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Understanding the Relationships between Pregnancy, Childbirth and Incontinence

by

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Dedication

This thesis is dedicated to my husband - my best friend, my love. Without your support and encouragement, I couldn't have gotten through this past five years. Thank you for always being there for me.

Abstract

The purpose of this thesis was to explore the relationships between pregnancy, childbirth and incontinence (both urinary and faecal) and the effect of preventive activities during pregnancy on continence. Two papers comprise this thesis. The first paper is a scoping review focused on the effect of pregnancy and childbirth on continence in the nulliparous woman. Several key considerations were identified that we suggest are crucial to understanding these relationships. Further high quality prospective research is proposed that investigates the relationships between pregnancy, natural childbirth and incontinence. The second paper is a systematic review focused on the effect of preventive measures during pregnancy on continence. Pelvic floor muscle training was found to be effective in reducing the incidence of incontinence at 3 mths postpartum. Few studies met our inclusion criteria thus limiting analysis of data. The final chapter of this thesis outlines a PhD project that addresses the gaps identified through the scoping and systematic reviews.

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List of Nomenclature and Abbreviations

For the purposes of clarity, “methods, definitions and units conform to the standards jointly recommended by the International Incontinence Society (ICS) and the International Urogynecological Association except where specifically noted” (Haylen et al., 2009, page 5).

I. Urinary Incontinence Symptoms:

i. Urinary Incontinence (UI) *(symptom)*: the complaint of any involuntary loss of urine.

ii. Urgency (urinary) incontinence: the complaint of involuntary loss of urine associated with urgency.

iii. Stress (urinary) incontinence: the complaint of involuntary loss of urine on effort or exertion, or on sneezing or coughing.

iv. Mixed (urinary) incontinence: the complaint of involuntary loss of urine associated with urgency and also with effort or physical exertion, or on sneezing or coughing.

II. Symptoms of Anorectal Dysfunction:

i. Faecal incontinence: the complaint of involuntary loss of faeces.

   a. Solid

   b. Liquid

   c. Passive faecal incontinence: such as soiling without sensation or warning or difficulty wiping clean.

   d. Coital faecal incontinence: occurring with vaginal intercourse.

III. Pad Testing: Quantification of the amount of urine lost over the duration of testing, by measuring the increase in the weight of the perineal pads (weighed pre- and post-testing) used.

IV. Urodynamic Investigations and Associated Pelvic Imaging:

i. Urodynamics: functional study of the lower urinary tract.

ii. Cystometry: measurement of the pressure/volume relationship of the bladder during filling and/or pressure flow study during voiding.

iii. Filling Cystometry: this is the pressure/volume relationship of the bladder during filling. It begins with the commencement of filling and ends when a "permission to void" is given by the urodynamicist.

iv. Urodynamic studies: these usually take place in a special clinical room (urodynamic laboratory) and involve (artificial) bladder filling with a specified liquid at a specified rate.

V. Ultrasound Imaging: Current routine possible uses of ultrasound in urogynecology and female urology include;

i. Position of bladder neck and on Valsalva

ii. Position of bladder neck during pelvic floor contraction

iii. Urine loss – full urethral opening during coughing, Valsalva, bladder contraction and micturition.

VI. Endosonography: this is the gold standard investigation in the assessment of anal sphincter integrity.

Adapted from: Haylen, B.T. et al., (2010). An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Neurourology and Urodynamics, 29*, 4.

Chapter 1

Introduction

Understanding the relationships between pregnancy, childbirth and incontinence

Incontinence (urinary and/or faecal) is a symptom commonly experienced by individuals as they approach older age (Boyington, Howard, Carter-Edwards et al., 2007; Hannestad, Rortveit, Sandvik & Hunskaar, 2000; Zhu, Lang, Wang et al., 2007). Unfortunately, it is also a symptom that is experienced by a significant number of women during their childbearing years (Guise, Morris, Osterweil et al., 2007; Kristiansson, Samuelsson, von Schoultz & Svardsudd, 2001; Thorp et al., 1999). Although most symptoms of incontinence during pregnancy and the postpartum period resolve, increasing age is often associated with a return or new onset of incontinence (Minassian, Stewart & Wood, 2008; Rekers, Drogendijk, Valkenburg & Riphage, 1992). Incontinence is not considered to be life-threatening, however this symptom may cause significant psychological and social distress for affected individuals and impact their quality of life (Hunskaar et al., 2005; Tennstedt, Fitzgerald, Nager et al., 2006). There are several different types of incontinence as well as a wide range in severity and frequency of symptoms. Although research in this field has accumulated sufficient data to describe how certain types of incontinence appear in specific populations, the published literature reflects a lack of understanding about the relationships between pregnancy, labour and birth management, prevention and treatment, and all types of incontinence.

Background

Epidemiology

The prevalence of incontinence has been reported between 1.4% (Perry et al., 2002) and 69% (Swithinbank et al., 1999) depending upon type of incontinence, descriptors used to define

incontinence, gender, age, race/ethnicity, and individual factors including parity and mode of delivery, surgical history, life stage, and presence of chronic diseases. Urinary incontinence (UI) is a symptom experienced twice as often by women compared to men (Hunskaar et al., 2005) and more often by certain subpopulations of women including postpartum women (Kristiansson et al., 2001; Thorp et al., 1999) and older women (Boyington et al., 2007; Zhu et al., 2007). In a large study by Hannestad et al. (2000), the prevalence of UI across the lifespan was found to present in a common pattern, where UI increases to middle age, levels off between the ages of 50 and 70 years and then increases steadily in older groups. Other authors have noted a similar prevalence, which has pushed investigators to focus on discovering the etiology of this phenomenon. Further, when one examines the many types of incontinence and prevalence by age, it is understood that stress incontinence is most common in the young to middle aged woman (Hannestad et al., 2000; Minassian, Stewart & Wood, 2008; Samuelsson, Victor & Tibblin, 1997; Zhu et al., 2007) while mixed and urge incontinence are more common in older women (Minassian, Stewart & Wood, 2008; Roberts et al., 1998; Zhu et al., 2007). Why the types of UI differ and change across the lifespan is not yet fully understood.

Faecal incontinence (FI) is reported less commonly than UI with prevalence between 0.9% (Perry et al., 2002) and 29% (Guise et al., 2007) in young to middle age and upward toward 54.4% in older institutionalized adults (Topinkova, Neuwirth, Stankova, Mellanova & Haas, 1997 as cited in Hunskaar et al., 2005). Again, women report FI more frequently than men and often, new onset FI is experienced following pregnancy and birth (Eason, Labrecque, Marcoux & Mondor, 2002; Guise et al., 2007).

The Anatomy and Physiology of Continence

Prior to engaging in any research focused on the physiology of female continence, it is vital to gain an understanding of the complexities of normal bladder and bowel control. The section that follows will provide a brief overview regarding the anatomical structures and processes important to continence.

Normal function of pelvic organs is directly dependant upon the integrity of the pelvic floor. The synergistic action of ligaments, fascia, and muscles of the pelvic floor give the pelvic viscera form, structure and strength (DeLancey, 2008; Petros, 2004). The pelvic floor includes three muscle layers and the puborectalis muscle, the perineal membrane as well as the related connective tissue structures and fascial attachments of the visera (DeLancey, 2008; Petros, 2004; Scarpero & Dmochowski, 2006). The bony pelvis (comprised of the ilium, ischium, pubis, sacrum and coccyx) acts as a "…scaffold from which the muscles and organs are suspended" (Hoyte, 2008, pg. 1), and is therefore important to continence. Further, control of the muscles, ligaments and fascia of the pelvic floor and organs of the pelvis (bladder, urethra, vagina, rectum, and uterus) are dependent upon normal neurological and vascular function. Damage to any of these structures by way of injury, disease or surgery can have a significant impact on continence (DeLancey, 2008; Vodušek, 2008).

The Muscles of the Pelvic Floor

The muscles of the pelvic floor form three layers: upper, middle and lower (Petros, 2004). These layers act in a coordinated fashion to control the movement of the pelvic organs in response to intra-abdominal pressure changes, thereby preventing organ prolapse and assisting in the closure of the urethra and anus. As well, certain muscular components act as supports for the pelvic viscera

(Barber et al., 2002; DeLancey, 2008; Herschorn, 2004; Hoyte, 2008; Petros, 2004; Scarpero & Dmochowski, 2006).

The upper muscle layer. The upper layer of muscles is horizontal in orientation and consists of the anterior part of the pubococcygeus muscle anteriorly and levator ani posteriorly as well as the obturator and piriformis muscles. The levator ani muscles (known separately as the pubococcygeus, iliococcygeus, and puborectalis) form a sheet-like complex that acts as a sling around and through the pelvis. The role of the levator ani is twofold: 1) to maintain the urogenital or levator hiatus (space which contains the urethra, vagina and anorectum) in a closed position maintaining the pelvic viscera and, 2) to produce certain actions in response to body functions that change intra-abdominal pressure (e.g. to contract reflexively with coughing in order to maintain continence). The levator ani muscles are mandatory for normal and active closure of the urethra, vagina, and rectum (Barber et al., 2002; DeLancey, 2008; Petros 2004; Scarpero & Dmochowski 2006).

