study was specifically examining data collected early in the postpartum period. Typically, a diagnosis of PPD occurs later in the postpartum period; however, by hypothesizing a relationship between the symptoms of postpartum mood and an adverse event in labor and delivery, and for the purposes of earlier community screening, it appears to be logical and necessary to examine the psychometrics of the

EPDS at 2 weeks postpartum.

An exploratory aim of this pilot study was to see if the reliability estimates specific to the data collected at the 2 week postpartum time point were consistent with reliability estimates found on data collected during pregnancy, and on data collected during later postpartum time points.

#### 4.1.2 METHODS

This pilot study was a secondary data analysis for the study Antidepressant Use During Pregnancy (ADUP; MH R01 60335) to conduct reliability and validity estimates on the EPDS at 2 weeks postpartum. A total of 229 participants were drawn from *ADUP*. Participants were chosen for this pilot study if they had completed the 2 week postpartum visit. The demographic characteristics of the sample are summarized in Table 2. The participants were primarily white, married women with a mean age of 30.5 years (range 16-43).

Demogr	aphic Characteristics	1	%		
Race					
	White	1	79		
	African American	2	17		
	Other		4		
Marital Status					
	Married	1	70		
	Unmarried	68		30	
		Mean	SD	Range	
Age		30.5	5.8	16-43	
Years of Education		14.8	2.1	10-17	

# Table 2. Participant Demographics for Pilot Study (Total n=229)

The use of the ADUP data for a secondary data analysis was approved by the Institutional Review Board. All data were provided by the honest broker at the parent study site and were deidentified prior to receipt. Data were analyzed using SPSS (version 13, SPSS, Inc., Chicago, IL). Data from consented participants in the parent study were included in this study if the following instruments were completed during the defined study timeframes: 1.) EPDS, 2.) Hamilton Rating Scale for Depression (17-item), 3.) Medical Outcomes Survey Short Form -12 (SF-12).

#### Measures:

Edinburgh Postpartum Depression Scale - The EPDS is a 10-item self-report likert-scale. Each item receives a score of 0 ("No, never") to 3 ("Yes, most of the time"), with the higher numbers representing increased severity of a particular symptom. Responses for each of the 10 items are scored to produce a total score for each mother. Possible total range of scores is 0-30. A cut-off point of 12/13 at 6 weeks postpartum has a sensitivity of 68-95% when compared to a diagnosis of major PPD established through psychiatric interview (Dennis, 2004). A recommended cut-off point of 9/10 has been suggested to increase sensitivity for the purposes of community screening (Dennis, 2004).

Hamilton Rating Scale for Depression (HRSD) (17-item) – The HRSD is the most frequently used measure of outcome in antidepressant efficacy trials (Zimmerman, Posternak, & Chelminski, 2005). The scale includes core features of depression such as low mood and loss of interest in usual activities. Most, but not all, of the 17 items on the scale assess DSM-IV diagnostic criteria for depression. Historically, a cut-off score of less than or equal to 7 indicates the absence of depression and better quality of life (Zimmerman, Posternak, & Chelminski, 2005). Similar to other reliability estimates from other studies using the HRSD 17-item scale, Zimmerman et al reported an intra-class coefficient of reliability of .97 (Zimmerman, Posternak, & Chelminski, 2005). The HRSD -17 item consists of 17 items, nine of which are scored on a five-category Likert-scale (from 0 to 4) and the remaining eight on a three category Likert-scale (from 0 to 2). Total theoretical score range is from 0 to 52 (Light, et al, 2005). The HRSD 17-

item was selected for the validity analysis for this study because of its ease of use, its history of strong psychometric properties, and its sensitivity for measuring similar depressive symptoms to that of the EPDS.

Medical Outcomes Study SF-12 (Physical Component) - The MOS SF-12 is a measure of general health status developed to compare the impact of different diseases and conditions on health, or to monitor the health of individuals or groups over time. The MOS SF-12 contains a subset of 12 items from the original MOS measure, the MOS SF-36, including one or two items from each of the eight MOS SF-36 scales (Brazier & Roberts, 2004). The original MOS SF-36 has a long history of strong psychometric performance (Brazier & Roberts, 2004). The MOS SF-12 is scored to produce two summary scores, the physical and mental health summaries (PCS and MCS). In cross-validation with data from the Medical Outcomes Study, the PCS-36 and PCS-12 were highly correlated 0.95 (Brazier & Roberts, 2004). Scores on the PCS range from 0 to 100, with a population mean of 50. Higher scores reflect better physical functioning. Physical functioning is assessed on theSF-12 with items such as "Does your health limityou in climbing several flights of stairs?", and "Have you accomplished less than you would like as a result of your physical health?" (Katz et al, 2005). The MOS SF-12 (PCS) was selected as a measure for discriminant validity for this study because of its ease of use, its history of strong psychometric performance, and its contrasting assessment of physical data as opposed to the EPDS' mental assessment.