Also included in this layer are the obturator and piriformis muscles. The obturator composes the lateral pelvis originating at the internal surface of the obturator membrane, posterior bony margins of the obturator foramen, the pubic rami, and the ramus of the ischium and inserting into the medial surface of the greater trochanter. The obturator neurovascular bundle runs through the openings of the obturator foramen within the bony pelvis, and obturator canal within the muscle. The piriformis arises from the sacrum and inserts on the greater trochanter. This muscle lies below the sacral plexus, across its length, beneath the coccygeus.

The middle muscle layer. The middle layer is vertically oriented and consists of the longitudinal muscle of the anus (which takes fibres from the levator ani, the lateral part of the

pubococcygeus muscle and puborectalis). This muscle layer provides a downward force during effort for bladder neck closure, and assists with micturition (Petros, 2004).

The lower muscle layer. The lower layer of muscles acts as an anchoring layer. This layer is also known as the perineum and is comprised of the median bulbocavernous, right and left ischiocavernosus, and the deep and superficial transverse perinei muscles. This lower layer of muscle contracts to stabilize the distal parts of the urethra, vagina and anus and helps to contain the abdominal contents (DeLancey, 2008; Petros, 2004).

Puborectalis muscle. The puborectalis muscle traverses all three muscles layers and is oriented vertically. This muscle plays a pivotal role in anorectal closure and is also voluntarily controlled during 'squeezing' efforts to stop the flow of urine (Petros, 2004). This muscle originates medial to the pubococcygeus muscle and inserts into the posterior wall of the rectum.

The Connective Tissue Structures

Connective tissue is a generic term used to describe tissue that contains proteoglycans, collagen and elastin. Both collagen and elastin are affected and altered by the hormones of pregnancy (Iosif, 1989; Kristiansson et al., 2001; Thorp et al., 1999; Viktrup et al., 1992). These alterations may purposefully loosen and affect the structural integrity of the pelvic floor. The mechanisms responsible for these changes are not completely understood but have been implicated as a cause of female incontinence, especially during pregnancy (Iosif, 1989; Kristiansson et al., 2001; Petros, 2004; Thorp et al., 1999; Viktrup et al., 1992).

Perineal Membrane. The perineal membrane, which is a dense triangular area of fascia, arises from the inferior ischiopubic rami and attaches medially to the urethra, vagina and perineal

body (DeLancey 2008). This membrane (previously known as the urogenital diaphragm) "…bridges the gap between the inferior pubic rami bilaterally and the perineal body" (Herschorn, 2004, pg. S5), and supports and assists in closure of the distal urethra and vagina (DeLancey 2008; Herscorn, 2004).

The Perineal Body. The perineal body, a tendinous structure located midline between the anus and vagina, is the key anchoring point for contraction of the bulbocavernosus and external anal sphincter (DeLancey, 2008; Herschorn, 2004).

The Endopelvic Fascia. The endopelvic fascia lies immediately beneath the peritoneum and is one continuous unit with various thickenings or condensations (Herschorn, 2004). This structure attaches the pelvic organs to the pelvic walls and consists of a combination of blood vessels, nerve bundles and connective tissue. Many parts of the endopelvic fascia are named and include the uterosacral ligaments, cardinal ligaments, broad ligaments, parametrium, paracolpos, pubocervical fascia and rectovaginal fascia. Depending upon their purpose, the individual parts of the endopelvic fascia will contain different types of connective tissue fibres according to their role (Herschorn, 2004).

The Pelvic Organs

As mentioned previously, the bladder, urethra, vagina, rectum and uterus are contained within the pelvic floor. It is not within the scope of this paper to fully describe the functions of each of these organs.

Nervous and Vascular Supply

Continence depends upon the complex interaction between the brain, nervous system and

pelvic structures. A brief review of the most significant sources of nervous and vascular supply to the pelvic structures is provided below.

Nervous supply. The autonomic inferior hypogastric plexus (IHP) is the major nerve supply to the pelvic organs. It is composed of parasympathetic fibres from sacral nerve roots S3-5 and sometimes S2 as well as sympathetic fibres from T11-12/L1-2 (Butler-Manuel et al., 2000; Scarpero & Dmochowski, 2006). IHP is located on the pelvic sidewalls beneath the fascia and extends from the sacrum to the pelvic organs (Scarpero & Dmochowski).

Recent dissections have found that the pudendal nerve innervates the external anal sphincter, external urethral sphincter, perineal muscle, vagina, clitoris and perineal skin while the levator ani were found to be innervated by a nerve that originated from the 3rd to the 5th sacral foramina (now known as the levator ani nerve) (Barber et al., 2002). This nerve is potentially exposed to damage during childbirth from the feotal head during descent (Barber, et al., 2002).

Vascular supply. The pelvic organs do not have common embryology and therefore, their blood supply differs. That being said, the internal iliac artery or hypogastric artery is the main blood supply to the pelvis and pelvic viscera. There are contributions as well from the ovarian artery, vaginal artery, and umbilical artery (Scarpero & Dmochowski, 2006).

The pelvic floor plays an important role in continence and pelvic organ support. Throughout the lifespan, there are many normal developmental changes that can impact the structures of the pelvic floor and indirectly affect continence. For the female, pregnancy and childbirth involve normal physiological adaptations to the pelvic floor but as well, may involve complications of labour and/or medical interventions. Both the normal adaptations and iatrogenic events have the potential

to negatively affect continence.

My Interest

In my clinical roles as registered nurse, midwife and most recently nurse practitioner (NP), I have been fortunate to provide care to many pregnant, parenting and ageing women. Over the years, I have come to understand how frequently and significantly women are affected by incontinence. I am continually amazed at the numbers of women whom I encounter that struggle with incontinence and explain it away as a simple consequence of having had children. This recurrent theme has motivated me toward understanding more about the relationships between pregnancy, childbirth and incontinence.

There is a vital role for medical interventions during labour under certain circumstances. Some of these interventions can however, have long-term consequences for women. Further, many childbirth professionals use techniques such as induction, augmentation, epidural, directed pushing and episiotomy even though all have been identified as risk factors for incontinence (Bohra, Donnelly, O'Connell, Geary, Macquillan, & Keane, 2003; Carroli & Belizan, 2009; Fitzpatrick, Harkin, McQuillan, O'Brien, O'Connell, & O'Herlihy, 2002; Robinson, Norwitz, Cohen, McElrath, & Lieberman, 1999).

Birthing philosophies that require the use of medical control and labour management have the potential to seriously and negatively impact a woman's continence status both in the short and long-term (Bohra et al., 2003; Carroli & Belizan, 2009; Fitzpatrick et al., 2002; Robinson et al., 1999). However, such models of care are quite common, making it difficult to develop an understanding of the underlying relationships between pregnancy, birthing and incontinence. Although it is clear

from the literature that a relationship does exist, there is not yet agreement regarding the nature of this relationship and how childbirth should be approached in order to protect continence.

Purpose of Thesis

The purpose of this thesis and each of its component papers is to facilitate a deeper understanding of the relationships between pregnancy, labour and birth management, intervention for the purposes of prevention of UI and/or FI, and incontinence. Outcomes of the thesis will include development of two publication quality papers (Chapters Two and Three) and integration of the papers into a foundation for further research and doctoral work focused on identifying risk factors for incontinence during pregnancy and childbirth (Chapter Four).

Method

This thesis reviews the current literature and summarizes what is currently known about the relationships between pregnancy, childbirth management and incontinence. The guiding questions for the first paper (Chapter Two) were: 1) what is known about the relationship between pregnancy and incontinence; and 2) what is known about the relationship between childbirth and incontinence? These questions were addressed through a scoping review. The guiding question for the second paper (Chapter Three) was: what is the long-term (up to ten years post index pregnancy) effect of preventive interventions intended to protect continence during pregnancy and in the postpartum period? This question was address through a systematic review.

The Papers

Paper One

The first paper in this thesis is a scoping review and examines the available literature specific

to the relationships between pregnancy, childbirth and incontinence. There is a significant amount of published research that has investigated the physiology and mechanics of pregnancy, childbirth and incontinence (Aasheim, Nilsen, Lukasse & Reinar, 2007; Beckmann & Garrett, 2006; Carroli & Belizan, 1999; Fernando, Sultan, Kettle, Thakar & Radley, 2006; Handa, Harris & Ostergard, 1996; Kettle, Hills & Ismail, 2007; Kristiansson et al., 2001; Tincello, Adams & Richmond, 2002) however, there are a limited number of papers available that summarize the research and fully describe how a first pregnancy and childbirth influence continence. Initially, I had hoped to address this gap in the literature by completing a systematic review. Through the process of preparing this paper and thesis, it became apparent that there are very few studies that meet the inclusion criteria that I had originally proposed. Specifically, most investigators failed to analyze and report findings on nulliparous women separately from multiparous women. This is a crucial consideration because every pregnancy and vaginal delivery has the potential to impact continence (Wilson, Herbison & Herbison, 1996). I was unwilling to compromise on the inclusion criteria for this review because I strongly believe that nulliparous women are the most appropriate sample for such an investigation. This scoping review is based on a framework developed by Arksey & O'Malley (2005) and maps this field of study describing the range of available evidence. Further, this review allowed us to identify gaps in the existing literature, which will act as the foundation for design of further research.

Paper Two

The second paper is a systematic review of the literature regarding prevention activities during pregnancy and the postpartum period and the effect of these interventions on urinary and faecal incontinence. Although there is published research that demonstrates the short-term positive

effects of pelvic floor exercises (Mørkved, BØ, Schei & Salvesen, 2003; Sampselle et al., 1998) and other techniques such as perineal massage from 36 weeks (Eogan, Daly, & O'Herlihy, 2006) or warm packs during labour (Dahlen et al., 2007), there are few studies that address the long-term effects of these types of intervention. Thus the purpose of this paper is to explore the literature focused on prevention of incontinence during pregnancy and after delivery and determine what evidence exists to support preventive measures.

Conclusion: Contribution to Nursing Practice

Nurses working in the perinatal, labour and delivery and postpartum environments are in a position to significantly impact the health of women. Whether it is through the provision of information and education during pregnancy or by their actions during labour, nurses can influence continence-related childbirth outcomes. It is my hope that through the process of this thesis, I will be able to describe the potential positive effects of non-invasive approaches to care in the peripartum environment specific to protection of continence.

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Chapter 2

Paper One: The relationships between pregnancy, childbirth and incontinence: A scoping review.

The relationships between pregnancy, childbirth and incontinence: A scoping review.

Background

Incontinence (urinary and/or faecal) is a symptom commonly experienced by individuals as they approach older age (Boyington, Howard, Carter-Edwards et al., 2007; Hannestad, Rortveit, Sandvik & Hunskaar, 2000; Zhu, Lang, Wang et al., 2007). Unfortunately, it is also a symptom that is experienced by a significant number of women during their childbearing years (Guise, Morris, Osterweil et al., 2007; Kristiansson, Samuelsson, von Schoultz & Svardsudd, 2001; Thorp et al., 1999). Incontinence is not considered to be life threatening however this symptom may cause significant psychological and social distress for affected individuals and impact their quality of life (Hunskaar et al., 2005; Tennstedt, Fitzgerald, Nager et al., 2006).

There is a considerable amount of published research that has investigated the alterations to physiology as well as the mechanics of the pelvic floor during pregnancy and childbirth. There is also a sizeable amount of evidence in the literature specific to the incidence and prevalence of childbirth related incontinence. However, there is little agreement regarding the relationships between pregnancy, childbirth and incontinence. Some authors cite vaginal birth as the cause of incontinence (Lukacz, Lawrence, Contreras, Nager, & Luber, 2006) while others have demonstrated similar rates of incontinence in groups of women who delivered via caesarean section (Liang et al., 2007).

Although it is clear that some sort of relationship exists between pregnancy, childbirth and incontinence there is not agreement regarding the nature of this relationship. As well, there is potential that certain techniques and interventions used in childbirth might protect continence or

lead to incontinence, but the effectiveness of different approaches is not well understood. Increased understanding of risk factors for incontinence during pregnancy and identification of childbirth management approaches that protect or impede continence will assist clinicians and women toward a better understanding of how to protect continence mechanisms in pregnancy and childbirth.

The Review

Aims

The aim of this review was to examine the range of evidence specific to the relationships between pregnancy, childbirth and incontinence. Further we hoped to identify gaps in the literature that might be the focus of future research projects. Our scoping review was directed by the questions: 1) what is known about the relationship between first pregnancy and de novo incontinence; and 2) what is known about the relationship between first childbirth and de novo incontinence?

Nulliparous women who were continent prior to pregnancy were considered the most appropriate sample for research specific to childbirth related incontinence as their bodies were not yet exposed to the hormones of pregnancy, to the weight of the fetus, or to the instruments utilized during labour to assist with passage of the fetus through the birth canal – all important potential causes of de novo incontinence (Abramowitz et al., 2000; Belmonte-Montes, Hagerman, Vega-Yepez, Hernandez-de-Anda, & Fonseca-Morales, 2001; Boyles, Li, Mori, Osterweil, & Guise, 2009; Eftekar, Hajibaratali, Ramezanzadeh, & Shariate, 2006; Fenner, Genberg, Brahma, Marek, & DeLancey, 2003; Fitzpatrick, Behan, O'Connell, & O'Herlihy, 2003; Guise et al., 2007; Harvey ,

Johnston, & Davies, 2008; Kristiannson et al., 2001).

Method

A preliminary scan of the literature completed in September 2008 reinforced the need for clarification of key concepts underpinning this area of research. For this reason we chose to undertake a scoping review based on a methodological framework developed by (Arksey & O'Malley, 2005). Our review is meant to map this field of study by describing the range and nature of available research as well as to identify research gaps in the existing literature. In keeping with scoping methodology, this review does not include an assessment of study quality or statistical analysis of data.

Terminology

For the purposes of clarification, the term *actively managed labour* is used throughout the body of this paper to describe an approach to labour that involves prescribed interventions meant to: initiate dilation of the cervix; control the rate and/or intensity of contractions; control the amount of time for feotal descent; and minimize risk for perineal tearing. The alternative to actively managed labour is the *natural childbirth* approach in which labour is allowed to start and progress without the prescribed interventions listed above.

Search methods

Identifying relevant studies

For this review, inclusion criteria for studies were: written in English between the years 1960 and 2009; involved human female subjects between the ages of 14 and 50 years of age (childbearing age); and provided information about management of labour and mode of delivery. The authors

must have reported outcomes for nulliparous women with no pre-pregnancy urinary incontinence (UI) or faecal incontinence (FI). The primary or secondary outcome of interest must have been UI or FI. Study sites must have been in industrialized countries. All quantitative retrospective and prospective studies as well as gray literature that could be identified through the search strategy described below were eligible for inclusion. Gray literature was defined as conference proceedings, working papers and theses. Adhering to these inclusion criteria limited the number of potential papers in our scoping review but also allowed for a more focused examination of the issues important to this area of research.

All major electronic databases were searched January 2009 and included: CINAHL (1960 to 2009), Medline (Ovid interface 1950 to 2009), the Cochrane Library's Evidence Based Medicine Reviews (EBMR – Central Register of Controlled Trials 1960 to 2009), and EMBASE (1980 to 2009). The search was documented in order to demonstrate rigor and for purposes of reproducibility. Search terms were identified with the assistance of a Research Librarian and included the following MeSH terms (all were exploded): obstetric, labour, complications, parturition, delivery, birth, episiotomy, forceps, vacuum, instrument, and incontinence. Reference lists of relevant papers and conference programs were analyzed for potentially useful sources of research not previously located, including gray literature.

Study selection

Studies were selected using a two-stage process. First, all titles and abstracts yielded by the electronic searches were scrutinized (S.L.P. and K.H.) and full manuscripts of potentially eligible citations were obtained. Second, studies were carefully critiqued to ensure they met all of our

predefined inclusion criteria.

Charting the data

Arksey and O'Malley (2005) suggest that extracting relevant data for each study, entering it on to a data charting form, and then later summarizing the literature according to themes is the most useful way of approaching this stage of the review. Therefore, the data collected from each research report included in our review is standardized and reflects general study information as well as specific information considered relevant for our analysis. If reported, the following data were extracted from each paper:

- research methods
- the study sample
- outcomes of interest
- findings relevant to outcomes of interest

Results

Search outcome

The electronic search yielded 2604 citations (see Figure 2-1). On examination of titles and abstracts, 126 were found to be relevant to the review and full papers were obtained for these. The reference lists of these papers revealed three further citations. After reading each of the papers and reflecting on our inclusion criteria, 28 studies were included in this scoping review.

Conference proceedings from the 2009 Annual International Continence Society were reviewed and yielded two abstracts however neither of these papers met our inclusion criteria. A working paper identified through discussion with an expert in the field was requested in November

2008 but not received (Schulz, 2009, unpublished).

Excluded studies

One hundred and one papers were excluded from this scoping study because they did not meet our predetermined inclusion criteria (Figure 2-1). The majority (n=49) of the excluded studies allowed participation of women who reported UI or FI pre-pregnancy. The second most common reason for exclusion was due to authors' failure to report nulliparous and multiparous data separately (n=27). We felt studies that included women who were incontinent prior to pregnancy and/or multiparous introduced two strong confounding variables that would fail to clearly improve understanding of relationships between the key variables of interest. Finally, studies were excluded because UI or FI was not an outcome of interest. This group of excluded studies was focused on outcomes such as perineal tearing and not subjective or objective measures of incontinence (n=9).

Included studies

Twenty eight studies met all of our inclusion criteria. Only seven reported outcomes that reported regarding the relationship between pregnancy and de novo pregnancy or postpartum incontinence. In fact, the majority of studies included in this review (n=21) were focused primarily on examining the relationship between childbirth and de novo postpartum incontinence.

Design

Most of the studies were retrospective in design for pre-pregnancy and pregnancy data with only 11 studies recruiting participants prior to delivery. As a result, most studies relied on participant recall up to 10 mths for data specific to pre-pregnancy and pregnancy continence status and other factors including BMI.

Interventions

The majority of studies reported post hoc analysis of the relationship between interventions during labour and childbirth and incontinence. Reported interventions included: induction, epidural, augmentation, episiotomy, use of assistive devices (forceps or vacuum) and caesarean section.