Two weeks postpartum was selected as the time point of interest because of the potential effects of adverse, unplanned labor and delivery events. A negative response to such adverse events may result in altered maternal mood early in the postpartum period. Alterations in maternal mood can lead to PPD.

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A detailed descriptive analysis of the data was performed. Frequencies and descriptive statistics were analysed on the following data groups: 1.) EPDS scores at all pregnant and postpartum time points in aggregate, 2.) EPDS scores for each of the pregnancy time points (20, 30, 36, 42 weeks gestations), 3.) EPDS scores for each of the postpartum time points (2, 12, 26 and 52 weeks postpartum), 4.) EPDS scores only at 2 weeks postpartum, 5.) HRSD-17 scores only for 2 weeks postpartum, 6.) MOS SF-12 (PCS) scores only at 2 weeks postpartum. The Cronbach formula for coefficient alpha was used to assess the internal consistency for the EPDS at all time points. Spearman's Rho correlation coefficients were used to describe the internal item structure of the EPDS. It was expected that the reliability assessments for this study for total item scores, pregnancy/postpartum states and the 2 weeks postpartum time point to estimate high reliability. It was expected that the individual item correlations be significant for this sample. Spearman's Rho values were used to assess the relationship between the EPDS total scores at 2 weeks postpartum and the Hamilton Rating Scale for Depression 17-item total scores at 2 weeks postpartum in order to ascertain a measure of convergent validity. It was hypothesized that the HRSD and EPDS scores for this sample were highly correlated. Spearman's Rho values were also used to assess discriminant validity by measuring the relationship between the EPDS total scores at 2 weeks postpartum and the MOS SF-12 (PCS) at 2 weeks postpartum. It was hypothesized that the scores from each of these measure were not significantly correlated.

## 4.1.3 RESULTS

Frequency data are described in Table 3. Of the 912 available EPDS total scores from all time points obtained from the sample, 550 (60.3%) were scores obtained during pregnancy, and 362 (39.7%) were scores obtained during the postpartum period. Of the postpartum scores, 156 (39.7%) were obtained at the 2 week postpartum study visit.

	Scores	%	Missing	Mean	Range
Total # EPDS Scores					
Total Sample	912	100	0	5.5	0-29
Total from Pregnancy*	550	60.3	0	6	0-29
Total from Postpartum**	362	39.7	0	4.7	0-26
Total from 2 Weeks PP	156	43	0	4.7	0-20
Total # HRSD-17 Scores at 2 Weeks Postpartum					
	156	na	0	5.8	0-24
Total # SF-12 (PCS) at 2 Weeks Postpartum					
	154	na	2	44	1-64

 Table 3. Frequency Data for Pilot Study

\* Time points at 20, 30, 36, 42 weeks gestation

\*\* Time points at 2, 12, 26, 52 weeks postpartum

Reliability estimates for the EPDS were strong throughout the analysis for all time points. Estimates given were based on standardized items and covariance analysis. Reliability of the EPDS at 2 weeks postpartum measured by Cronbach's alpha was .875. EPDS reliability for all time points in both pregnancy and postpartum was .908. Reliability of pregnancy and postpartum states separately was .908 and .885 (Table 4).

	Standardized Alpha
Pregnancy	.908
Postpartum	.885
2 Weeks Postpartum	.875

The EPDS was shown to have strong construct validity at the 2 week postpartum time point. The EPDS was significantly correlated with the HRSD-17 with a Spearman Rho value of .575 (p < .001). The EPDS was mildly correlated with the MOS SF-12 (PCS) at 2 weeks postpartum with a Spearman Rho value of -.184 ( $\rho = .022$ ) (Table 5).

		Rho
EPDS	with HRSD-17 at 2 Weeks Postpartum	0.575*
EPDS	with SF-12 (PCS) at 2 Weeks Postpartum	-0.184**
EPDS with HRSD-17 all Postpartum		0.571*
EPDS	with SF-12 (PCS) all Postpartum	-0.074
*	Significant at the .01 level (2-tailed)	
**	Significant at the .05 level (2-tailed)	

## 4.1.4 DISCUSSION

The purpose of this pilot study was to analyze the reliability and validity estimates of the EPDS at measures taken at 2 weeks postpartum. An exploratory aim of this study was to see if the reliability estimates specific to the data collected at the 2 week postpartum time point were consistent with reliability estimates found on data collected during pregnancy, and on data collected during all postpartum time points. Many studies have used the EPDS for measurement of maternal mood and PPD. Prior studies have reported that the EPDS is reliable, valid, brief,

easy to administer and use, and highly accepted across varying cultures and socio-economic statuses (Cox, et al, 1987). Psychometric testing completed by the instrument developers reported that a cut- off point of 12/13 at 6-weeks postpartum resulted in sensitivity estimates of 68-95% and specificity ranging from 78-96% when compared to a diagnosis of major postpartum depression established through psychiatric interview (Cox, et al, 1987). Boyd, et al (2005) completed a brief review of all postpartum depression screening instruments and found that across all studies, the EPDS had internal consistency estimates ranging from .73-.87 and test-retest reliability ranging from .53-.74 (time points ranging from 3 to 12 weeks).