Reporting of outcomes

The primary outcome for most studies was incontinence (UI and/or FI). Some studies however, focused primarily on perineal defects and as a secondary outcome investigated the relationship between the presence or absence of a defect and incontinence.

Summarizing the results

Due to the fact that so few studies focused on examination of the relationship between pregnancy and de novo incontinence, we chose to summarize the included studies according to whether or not they reported regarding de novo pregnancy incontinence. Table 2-1 summarizes studies that reported results specific to de novo pregnancy incontinence (UI or FI) while Table 2-2 summarizes studies that reported solely on postpartum incontinence (UI or FI).

The scoping study is meant to provide an overview of a wide breadth of literature specific to the question of interest rather than to statistically synthesize evidence as is done with a systematic review. We found that the large body of material included in this scoping study presented a challenge because of its heterogeneity in sample characteristics, primary outcome and intervention. For this reason, we chose to prioritize certain aspects of the literature for the purposes of clarity in reporting.

Four themes were identified as priority to addressing our questions of interest. These

themes were chosen because they were the most commonly reported and discussed concepts throughout the included literature: 1) pre-pregnancy basal metabolic index (BMI) and infant birth weight; 2) de novo pregnancy incontinence as a predictor of long-term incontinence; 3) instrument-assisted vaginal delivery and de novo postpartum incontinence; and 4) active management of labour and the effect on outcomes of vaginal birth. Data from included studies are summarized in narrative according to each of these four themes.

1. Pre-pregnancy BMI and infant birth weight

Many of the studies included in their data collection and analysis, examination of the effect of BMI and infant birth weight on UI or FI (Boyles et al., 2009; Burgio et al., 2007; Eftekhar et al., 2006; Fenner et al., 2003; Glazener et al., 2006; Harvey et al., 2008; Thomason, Miller, & Delancey, 2007; van Brummen, Bruinse, van de Pol, Heintz, & van der Vaart, 2006). Interestingly, high pre-pregnancy BMI (>30) was consistently associated with an increase, and frequently a statistically significant increase in risk of de novo pregnancy and/or postpartum UI (Boyles et al., 2009; Eftekhar et al., 2006; Glazener et al., 2006; Harvey et al., 2008; Thomason et al., 2007) as well as FI (Burgio et al., 2007). Although maternal weight gain during pregnancy was not found to increase the risk of de novo pregnancy or postpartum incontinence, infant birth weight > 3200g was deemed a significant predictor of de novo postpartum UI (Boyles et al., 2009; Eftekhar et al., 2006) and FI (Fenner et al., 2003; Guise et al., 2009).

2. *De novo pregnancy incontinence as a predictor of long-term incontinence.*

De novo pregnancy incontinence during a first pregnancy was predictive of long-term incontinence (up to 1 year postpartum) (Eason, Labrecque, Marcoux, & Mondor, 2004; Thomason et

al., 2007). In fact, all of the studies that included de novo pregnancy incontinence as well as postpartum incontinence as outcomes of interest demonstrated a positive correlation between these two variables (Burgio et al., 2007; Eason et al., 2004; Thomason et al., 2007). The key factor in this relationship might again be a high (>30) pre-pregnancy BMI. When BMI was included in statistical modeling it was consistently found to be a significant predictive factor for both de novo pregnancy and postpartum UI or FI. Unfortunately, many of the studies included in this review were retrospective in nature making it difficult to clearly identify the contribution of BMI and pregnancy-related changes in the body to the development of de novo incontinence during or after pregnancy.

3. *Instrument-assisted vaginal delivery and de novo postpartum incontinence.*

Defects to the perineal body and/or sphincter defects were found in most studies to be significantly positively correlated with de novo or worsening postpartum UI and/ or FI (Abramowitz et al., 2000; Belmonte-Montes, Hagerman, Vega-Yepez, Hernandez-de-Anda, & Fonseca-Morales, 2001; Borello-France et al., 2006; Boyles et al., 2009; Burgio et al., 2007; Dietz & Lanzarone, 2005; Sultan, Kamm, Hudson, Thomas, & Bartram, 1993; van Brummen et al., 2006). When identified, defects were significantly positively correlated with instrumental delivery (use of forceps or vacuum) (Abramowitz et al., 2000; Belmonte-Montes et al., 2001; Fenner et al., 2003; Fitzpatrick, Behan, O'Connell, & O'Herlihy, 2003). Use of an instrument is highly positively correlated with episiotomy (Nazir, Carlsen, & Nesheim, 2002). Three studies (Belmonte-Montes et al., 2001; Mazouni, Bretelle, Battar, Bonnier, & Gamerre, 2005; Peschers et al., 2003) described the use of episiotomy for most or all women regardless of labour progress even though it has been shown through systematic review to be highly positively correlated with an increased risk of postpartum FI (Carroli & Mignini, 2009).

4. Active management of labour and the effect on outcomes of vaginal birth.

Some of the studies included in this review reported retrospective examination of interventions used during labour and birth in relation to de novo postpartum incontinence. Peschers et al., (2003) stated a "high" use of epidural, which they have demonstrated as leading to a significant increase in the length of the 2nd stage of labour. Unfortunately, these authors did not analyze how the increased length of 2nd stage affected continence post delivery. In another example, Liang et al., (2007) described their commitment to an *active management* approach but gave no details as to the actual techniques utilized for induction and augmentation. Again, these authors did not analyze for the presence of a relationship between active management interventions and continence.

Several studies reported on differences in prevalence of incontinence between vaginal birth and caesarean section (C/S). In some cases, caesarean section was found to be protective against de novo postpartum incontinence (Boyles et al., 2009; Eftekhar et al., 2006), however this was not consistent. In fact, in three studies (Borello-France et al., 2006; Guise et al., 2009; Liang et al., 2007) it was reported that at 3-6 mths postpartum there was no significant difference between the vaginal and C/S groups specific to incidence of incontinence.

Discussion

Through the process of completing this scoping review we were able to delineate some key variables to include in future research. These include: pre-pregnancy BMI and infant birth weight; the predictive potential of de novo pregnancy incontinence on long-term incontinence; interventions used during labour and birth; and actively managed vaginal birth versus natural

childbirth. Several factors put women at risk for de novo pregnancy or postpartum incontinence – some being modifiable factors (e.g. pre-pregnancy BMI), and other situational (e.g. use of assistive devices at delivery). As no well designed descriptive or comparative studies of natural childbirth were found, it is not possible to identify the role of natural vaginal birth in the development of de novo childbirth incontinence.

The included studies indicate that the state of the science on the relationship between vaginal birth and incontinence is weak and the etiology is likely multifactoral. The role of pregnancy to the development of de novo incontinence is not well understood. Two studies were identified during our literature search that focused on the change in concentration of the pregnancy hormone relaxin and the effect on continence. At this time, there is insufficient published data available to describe the natural or pathophysiological impact of hormonal fluctuations on continence. Further, no study to date has included all of the key concepts from all four of the themes identified in our review. Without a clear understanding of the entire picture of how pregnancy and natural vaginal birth affects continence mechanisms, it is not possible for C/S to be deemed protective of the pelvic floor and vaginal birth deemed the cause of incontinence.

Of the 28 studies included in this review, six reported use of active management of labour but only two analyzed the effect of these interventions on either UI or FI (Liang et al., 2007; Sartore et al., 2003). The majority of did not fully describe the approach to labour management (active, natural or some alternative). We were left to assume that labour management approach and hence, any interventions, were chosen by the birth attendant based on their training, experience, hospital protocol and situational factors. From a clinical research perspective, absence of data specific to

intervention type in conjunction with the heterogeneity across studies makes it impossible generalize findings. Inclusion of the details about labour and birthing interventions is essential in this type of research because of the potential impact of each and every intervention on the woman, the fetus, the labour and the pelvic floor.

The inconsistent reporting of labour management approach and the frequent use of epidural and episiotomy across studies makes it difficult to accept claims that vaginal birth is the cause of de novo childbirth incontinence and further, that C/S is protective. No studies were identified in our search of the literature that described a natural or non-interventionist approach toward labour and birth. In fact, the current literature on childbirth related incontinence contains a variety of poorly described interventions that are confounders to our understanding of the relationship between vaginal birth and de novo childbirth incontinence. To further confuse the issue, no studies of nulliparous women were identified that attempted evaluation of both the relationship of pregnancy and approach to childbirth to de novo childbirth incontinence. In the absence of well controlled published studies that compare objectively measured continence outcomes between actively managed labour vs. natural vaginal birth, it is difficult at this time to clearly determine which childbirth practices either protect or contribute to incontinence. Further, the role of pregnancy in this relationship has not been clearly articulated.

Conclusion

Much attention has been paid to the links between vaginal birth and incontinence and the protective nature of C/S. Much of the published literature focused on this area of research is retrospective and inclusive of women who are both multiparous and incontinent prior to pregnancy.

These factors limit the authors' ability to make conclusions about how pregnancy and vaginal delivery are related to incontinence.

All of the studies included in this scoping review met our specific inclusion criteria. From analysis of the standardized data provided by each of the studies, four themes were revealed which we consider to be key considerations underpinning this complex area of research. Reflecting upon the findings outlined in the body of this paper, we suggest that future studies be prospective in design and considerate of the potential impact of pre-pregnancy BMI, pregnancy, and interventions used during labour and birth on the pelvic floor and continence. To date, no study has been undertaken to specifically examine the relationships between natural vaginal birth and incontinence. Only through prospective observation of pregnancy with comparison of natural vaginal birth versus actively managed labour and delivery and long-term follow up of objectively assessed continence can any relationships be defined.

Figure 2-1: Result of literature search.

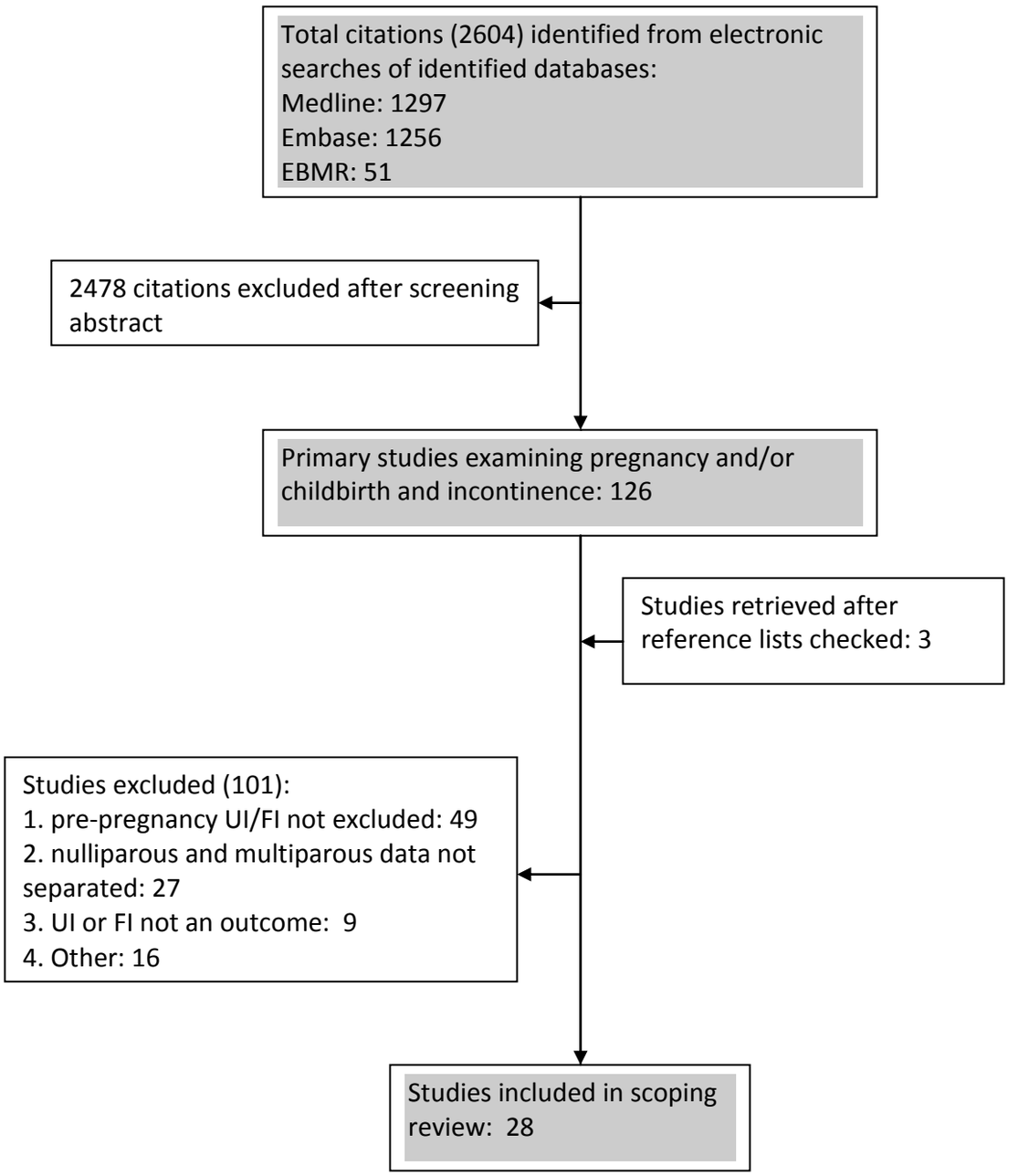

Table 2-1: Summary of studies that report regarding de novo pregnancy incontinence.

Authors	Research methods	Study sample	Outcomes of interest	Findings relevant to outcomes of interest	Active management?
Eason et al., 2004	Prospective cohort nested randomized controlled trial of perineal massage; questionnaire	Convenience sample of pregnant women; N=1527 (nulliparous N=1034) (no power calculation mentioned)	UI during pregnancy and at 3 mths pp	1. de novo UI more frequent in parous women than nulliparous. 2. pp UI independently associated with incontinence before pregnancy and during pregnancy. 3. pp UI strongly associated with high pre-pregnancy BMI. 4. Worsening UI in pp period more common with forceps.	Unknown.
Eftekhar et al., 2006	Prospective observational; validated questionnaire	Convenience sample of primiparous women; N=702 (no power calculation mentioned)	UI during pregnancy and at 4 mths pp.	1. Prevalence of UI significantly lower for women who had an elective C/S prior to onset of labour. 2. Higher prevalence of UI for C/S for obstructed labour compared with spontaneous vaginal delivery. 3. Prevalence of UI highest among women aged >35yrs, and/or with BMI >30 before pregnancy, and/or infant birth weight >3000g.	Unknown.
Ekstrom et al., 2008	Prospective observational; validated questionnaire	Convenience sample of primiparous women either having an elective C/S or planning a vaginal birth; N=435 (elective C/S N=220 and vaginal delivery N=215).	UI during pregnancy and at 3 and 9 mths pp.	1. prevalence of pp UI increased significantly from pregnancy in vaginal delivery group. 2. no significant differences in prevalence of pp UI between instrumental delivery and unassisted natural birth. 3. prevalence of pp UI at 3 mths increased significantly in C/S group but was non-significant at 9 mths.	Episiotomies not performed routinely; midwife managed births.
Glazener et al., 2006	Prospective observational; questionnaire	Convenience sample of pp primiparous women; N=3489 (no power calculation	Performance of pelvic floor muscle training (PFMT), UI during pregnancy and	1. Maternal age at delivery, mode of delivery and BMI significantly associated with de novo pregnancy or pp UI (spontaneous vaginal delivery vs. C/S). 2. Assisted vaginal delivery (forceps or vontouse) did not increase risk beyond	Unknown.

		mentioned).	at 3 mths pp, quality of life.	that associated with spontaneous vaginal delivery.	
Kristiansson et al., 2001	Prospective observational; questionnaire, hormone assay	Convenience sample of pregnant women; N=195 with nulliparous N=67.	Relaxin concentration during pregnancy, UI during pregnancy (at 24 & 36 weeks)	1. Low serum relaxin level (<700ng/l was a statistically significant independent predictor of UI during pregnancy.	N/A
Thomason et al., 2007	Retrospective observational; questionnaire and standing cough stress test	Convenience sample of primiparous women; N=121	UI during pregnancy and at 6 and 9 mths pp.	1. Higher BMI related to incontinence. 2. Report of frequent leakage during pregnancy related to continued frequent leakage pp.	N/A
Wijma et al., 2001	Prospective observational; questionnaire, 24 hour pad test, pelvic floor examination	Convenience sample of nulliparous pregnant women age-matched with nulliparous non-pregnant women; N=117	Changes to urethro-vesical junction, UI during pregnancy at 12-16 weeks, 28-32 weeks and 36-38 weeks.	1. No relationship was found between changes to urethro-vesical junction and UI and pad tests to either outcome measure. 2. Incidence of UI increased significantly as pregnancy progressed. 3.Urethro-vesical junction resting angle significantly different between pregnant and non-pregnant controls even at 12-16 weeks gestation.	N/A

Legend: pp = postpartum; UI = urinary incontinence; FI = faecal incontinence; BMI = body mass index; mths = months

Table 2-2: Summary of studies that report regarding de novo postpartum incontinence.