As predicted, the EPDS was shown to have strong reliability across all time points in pregnancy and postpartum. All Inter-item correlations were significant. Spearman's Rho values ranged from .308 - .734 and were significant at the .01 level (2-tailed) (see Table 6). Reliability measures were consistent, and variability in scores ranged 3 % with the lowest estimate being at the 2 week postpartum time point. These findings are similar to prior studies that have used the EPDS (Dennis, 2004; Boyd & Somberg, 2005).

	Laugh	Enjoy	Blame	Anxious	Scared	Stay/to	p Sleep	Sad	Cry
Laugh									
Enjoy	.734								
Blame	.427	.405							
Anxious	.399	.417	.621						
Scared	.367	.395	.548	.701					
Stay/top	.480	.487	.540	.522	.477				
Sleep	.473	.506	.516	.490	.513	.507			
Sad	.549	.579	.578	.572	.550	.614	.654		
Cry	.488	.497	.487	.463	.459	.516	.541	.706	
Harm	.355	.364	.336	.308	.326	.332	.382	.386	.359

## Table 6. Spearman's Rho Inter-Item Correlation for All Scores

\* All estimates significant at the .01 level (2-tailed)

The EPDS estimate of construct validity at the 2 week postpartum time point resulted in strong validity. As predicted, the EPDS was significantly correlated with the HRSD-17 at 2 weeks postpartum; thus, proving to be a significant indicator of convergent validity. Similarly, discriminant validity was measured by a correlation measure between the EPDS and MOS SF-12 (PCS) scores at 2 weeks postpartum. The low value of Spearman's Rho (-.184) was indicative of discriminant validity. The significance of the p value, despite a low correlation, was not

unexpected due to the large same size.

There were several limitations of this study that require discussion. First, typical with many self-report psychosocial instruments, the data were not normally distributed due to the multitude of zero scores by participants indicating the absence of a particular symptom. This resulted in an abnormal distribution of data and the need to use Spearman's Rho for correlation calculations as opposed to Pearson Product Moment correlations.

A second limitation of this study involved the actual time of the study visit for the 2 week postpartum score. Although it is being recorded by the parent study as the 2 week EPDS score, a few of the time frames for visits may have varied from anywhere between 7 and 14 days. This would affect the validity assessment reported specifically for the 2 week postpartum time point. Later time points may have significantly affected the EPDS, HRSD-17, and MOS SF-12 (PCS) scores and subsequently the reliability and validity estimates.

Another limitation is the lack of a heterogeneous sample. As described, the sample from the parent study was mostly white, married, and educated. The generalizability of use with samples of different demographic characteristics needs to be demonstrated.

The fourth limitation to be discussed concerns the lack of an estimate of test-retest reliability. Although the data provided for this study was longitudinal in nature, the transient state of depression, and the length of time between time points, an estimate of test-retest reliability for the participants was not provided. An EPDS score indicating the presence or absence of depressive symptoms at the 2 week time point could be vastly different from a score given at 12 weeks due to the sometimes transient and fluctuating nature of the disease, particularly if it were following an adverse, unplanned labor and delivery event.

Finally, some may argue that specifically defining the 2 week postpartum period for use

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in estimating the validity estimate may be too narrow. However, because of a specific planned research trajectory of studying women following an adverse, unplanned event in labor or delivery event, this study was relevant and could be of interest to future investigators interested in studying depressive symptoms in the early postpartum period. In response to this argument, data correlation estimates were given for all postpartum time points using scores from the EPDS, HRSD-17, and MOS SF-12 (PCS), and similar estimates of reliability and validity were reported. Future research on validity estimates may include other specific postpartum time points in order to assess the longitudinal stability of the psychometric properties of the EPDS.

Due to the results of this analysis, it is concluded that the hypotheses for this pilot study were met and that the EPDS is a reliable and valid instrument for use in planned research that specifically looks at data at the 2 week postpartum time point.

#### 5.0 **RESULTS**

The study results are organized into four sections. First are the sample characteristics. Second are the descriptive statistics for the independent, dependent and moderating variables. Third are the results for the specific aim. Fourth and last are the results for the secondary aim.

## 5.1 SAMPLE CHARACTERISTICS

There were 123 women with complete data that met the criteria for this study. The sample of women was primarily Caucasian (80%) which is consistent with the demographics of Allegheny County, Pennsylvania. Of the 123 women, 19 were African American and 6 were within other racial groups. Ninety-six women were married or cohabitating with a significant other. Only 27 of the women reported themselves as single. The majority of the women had more than a high school education with 85 of them reporting college degrees or graduate college education. The mean age of the women was 30.5 years old. The mean number of children for the women was about 2. Twenty-six percent of the women reported being depressed at some point during the pregnancy and 21 women were taking antidepressants at the time of delivery. Further information on the sample characteristics are provided in Table 7.