Authors	Research methods	Study sample	Outcomes of interest	Findings relevant to outcomes of interest	Active management?
Abramowitz,et al., 2000	Prospective observational; questionnaire, clinical exam, endoanal ultrasound (U/S).	Convenience sample of pregnant women; N=259 with N=134 no previous vaginal delivery (no power calculation done).	Anal sphincter disruption, FI during pregnancy and at 6-8 weeks pp.	1. significant increase in incidence of FI for flatus and liquid stools post delivery. 2. significant incidence of sphincter defect post delivery. 3. independent risk factors for FI included; spontaneous perineal tears, forceps, prolonged 1st stage and sphincter defects. 4. sphincter defects significantly associated with; forceps, episiotomy, perineal tears, prolonged 1st and/or 2nd stage, epidural, posterior presentation.	All episiotomies were posterolateral, midwives completed delivery including episiotomy and obstetricians did forceps.
Arya,et al., 2001	Prospective observational; telephone survey (validated) with blinded research nurse	Convenience sample of primiparous women delivering via forceps, vacuum or spontaneously; N=315 (power achieved)	de novo postpartum (pp) UI at 2 weeks, 3 mths and 1 yr.	1. incidence of UI similar in the groups at 2wks pp but forceps group significantly higher incidence and severity at 1 yr pp. 2. incidence of de novo pp UI increased over time in forceps group only	Unknown; episiotomy for all forceps deliveries and 97% of vacuum.
Belmonte-Montes et al., 2001	Prospective observational; questionnaire, clinical exam and endoanal U/S.	Convenience sample of primiparous women; N=98 (no power calculation done).	Anal sphincter defect, FI during pregnancy and at 6 weeks pp.	1. significant association between sphincter defect and FI. 2. significantly higher incidence of sphincter defect with instrumental delivery.	Active management. ALL patients had midline episiotomy.
Borello-France et al., 2006	Prospective observational; interview, questionnaire (validated).	Convenience sample of primiparous women; N=728 (no power calculation done).	UI and FI at 6 weeks and 6 mths pp.	1. Women who had C/S were as likely to report symptoms of UI or FI at 6 mths pp when compared to women who delivered vaginally with no clinically recognized 3rd or 4th degree tears. 2. Women who had 3rd or 4th degree tears were more likely to report FI at 6 wks and 6 mths.	Unknown.

				3. Women who delivered vaginally were more likely to report UI at 6 mths than women who had C/S however, not statistically significant.	
Boyles et al., 2009	Retrospective; mailed survey (not validated)	Convenience sample; N=5599 (power achieved)	de novo pp UI at 3 and 6 mths	1. de novo pp UI associated with vaginal delivery, older age (>30 yrs), higher BMI (>30) at time of delivery, longer 2nd stage (>45 minutes), history of constipation, jogging during pregnancy, and infant weight >3600gms 2. perineal laceration and assisted delivery increased risk of UI significantly 3. C/S protective even with labour and pushing.	Unknown.
Burgio et al., 2007	Prospective observational (secondary analysis); interview using questionnaire	Cohort of primiparous women; N= 759 (no power calculation done).	UI and FI at 6 mths pp	1. higher pre-pregnancy BMI, older age, 3rd or 4th degree tear, antenatal UI significantly associated with pp FI.	Unknown.
Dietz et al., 2005	Prospective observational; interview and measure of hiatal dimension using ultrasound	Convenience sample of nulliparous pregnant women; N=61 (no power calculation mentioned)	Hiatal dimensions, bladder function (subjective) and strength of pelvic floor contraction (subjective)	1. defects (changes in hiatal dimension) significantly associated with maternal age only.	Unknown.
Farrell et al., 2001	Prospective observational; questionnaire	Convenience sample of primiparous women; N=484 (power achieved)	UI during pregnancy and at 6 weeks and 6 mths pp.	1. Spontaneous vaginal delivery associated with increased risk of UI at both 6 weeks and 6 mths. 2. Assisted delivery (forceps) increased risk of UI significantly.	Unknown.
Fenner et al., 2003	Retrospective observational; questionnaire	Convenience sample of primiparous women who	Incidence of sphincter laceration, UI and FI after 6	1. Sphincter laceration associated with higher incidence of worse bowel control pp and incidence is 10X higher for 4th degree lacerations.	Unknown.

		delivered 6 mths prior to mail out; N=2858 (no power calculation done).	mths pp.	2. Sphincter lacerations significantly associated with midline episiotomy, instrument-assisted birth, infant weight >4000g, prolonged 2nd stage. 3. >50% of women reported new or worsening UI after pregnancy.	
Fitzpatrick et al., 2003	Randomized-control trial of forceps vs. vacuum; questionnaire, anal manometry, anal U/S.	Convenience sample of nulliparous women recruited 28-32 weeks; N=130 (power achieved).	FI and sphincter function during pregnancy and at 3 mths pp	1. Use of episiotomy & incidence of 3rd degree tear did not differ significantly between groups. 2. Significant increase in incidence of FI with forceps vs. vacuum	Active management: epidural for all women, early amniotomy, augmentation, timed active pushing, timed instrumental delivery or C/S
Fitzpatrick et al., 2002	Randomized-control trial of delayed vs. immediate pushing at full dilatation; questionnaire, routine postnatal exam, anal manometry, anal U/S and pudendal nerve latency	As above	As above	1. Delayed pushing vs. immediate pushing does not alter instrumental delivery rate, episiotomy rate, incidence of significant perineal trauma or continence.	As above.
Guise et al., 2009	Retrospective population based; questionnaire	Convenience sample of primiparous women; N= 5491	pp FI (mean 4 mths).	1. pp FI similar among women who delivered via C/S and who delivered vaginally without perineal laceration or instrument assist. 2. BMI >30, infant birth weight >3200g, pushing >2hrs, perineal/anal laceration and constipation significantly positively correlated with pp FI.	Unknown.

Harvey et al., 2008	Nested analysis of data from prospective observational; questionnaire (validated), hormone assay, pelvic floor evaluation.	Convenience sample of nulliparous women; N=50 (no power calculation mentioned).	Relaxin concentration during pregnancy, presence of prolapse pp and pp UI (at approx. 21 mths).	1. Maternal BMI >30 associated with pp UI. 2. Decrease in serum relaxin concentration between 24 and 28 wks significantly associated with pp UI.	Not applicable (N/A).
Liang et al., 2007	Prospective observational; interview and questionnaire	Convenience sample of nulliparous women; N=264	Length of labour, course of labour, UI during pregnancy and at 3 mths pp.	1. No difference between vaginal or C/S regarding incidence of UI at 3 mths pp. 2. No difference between those who received epidural or did not receive regarding incidence of pp UI.	Active management including; induction, augmentation, frequent vaginal examinations, standard IV infusion, epidural upon request.
Mazouni et al., 2005	Retrospective; questionnaire	Convenience sample of primiparous women who had instrumental delivery – recruited post delivery ; N=159	FI at >17 mths (mean 27 mths) pp.	1. Large feotal head associated with significant increase in risk of de novo pp FI. 2. General prevalence of de novo pp FI was 24.5% (higher than general population).	High use of episiotomy (97%) and epidural (87%).
Peschers et al., 2003	Prospective observational; questionnaire, pelvic floor examination	Case-matched cohort study of primiparous women; N=50 matched pairs (no power calculation done).	pp UI and FI, occult anal sphincter defects.	1. No difference in UI or FI demonstrated between vacuum and spontaneous delivery. 2. High prevalence (not significant) of de novo pp UI and FI for both vacuum and spontaneous vaginal delivery.	High (76%) use of epidural in cases (signficant) which = longer 2nd stage (significant).

Nazir et al., 2002	Prospective observational; questionnaire (validated), and anal manometry	Convenience sample of nulliparous women recruited at 17 weeks; N=111.	FI, anal sphincter defect during pregnancy, at 5 mths pp and after 1 year.	1. Larger baby head circumference associated with a significantly increased risk of pp FI for flatus at 5 mths. 2. Epidural use significantly increased use of instrument at delivery.	Unknown.
Sartore et al., 2003	Prospective observational; interview, questionnaire and pelvic floor examination	Case-matched cohort study of primiparous women; N=70 matched pairs	UI or FI at 3 mths pp.	1. No significant differences in UI or FI between women who had epidural or did not.	Unknown.
Sultan et al., 1993	Prospective observational; interview, anal U/S, anal manometry, pudendal nerve motor latency and perineometry.	Convenience sample of nulliparous women recruited at 34 weeks; N=79	FI and sphincter defect during pregnancy and at 6 weeks and mths pp.	1. Significant association between sphincter defects and development of FI.	Unknown.
van Brummen et al, 2006	Prospective observational; questionnaire	Convenience sample of nulliparous women recruited during 1st trimester; N=487	FI during pregnancy and at 3 and 12 mths pp.	1. No significant difference in the prevalence of FI at 36 weeks, 3 and 12 mths pp with 12 weeks gestation. 2. Third or 4th degree sphincter tear was independently associated with occurrence of de novo pp FI and of FI lasting to 12 mths pp. 3. High BMI (at 12 mths pp) associated with both constipation and flatus incontinence at 12 mths pp.	Midwifery-lead deliveries.
Varma et al., 1999	Retrospective observational; questionnaire, endoanal U/S, manometry	Convenience sample of primiparous women recruited in hospital after delivery; N=106	FI during pregnancy and at 1 month pp, anal defects pp.	1. 100% of sphincter injuries occurred with use of forceps. 2. No reported cases of FI at 1 month pp even though 73.5% were vaginal deliveries and sphincter defects were present in 9 women.	Episiotomy rate in study 18% (low).

Legend: pp = postpartum; UI = urinary incontinence; FI = faecal incontinence; BMI = body mass index; mths = months

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Chapter 3

Paper Two: Prevention of de novo childbirth incontinence: A systematic review of the literature.

Prevention of de novo childbirth incontinence: A systematic review of the literature.

Background

The pelvic floor plays an important role in pelvic organ support and maintenance of continence. Throughout a woman's lifespan, there are many normal developmental changes that can impact the structures of the pelvic floor thereby affecting continence. Pregnancy and childbirth are examples of this type of normal alteration in physiology. Unfortunately for some women, through natural processes or as a result of medical intervention, the pelvic floor is damaged during childbirth leaving these women to suffer with incontinence for mths or years.

There is disagreement amongst childbirth professionals as to how best to support women in their efforts to maintain pelvic floor integrity and to prevent incontinence during pregnancy or post-delivery. Some suggest Caesarean Section (C/S) without labour (Hannah et al., 2002) even though this invasive approach carries with it serious risk to both the fetus and the woman. Others suggest preventive activities like perineal massage from 36 weeks (Eogan, Daly, & O'Herlihy, 2006), pelvic floor muscle training (PFMT) during pregnancy and/or post-delivery (Salvesen & Morkved, 2004; Whitford, Alder, & Jones, 2007a) or perineal warm packs during labour (Dahlen et al., 2007). While some studies have demonstrated short-term effectiveness of these interventions (Chiarelli & Cockburn, 2002; Starck, Bohe, & Valentin, 2006; Walsh, Mooney, Upton, & Motson, 1996; Whitford, Alder, & Jones, 2007b), there is little known about long-term outcomes of these prevention techniques. Thus the purpose of this paper was to explore the literature focused on prevention of incontinence during pregnancy and after delivery so that some guidelines for practice could be established.

The Review

Aims

We conducted a systematic review of the literature in order to assess the state of the science regarding prevention of childbirth-related incontinence. The aims of our review were: 1) to identify current research focused on the effect of preventative activities during pregnancy as well as during the postpartum period on urinary and/or faecal incontinence; and 2) to identify gaps in knowledge specific to the long-term effect of preventive interventions.

Design

For this systematic review we utilized the methodology outlined by the Joanna Briggs Institute (JBI). This particular methodology involves development of a review protocol that not only addresses critical decisions about study quality prior to undertaking the review but also ensures scientific rigor and minimizes bias through the process of peer review (Pearson, Field, & Jordan, 2007). Development of the protocol provided us with the opportunity to be extremely specific regarding our search strategy and inclusion criteria but also assisted us in the construction of our quality assessment, critical appraisal and data extraction tools.

Search methods

The question that directed our review was: what is the long-term (up to ten years post index pregnancy) effect of preventive interventions intended to protect continence during pregnancy and in the postpartum period? We considered all studies written in English between the years 1960 and 2009 that involved human female subjects between the ages of 14 and 50 years of age (childbearing years) and that examined the short and long-term outcomes associated with preventive

interventions for pregnancy and/or childbirth related incontinence. Included studies must have met all of the following criteria for subjects: a) nulliparous; b) full term pregnancy; and c) delivered vaginally or via C/S. Preventive interventions could include education provided by a physician, nurse, midwife or physiotherapist with or without directed practice of pelvic floor exercises, perineal massage during pregnancy, or perineal warm packs during labour. Outcome measures were to include incontinence of urine, flatus or feces. Study sites must have been in industrialized countries. All quantitative retrospective and prospective studies as well as gray literature were considered for this review.

Search terms were identified with the assistance of a Research Librarian and included the following MeSH terms (all were exploded): pregnancy, parturition, obstetrics, delivery/obstetric, labor or labour, episiotomy, vacuum extraction, forceps, urinary incontinence or faecal incontinence, prevention or preventive measures, pelvic floor exercise, perineal massage, perineal warm packs.

Search outcome

All major electronic databases were searched January 2009 and included: CINAHL (1960 to 2009), Medline (Ovid interface 1950 to 2009), the Cochrane Library's Evidence Based Medicine Reviews (EBMR – Central Register of Controlled Trials 1960 to 2009), and EMBASE (1980 to 2009). Reference lists of relevant papers were analyzed for potentially useful sources of research not previously located including gray literature.

Study selection

Studies were selected using a two-stage process. First, all titles or abstracts yielded by the

electronic searches were scrutinized (S.L.P. and K.H.) and full manuscripts of potentially eligible citations were obtained. Second, studies meeting our predefined criteria were considered for inclusion based on completion of a methodological quality assessment form designed and validated for the purposes of this review (Appendix A). This quality assessment form addressed only the most basic but relevant methodological aspects of our inclusion criteria. Data from selected studies is summarized in Tables 3-1 and 3-2 according to study focus.

Critical appraisal

Papers retained following the quality assessment phase were critically appraised according to criteria suggested by the JBI and appropriate for experimental studies. Critical appraisal considered: sample size (adequate to meet power); intervention and comparison groups (blinded randomization, comparable groups at entry) methods of data collection (prospective continence assessment using validated tools and/or objective measures); statistical analysis (appropriateness of statistical methods chosen); and interpretation and reporting of outcomes. Table 3-3 provides data specific to the critical appraisal of all studies included in this review.

Data extraction

A data extraction tool was designed and validated for the purposes of this review (Appendix B).

Synthesis

The included studies utilized a variety of interventions, data collection methods, and follow-up intervals. Incontinence was also measured differently in each of the studies. This heterogeneity between studies, in combination with the fact that so few studies were included in the review,

limited us to synthesis in narrative format rather than by data pooling (e.g. meta-analysis). Discussion regarding the included studies is organized by preventive intervention and reflects data provided in Tables 3-1, 3-2 and 3-3.

Results

The electronic search yielded 694 citations (Figure 3-1). On examination of titles and abstracts, 32 were found to be relevant to the review and full papers were obtained for these. The reference lists of these papers revealed four further citations.

Excluded studies

The most common unmet criteria was failure to report nulliparous and multiparous data separately (n=9). Having nulliparous women as the focus of our review was important as this group best represents those individuals whose incontinence was likely triggered by pregnancy or childbirth. Further, previous studies have demonstrated a cumulative effect for incontinence with multiparity (Wilson, Herbison, & Herbison, 1996).

Another common reason for exclusion was the lack of incontinence as an outcome. Some studies reported perineal pain, perineal trauma or vaginal strength but not incontinence (n=8). Finally, papers were excluded because of retrospective design and inclusion of women who had experienced childbirth related incontinence more than 10 years prior to the time of the study. It has been shown that recall of childbirth-related incontinence is often poor (Viktrup & Lose, 2001). We therefore, decided to limit our analysis to 10 years post-index pregnancy.

Included studies

Only five studies met all of our inclusion and quality assessment criteria. Four of the studies

focused on PFMT as an intervention while the final study focused on perineal massage. Critical appraisal of all included studies revealed deficiencies in method and interpretation of data that make synthesis of results difficult. The heterogeneity between studies with respect to definition of UI or FI, intervention protocols, measurement of symptoms, and follow-up interval makes it difficult to say which specific intervention elicits an effect or whether the demonstrated effect can be reproduced. As well, such heterogeneity made statistical pooling of data inappropriate for this review.

Studies focused on Pelvic Floor Muscle Training

Four studies that focused on PFMT were included in this systematic review and each of the included studies examined UI as an outcome (Agur, Steggles, Waterfield, & Freeman, 2008; Morkved, Bo, Schei, & Salvesen, 2003; Reilly et al., 2002; Sampselle et al., 1998) . No studies focused on the effect of PFMT specific to the prevention of FI, met our inclusion criteria.

There were several areas of methodological concern amongst the included PFMT studies. Firstly, three of the four studies used non-standardized subjective measures of incontinence making it difficult to determine type of UI (stress vs. urge) and to compare incidence of UI across the studies. Only Reilly et al., (2002) measured UI at three mths postpartum using a recognized objective measure (the one hour pad test). Secondly, Reilly et al., (2002) recruited participants for symptoms or characteristics that put them at high risk for incontinence therefore the study did not represent risk in a general population of women. Finally, the validity and generalizability of several studies is of concern specific to small sample sizes that do not meet power (Agur, Steggles, Waterfield, & Freeman, 2008; Eogan et al., 2006; Morkved, Bo, Schei, & Salvesen, 2003; Reilly et al., 2002;

Sampselle et al., 1998). All investigators completed sample size calculation prior to the start of recruitment but due to high dropout rates, participant numbers in any study were insufficient to achieve statistical power.

All of the PFMT studies were randomized controlled trials (RCT) and the steps taken by the investigators to ensure minimization of bias did include random allocation of the subjects as well as blinding of assessors and investigators to group assignment (Agur et al., 2008; Fitzpatrick, Behan, O'Connell, & O'Herlihy, 2000; Morkved et al., 2003; Reilly et al., 2002; Sampselle et al., 1998).

Of interest was the analyses done by study investigators on potentially confounding variables like mode of delivery (vaginal or C/S), age and body mass index (BMI). Vaginal delivery has been cited in the literature as contributing to incontinence (Boyles, Li, Mori, Osterweil, & Guise, 2009; Glazener et al., 2006) however, there were no significant differences in symptoms of UI between the vaginal or C/S groups in all of the PFMT studies included in this review.

Specific to the impact of BMI on incontinence, Reilly et al., (2002) demonstrated that higher postpartum BMI was positively correlated with symptoms of UI postpartum. Unfortunately, these authors were the only investigators included in this review to examine the relationship between BMI and incontinence therefore it is not possible to infer a causal relationship based on such little data.

The PFMT studies included in our systematic review were methodologically poor overall. Regardless, the studies did suggest that PFMT practiced during pregnancy was effective in decreasing symptoms of UI in the immediate (3 mths) postpartum period. Incidence of UI was significantly different between intervention (PFMT) groups compared to control groups in three of the four studies included in this review. Unfortunately, it is not possible based on the studies

included in this review, to identify a protocol for PFMT that is effective as each study described a different approach to the exercise regime.