		Ν	%
Race			
	Caucasian	98	80
	African American	19	15
	Other	6	5
Marital Status			
	Married	89	72
	Single	27	22
	Cohabitate	7	6
Education Level			
	Less Than High School	6	5
	High School Graduate	9	7
	Some College	23	19
	College Graduate	50	41
	Post Graduate	35	28
Depressed D	uring Pregnancy	32	26
Antidepressa	nt Use at Delivery	21	17

## Table 7. Demographic Characteristics of Sample (n=123)

	Mean	SD	Min	Max	
Age	30.5	5.7	18	43	
Parity	1.9	1.0	1	6	

#### Table 7: Demographic Characteristics of Sample (n=123) Continued

### 5.2 DESCRIPTIVE STATISTICS

### 5.2.1 INDEPENDENT VARIABLE: ADVERSE EVENTS

Of the 123 women in the sample, the number of women identified as having an adverse, unplanned event in labor or delivery was 57 (46%). The adverse, unplanned events identified for the sample from the PES are described in Table 8. The most prevalent occurrence of an adverse event involved either a vacuum extraction or a cesarean delivery (both at 19% each), followed by significant lacerations or blood loss at 15%. The least common adverse events included prolonged first stage of labor, development of preeclampsia in labor, cord prolapse, and shoulder dystocia- all at 2% each. The occurrence of multiple events was not quantified for the purposes

of this study; however, it is important to note that the events listed in table are not mutually exclusive.

	Ν	%
Vacuum Extraction	10	19
Cesarean Section due to FTP, CPD, FTD	10	19
Significant lacerations or blood loss	8	15
Term Infant to NICU-Unplanned	6	11
Emergency C-Section due to abruption or fetal distress	6	11
Prolonged second stage of labor	5	9
Forceps delivery	3	6
Amniofusion for meconium or abnormal HR monitoring	3	6
Precipitous delivery	2	4
Prolonged first stage of labor	1	2
Development of preeclampsia in labor	1	2
Cord Prolapse	1	2
Shoulder dystocia	1	2
Total N	57	46

## Table 8. Adverse, Unplanned Events Identified in the Sample

# 5.2.2 DEPENDENT AND MODERATING VARIABLES: MATERNAL MOOD, FUNCTIONAL STATUS, INFANT CARE, SOCIAL SUPPORT

The mean, standard deviation, range of scores, minimum and maximum scores for the 3 dependent variables are described in Table 9. Average maternal mood score was 4.69. Over 26 (21%) of the postpartum mothers scored above or equal to the cut-point score of 9. Mean functional status after childbirth was 69.5. The mean infant care score was 104.8. Average total social support was 185.3. The mean social support score was 185.3.

Mean <u>+</u> SD	Range	Min	Max
4.69 <u>+</u> 4.8	20	0	20
69.5 <u>+</u> 15.8	55.4	7	99.2
104.8 <u>+</u> 33.8	33.8	61	214
185.3 + 86	385	3	388
	SD $4.69 \pm 4.8$ $69.5 \pm 15.8$ $104.8 \pm 33.8$	SD $4.69 \pm 4.8$ 20 $69.5 \pm 15.8$ 55.4 $104.8 \pm 33.8$ 33.8	SD $4.69 \pm 4.8$ 20 0 $69.5 \pm 15.8$ 55.4 7 $104.8 \pm 33.8$ 33.8 61

## Table 9. Measures of Central Tendency for the Independent Variables

## 5.3 PRIMARY AIM

For the primary aim, it was hypothesized that unplanned, adverse birth events were associated with altered maternal mood, maternal functional status and infant care at 2 weeks postpartum. In order to examine the relationship between adverse birth events and maternal mood, functional status and infant care, a secondary analysis of data from the study on Antidepressant Use During Pregnancy (ADUP; NIH R01 MH60335) was completed.

#### 5.3.1 MATERNAL MOOD

Because the data collected on the EPDS were not normally distributed, EPDS scores were categorized into 2 groups for use with binary logistic regression analysis. As per the recommended guideline given for the purpose of depression screening (Dennis, 2004), total scores ranging from 0-8 were given a value of [=0] and total scores equal to or greater than 9 were given a value of [=1]. To investigate whether a relationship existed between the adverse birth events and maternal mood, logistic regression was used to compare each group of EPDS scores by the adverse event incidence (no event occurrence [=0] versus any event occurrence [=1]).

Upon examination of the logistic regression results, except for the covariate of depression in pregnancy (odds ratio=6.94, 95% confidence interval: 2.11, 21.844, p=.001), an adverse event in labor or delivery did not predict maternal mood when using the 2 categories of scores as provided by the EPDS data (odds ratio=1.38, 95% confidence interval: 474, 3.79, p=.536). None of the other covariates were significant in the multiple regression analysis. Further detail regarding the logistic regression results are described in Table 10.

	Odds Ratio	Lower	Upper
Depression in Pregnancy	6.79**	2.11	21.844
Adverse Event	1.34	.474	3.79

## Table 10. Logistic Regression Results for Maternal Mood

### 5.3.2 FUNCTIONAL STATUS

To investigate whether a relationship exists between the adverse birth events and the outcomes of maternal functional status, statistical modelling using multiple linear regression analysis was used to compare this continuous type maternal outcome by adverse event incidence (no event occurrence [=0] versus any event occurrence [=1]). The analytic approach for both the primary and secondary aims allowed for the inclusion and examination of potential confounding variables, maternal age, parity, education level, depression in pregnancy, and antidepressant use at delivery, while modelling the primary relationships of interest. The level of statistical significance was set at .05. Residual analyses were conducted on all models to assess model fit. Although several model misspecifications and influential observations seemed apparent, based on sensitivity analyses, the regression results for each model did not change significantly with the removal of any influential observations.

Based on the change in  $R^2$  using multiple linear regression, less than 1 % of additional variance was explained in functional status ( $R^2$ =.696, p=.66) following an adverse event in labor or delivery. The aggregate effect of the covariates entered into block 1 of the hierarchical model was significant for functional status ( $R^2$ =.695, p<.001). Further detail regarding the multiple linear regression results for functional status are described in Table 11.

	$R^2$	SE	р	R <sup>2</sup> Change
Covariates*	.695	9.1	<.001	na
Adverse Event Indicator	.696	9.14	.66	.001

## Table 11. Multiple Linear Regression Coefficients for Functional Status

\*Maternal age, parity, education level, antidepressant use at delivery, depression during pregnancy

## 5.3.3 INFANT CARE

To investigate whether a relationship exists between the adverse birth events and the outcomes of infant care, statistical modeling using multiple linear regression analysis was used to compare this continuous type maternal outcome by adverse event incidence (no event occurrence [=0] versus any event occurrence [=1]).

Based on the change in  $R^2$  using multiple linear regression, less than 1% of additional variance was explained in infant care ( $R^2$ =.321, p=.41). The aggregate effect of the covariates entered into block 1 of the hierarchical model was significant for functional status ( $R^2$ =.317, p<.001). Further detail regarding the multiple linear regression results for infant care are described in Table 12.

Change	R <sup>2</sup>	SE	р	R <sup>2</sup>
Covariates*	.317	.116	<.001	na
Adverse Event	.321	.116	.418	.004

### Table 12. Multiple Linear Regression Coefficients for Infant Care

\*Maternal age, parity, education level, antidepressant use at delivery, depression during pregnancy

## 5.4 SECONDARY AIM

For the secondary aim, it was hypothesized that social support directly influences the maternal response at 2 weeks postpartum to negative birth events and may moderate the effect of unplanned adverse events during labor/delivery. To explore if social support was a moderator in the relationship between unplanned birth events and maternal mood, functional status, and infant care, an analytic approach similar to that described for the analysis of data for the primary specific aim was employed. The hierarchical regression models developed for each outcome variable in the primary aim was expanded to also include the main effect for social support and

the interaction effect of the adverse event indicator with social support after controlling for the covariates of maternal age, parity, education level, antidepressant use during delivery, and depression during pregnancy. Residual analyses were conducted on this model as well. All model misspecifications or influential observations were removed and the analyses were repeated to determine if statistical results would change. In all cases, statistical results did not change with the removal of any influential observations.

#### 5.4.1 MAIN EFFECT OF SOCIAL SUPPORT

Social support was a weak predictor of maternal mood with a likelihood ratio of 92.14 when added to the initial hierarchical model for logistic regression (odds ratio: 1.008, 95% confidence interval: 1.001, 1.016, p=.02). Adding social support to the hierarchical model for multiple linear regression was the strongest explanatory variable with an additional 1.6% of explained variance in functional status ( $R^2$ =.712, p=.014), and 9% additional explained variance in infant care ( $R^2$ =.415, p<.001).

## 5.4.2 MODERATING EFFECT OF SOCIAL SUPPORT

The interaction of social support and the adverse event indicator when added to the logistic regression model to predict mood was borderline significant (odds ratio=1.015, 95% confidence interval: .999, 1.028, p=.045). The interaction of social support and the adverse event indicator when added to the multiple linear regression hierarchical model explained less than 1% of

additional variance in functional status ( $R^2$ =.721, p=.056), and no additional variance in the infant care ( $R^2$ =.415, p=.92). The effect of social support was linear and linear in the logit when added to the multiple linear regression models and logistic regression model, respectively. This was evaluated by adding a transformed variable of social support (square root) to the hierarchical regression models already defined. Detailed results for social support when added to the logistic regression and multiple linear regression models are provided in Tables 13, 14 and 15.

	95% C.I for Odds Ratio		
	Odds Ratio	Lower	Upper
Depression in Pregnancy	6.79**	2.11	21.844
Adverse Event	1.34	.474	3.79
Social Support	1.008**	1.001	1.016
Social Support*Adverse Event	1.01	.999	1.028

 Table 13. Logistic Regression Results for Maternal Mood and Social Support

\*\*Significant at .05 level

 Table 14. Multiple Linear Regression Coefficients for Functional Status and Social Support

	$R^2$	SE	р	R <sup>2</sup> Change
Covariates*	.695**	9.1	<.001	na
Adverse Event	.696	9.14	.66	.001
Social Support	.712**	8.93	.014	.016
Social Support*Adverse Event	.721	8.82	.056	.009

\* Maternal age, parity, education level, antidepressant use at delivery, depression during pregnancy

\*\*Significant at the .05 level

	$R^2$	SE	р	R <sup>2</sup> Change
Covariates*	.317*	.116	<.001	na
Adverse Event	.321	.116	.418	.004
Social Support	.415*	.109	<.001	.093
Social Support*Adverse Event	.415	.109	.92	0
* Maternal age, parity, education pregnancy	level, antidej	pressant use a	at delivery, de	pression during
**Significant at the .05 level				

## Table 15. Multiple Linear Regression Coefficients for Infant Care and Social Support

#### 6.0 **DISCUSSION**

The discussion section is organized into six sections. First are the statements addressing the characteristics of the sample. Second is a discussion of the results including the following variables: adverse birth event, functional status, maternal mood, and social support. The third section addresses the clinical implication of my statistically significant finding. Fourth are limitations of the study which include: outcomes, study design, and sample. Fifth are suggestions for future research which include: timing, instruments, definition of adverse events, and concept measurement. Sixth and last is the concluding statement.

### 6.1 CHARACTERISTICS OF THE SAMPLE

The women in this sample were primarily white, married and educated. After reviewing the literature on racial, ethnic, and socio-demographic risk factors in PPD, it is evident that race and ethnicity do not qualify as primary, consistent risk factors for PPD. Rather, it clear that the aggregate of many psycho-social, demographic, cultural and maternal factors influence PPD. Therefore, although the sample characteristics, which are consistent with demographic data for Allegheny County, PA, are not diverse, the characteristics are consistent with the past literature in this area of study.

## 6.2 DISCUSSION OF RESULTS

The purpose of this secondary analysis was to examine the relationship between unplanned, adverse birth events during labor or delivery and maternal mood, maternal functional status, and infant care at 2 weeks postpartum. The findings in this study did not indicate that women with adverse, unplanned events in labor or delivery had varying outcomes related to mood, functional status, or infant care at 2 weeks postpartum

A secondary aim was to explore if social support was a moderator for the relationship between unplanned, adverse birth events and maternal mood, functional status, and infant care at 2 weeks postpartum. The findings in this study did not indicate that social support was a moderator for the relationship between unplanned, adverse birth events and maternal mood, functional status, and infant care at 2 weeks postpartum.

Although perceptions of negative birth experiences, physical health following delivery, cesarean and assisted vaginal delivery in relation to a later diagnosis of PTSD and postpartum depression, and the main effects of social support have all been studied, there exists a gap in the literature specifically looking at a variety of unplanned, adverse events in labor or delivery, such as the events listed in Table 1, and maternal outcomes in the early postpartum period (2 weeks following delivery). When research studies have considered the question of negative birth experiences, the general paradigm is to compare emotional reactions to cesarean sections versus vaginal births; however, the types and circumstances surrounding a negative birth experience can encompass many different events as described in this study.

#### 6.2.1 ADVERSE BIRTH EVENTS

In a prospective, longitudinal study done by Creedy, et al, examining women (n=499) in the third trimester and following them until 4 to 6 weeks postpartum, it was discovered that one in three women (33%) identified a negative birth event and reported the presence of at least three trauma symptoms following the birth of their infant (Creedy, et al, 2000). In this study, as many as 46% of the women experienced an adverse event as identified by a retrospective medical review. Without specific interviews with the women in this study, it is unknown whether or not they perceived their deliveries as having an unplanned, adverse event. The acknowledgement of an adverse event by the women, such as in Creedy's study, could alter their self-report scores on the scales used in this study and thus the findings could have differed significantly.

Murphy, Pope, Frost, and Liebling completed a qualitative study (n=27 women) and determined that operative delivery had a noticeable impact on women's views about future pregnancy and delivery (Murphy, et al, 2003). Three important conclusions were reached by the investigators: (1) antenatal variables did not contribute to the development of acute or chronic trauma symptoms, (2) women who experienced both a high level of obstetric intervention and dissatisfaction with their intrapartum care were more likely to develop trauma symptoms than women who received a high level of obstetric intervention or women who perceived their care to be inadequate, and (3) PTSD is evident in women after a childbirth experience that include intrusive obstetric intervention during labor and delivery, and the care provided to women in labor. Their study also examined women during later time points in the postpartum time period. Being a qualitative study, the investigators were able to collect richer data as it relates to the

women's perceptions; therefore possibly explaining their rich qualitative findings, as opposed to the insignificant quantitative findings in this study. In contrast, this study examined variables early in the postpartum period and did not have the benefit of maternal qualitative interviews. The inability to measure women's expectations of their labors, and their subsequent perceptions of the event following their labors, greatly impacted our ability to accurately measure the adverse effects of certain events. Similarly, cultural and experiential differences were unknown in this study and may have significantly impacted the womens' personal modeling of crisis situations and their subsequent coping strategies.

#### 6.2.2 FUNCTIONAL STATUS

Similar to the measurement of functional status after childbirth, Lydon-Rochelle,

Holt and Martin assessed the association between method of delivery and the general health status, sexual, bowel and urinary functioning of primiparous women as measured at 7 weeks postpartum (Lydon-Rochelle, et al, 2001). At 7 weeks postpartum, women who had cesarean or assisted vaginal deliveries reported significantly lower postpartum general health status scores than women with unassisted vaginal delivery (e.g., did not use forceps or vacuum extraction). Additionally, women with assisted vaginal deliveries reported significantly lower postpartum time point may not accurately measure physical functioning, although it would seem logical that physical ailments as a result of childbirth would be more prevalent closer to the event causing the injury. This study did not find significant results for functional status at the 2 week time point as Lydon-Rochelle did at the 7 week time point. This study included more types of adverse events than just assisted vaginal

deliveries. It is possible that by only examining women from our sample with assisted vaginal deliveries, we could have found significant results similar to Lydon-Rochelle, et al.

#### 6.2.3 MATERNAL MOOD

Similar to Creedy, Shochet, and Horsfall's study, which examined psychological health following an adverse birth event, much of the focus in prior research related to maternal outcomes following an adverse birth event is in the area of Posttraumatic Stress Disorder (PTSD) (Creedy, et al, 2000). For instance, Creedy, et al, found that twenty-eight women in their sample (5.6%) met DSM-IV criteria for acute PTSD (Creedy, et al, 2000). In their study, the level of obstetric intervention experienced during childbirth (beta = 0.351, p < 0.0001) and the perception of inadequate intrapartum care (beta = 0.319, p < 0.0001) during labor were consistently associated with the development of acute trauma symptoms. Typically, studies investigating PTSD focus on later periods during the postpartum recovery where symptoms of PTSD become more evident and more debilitating and not early in the postpartum time period. In contrast, this study did not examine specific symptomotology of PTSD, but rather more general alterations in a larger category of maternal mood in the early postpartum period. The instrument used in this study to measure alterations in mood was not designed, nor nearly specific enough, to measure the mental and emotional impact of PTSD.

## 6.2.4 SOCIAL SUPPORT

Similar to prior studies examining postpartum social support, this study found that the main effect of postpartum social support was significant when predicting mood, functional status and infant care. It was weakly significant for predicting mood when combined with an adverse event; however, due to the borderline significance of the statistic, and the influential main effect of social support by itself, it is possible that this result does not bear true statistical significance. It would logical to assume that social support following an adverse labor event would result in substantial clinical significance. In other words, giving social support to a mother following a traumatic labor or delivery event would most likely yield positive results.

## 6.3 CLINICAL SIGNIFICANCE

Due to the significant relationship between social support and maternal outcomes, careful prenatal screening regarding postpartum social support should be conducted. By incorporating social support screening during the labor and delivery admission, nurses can serve to improve outcomes by providing resources for support in the event that social support is minimally available. Although by 4 to 6 weeks postpartum, alterations in mood, functional status or infant care may have already developed, or even subsequently resolved, postpartum visits should allow for appropriate screening of not only outcomes development, specifically mood alterations, but also the presence or need for additional social support. Nurses can play a key role in not only

assessing a mother's well-being during or following the birth of a child, but also can contribute to a patient's pool of resources that provides social support.

#### 6.4 LIMITATIONS

#### 6.4.1 CHOSEN OUTCOMES

This study did not look at all possible maternal outcomes. For instance, maternal role gratification and general health were not examined in this study, but are areas of potential focus for future studies. This study also did not look at all potential moderators that could influence maternal outcomes. Specifically, the study did not examine the woman's understanding of what actually happened during the course of her labor and delivery, nor were individual coping strategies measured.

### 6.4.2 STUDY DESIGN

General limitations of completing a secondary data analysis must also be addressed as the original hypothesis for the data being collected varies from the hypotheses proposed here, and the data collection methods were defined for the original ADUP study, not for the study being currently addressed.

### 6.4.3 SAMPLE

Another possible limitation of this study was the sample size. A larger sample could have resulted in more statistically significant findings when considering the presence of an adverse birth event with alterations in mood, functional status and infant care, and in the use of more complex models when considering moderation effects.

## 6.5 FUTURE STUDIES

### 6.5.1 TIMING

Similar to prior studies, future studies may include a longitudinal study examining the effects of adverse birth events over time. Research has shown that a diagnosis of PPD can surface between 1 and 6 months, with 3 months being the most common time point (Gaynes, et al, 2005). Most of the women in this sample were free of depression symptoms. In fact, only 21% scored above the cut-off point used for community screening. This study did not examine whether or not depression symptoms developed later in the postpartum period. A possible time point of comparison to re-analyze this data collected at 2 weeks could be 3 months postpartum.

In contrast to examining the potential effects during later time points, we could remain with our present estimation that the greatest impact from adverse birth events is in the early postpartum

period. By measuring maternal mood prior to 2 weeks postpartum, or at birth, we potentially could discover a significant difference in maternal mood between those women who did and did not have unplanned, adverse events during childbirth.

#### 6.5.2 INSTRUMENTS

Another future investigation could involve the instruments used for the study. Although the findings of the pilot study reported that the EPDS is a valid and reliable instrument for use at 2 weeks postpartum, not all of the instruments selected for this study have as strong of a psychometric history or a total score that is as simply obtained and as indicative of concept measurement as the EPDS. Rather than using total scores for some of the other instruments chosen for this study, we could focus on certain subscales of the outcomes measures used in this study. For instance, rather than look at all aspects of the Infant Care Survey, an analysis could be conducted specifically looking at the infant care activities involved with infant health. Similarly with functional status, the data could be analyzed specifically looking at functional status as defined for care of the infant. This approach would allow the investigator to focus on specific activities rather than broad-based total scores of a particular construct.

In addition to looking only at certain subscales of the measures already defined for this study, we could use entirely different scales with potentially stronger and more sustained histories of psychometric success, and not specifically developed for postpartum women. For instance, by using the Hamilton Rating Scale for Depression-29 item and the Medical Outcomes Survey SF-12 Physical Component Score, both at 2 weeks postpartum, we could potentially

elicit a statistically significant finding when examining maternal mood and functional status following an unplanned, adverse labor or delivery event.

#### 6.5.3 DEFINITION OF ADVERSE EVENTS

As previously mentioned, future analyses could include only specific types of adverse events for examination in this hierarchical model, such as forceps or vacuum extraction deliveries. Another approach could be to quantify or rank the adverse events in order of significance. One could easily argue that a placental abruption which resulted in an emergency cesarean section and a term newborn to the neonatal intensive care unit would most likely result in significant alterations in maternal mood as compared to someone who might have experienced significant vaginal and perineal lacerations. By differentiating between not only the severity of the event, but also by the number of events experienced, we could perhaps be able to better quantify the detrimental effects for the mother.

#### 6.5.4 CONCEPT MEASUREMENT

Within the healthcare community, there seems to be expert agreement that adverse birth events exist, and can potentially have a debilitating effect on the mother. The challenge appears to be the ability to accurately and systematically quantify the additional stress given that childbirth is already a life-changing, stressful event by itself. The ability to measure the additive effect of stress continues to be an opportunity for future research and instrument development. Since we already know that qualitative studies have found clinical significance in this area, one other potential avenue would be to explore a physiologic differentiator, such as cortisol levels at birth obtained from maternal serum or infant cord blood. With the absence of an instrument with a proven history of success for measuring the added stress of obstetrical events, a physiologic measure might be able to bridge the gap for researchers determined to quantify the stress level of the birth event.

## 6.6 CONCLUSION

Although the data used for this study met the requirements for the stated hypotheses, and the community-dwelling sample represented a diverse population in terms of health, and labor and delivery management, the occurrence of an adverse, unplanned event during labor or delivery did not appear to significantly impact several maternal outcomes at 2 weeks postpartum. This study adds to the literature by reinforcing the need for frequent, repetitive screenings of alterations or problems with mood, functional status, or infant care. Although it may appear logical that women with adverse events in delivery would exhibit signs of alterations early in the postpartum period, there is little reason to believe that women with uneventful, planned deliveries may not experience the same types of alterations; therefore, necessitating the need for consistent nursing quality, teaching, screening, and support following the birth of an infant.

## APPENDIX

## **IRB APPROVAL**

# University of Pittsburgh Institutional Review Board

#### **Exempt and Expedited Reviews**

University of Pittsburgh FWA: 00006790 University of Pittsburgh Medical Center: FWA 00006735 Children's Hospital of Pittsburgh: FWA 00000600

3500 Fifth Avenue Suite 100 Pittsburgh, PA 15213

Phone: 412.383.1480 Fax: 412.383.1508

TO: Ms. Diane Hunker

FROM: Christopher M. Ryan, PhD, Vice Chair

DATE: November 7, 2006

PROTOCOL: Effects of Birth Events on Postpartum Mood and Functional Status

IRB Number: 0610027

The above-referenced protocol has been reviewed by the University of Pittsburgh Institutional Review Board. Based on the information provided in the IRB protocol, this project meets all the necessary criteria for an exemption, and is hereby designated as "exempt" under section 45 CFR 46.101(b)(4).

• If any modifications are made to this project, please submit an 'exempt

modification' form to the IRB.

• Please advise the IRB when your project has been completed so that it may be officially terminated in the IRB database.

• This research study may be audited by the University of Pittsburgh Research Conduct and Compliance Office.

Approval Date: November 7, 2006

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