Studies focused on perineal massage

The one study included in this review that examined the effect of perineal massage focused on FI as an outcome. This study was originally designed as a randomized control trial but the investigators quickly realized that allowing women to self-select to intervention or control group would ensure a more committed practice of perineal massage. As a result of this self-selection to group, no randomization occurred.

There was no statistically significant difference between the groups (massage versus control) for symptoms of FI up to 3 mths postpartum. Women in the massage group were however, more likely to have delivered with an intact perineum and to have reported less perineal pain. As this was the only study included in our review that examined perineal massage as a preventive measure for incontinence, further investigation of this relationship is required.

Perineal warm packs

No studies that were focused on the use of perineal warm packs during labour met our inclusion criteria.

Discussion

This is the first systematic review that has investigated the effect of prevention interventions on childbirth related incontinence in nulliparous women. The fact that we included only those studies that reported outcomes specific to nulliparous women was critical to our understanding of the impact of the interventions of interest. Recent studies have highlighted the possible relationship

between pregnancy and incontinence (Burgio, Locher, Zyczynski, Hardin, & Singh, 1996; Chaliha, Khullar, Stanton, Monga, & Sultan, 2002; Kristiansson, Samuelsson, von Schoultz, & Svardsudd, 2001). The evidence suggests that each pregnancy carries with it a risk of incontinence making it crucial to investigate the effect of pregnancy and childbirth on continence status for nulliparous women. Only through such analysis can we begin to understand the inter-relationships that exist between pregnancy, childbirth and incontinence. Of note, nine studies were omitted from this review as they did not report any data analysis for nulliparous women. Had such analysis been completed, a larger number of studies would have met our inclusion criteria and a stronger understanding of the effect of preventive interventions might have been possible through statistical analysis.

The reliability and validity of our findings was dependent upon the rigor in our methodology. Use of the JBI methodology was key to ensuring rigor in the selection and analysis of studies. We acknowledge that our inclusion criteria were strict, particularly in terms of the focus on nulliparity. We believe however, that our restrictive criteria allowed us to gain a better understanding of the gaps in the literature with respect to our study aims and question of interest.

Of considerable interest for future research is investigation of approaches and techniques utilized by nurse-midwives to protect the integrity of the pelvic floor and ultimately continence. Only one study that focused on perineal massage met our inclusion criteria. The outcomes of this study did not demonstrate a significant reduction in symptoms of FI that could be attributable to the intervention. Further exploration is required to determine the effect of any conservative intervention (e.g. PFMT, perineal massage, warm packs during labour).

Conclusion

The current available evidence demonstrates that there is most likely some benefit to practicing PFMT during pregnancy with respect to reducing symptoms of UI postnatally. However, long-term studies are required in order to elucidate the specific regime that can repeatedly show an effect. As well, prospective long-term investigation of the effect of other conservative interventions such as perineal massage and perineal warm packs is required. Studies that include only nulliparous participants are required in order to provide researchers and childbirth professionals the evidence to support their decisions with respect to the prevention of UI and FI. Consideration of potentially confounding variables like mode of delivery, intervention during delivery (e.g. induction, directed pushing) age at index delivery and BMI are also necessary in order to ensure that any causal relationships between intervention and outcome are thoroughly examined.

Figure 3-I: Result of literature search

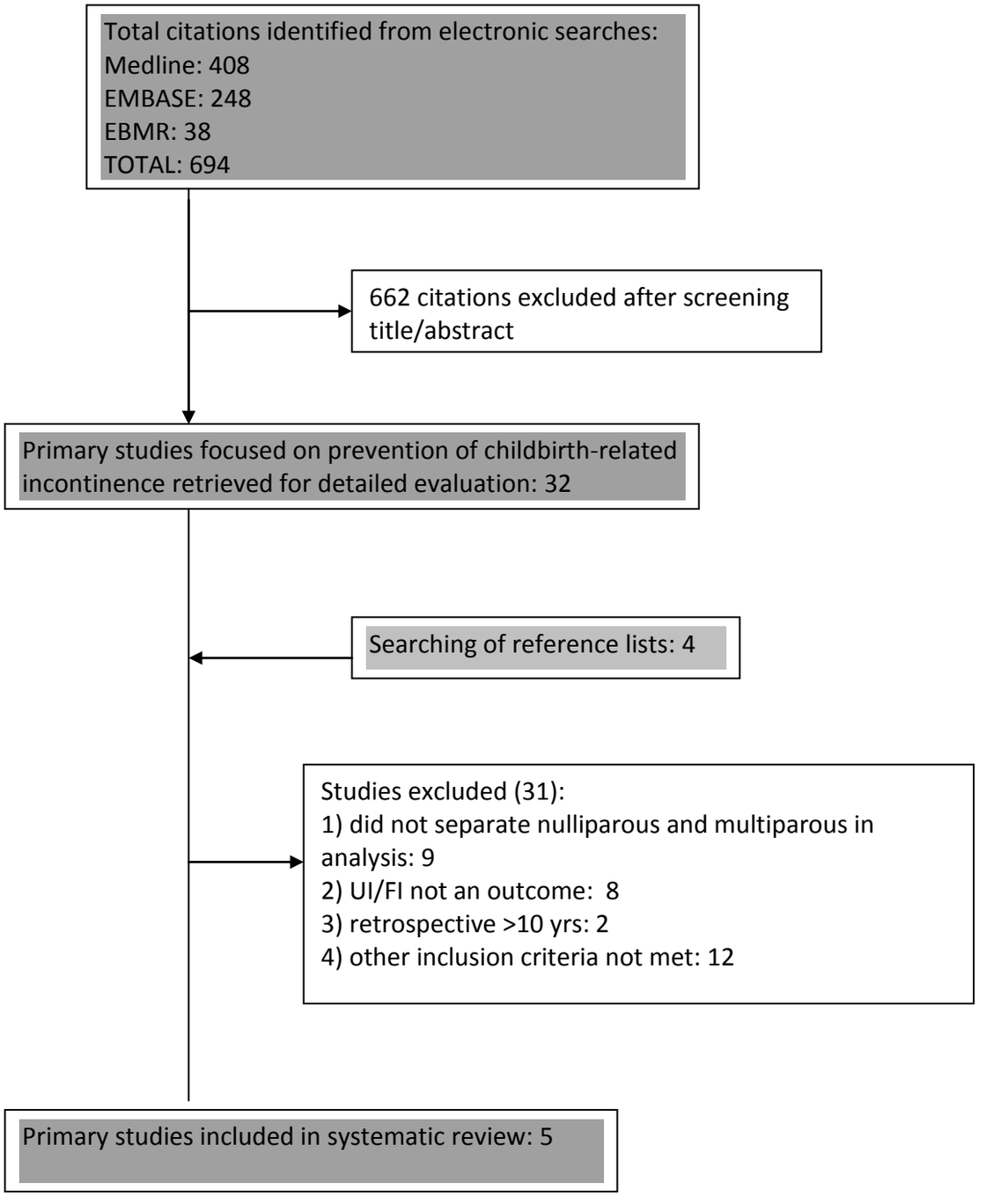

Table 3-1: Characteristics of included studies examining PFMT

Authors & year	Study Design	Methods of data collection	Sample	Intervention	Outcomes	Incidence and/or prevalence of UI and/or FI	Conclusions
Agur, Steggles, Waterfield & Freeman (2008).	Retrospective (follow-up to previous study by Sampselle et al.)	King's Health questionnaire, self-report of birthing history; self-report of UI and performance of PFMT 8 years following index pregnancy	N=164 contacted 8 years following index delivery	PFMT	UI at 8 yrs post-index delivery.	Incidence of UI for intervention group (35.5%) vs. control group (38.8%) – non significant.	No significant difference between groups at 8 years post-index delivery
Mørkved, BØ, Schei & Salvesen (2003).	Prospective; randomized control trial – women identified at 18wks gestation	Self-report of UI and performance of PFMT at 20wks, 36 wks and 3 mths pp.	N=301; PFMT group N=148 vs. control N=153	PFMT	UI at 36 wks during pregnancy and at 3 mths pp.	1. Incidence of UI at 36 wks: intervention group (32%) vs. control group (48%) , p=.007. 2. Incidence of UI at 3 mths pp: intervention group (20%) vs. control group (32%), p=.018.	Significant differences between groups for UI during pregnancy and at 3 mths pp.
Reilly, Freeman, Waterfield et al. (2002).	Prospective; randomized control trial – women identified at 20 wks gestation	King's Health questionnaire; self-report of UI along with ICS 1 hr. pad test, performance of PFMT and perineal U/S to measure bladder neck mobility at 20 wks, 34 wks and 3 mths pp.	N=230; PFMT group N=139 vs. control N=110	PFMT	UI at 3 mths pp.	1. Incidence of reported UI symptoms at 3 mths pp: intervention group (19.2%) vs. control group (32.7%), p=0.023.	Significant differences between groups for self reported UI at 3 mths post partum; no significant difference for positive pad test or pelvic floor strength
Sampselle, Miller, Mims et al. (1998).	Prospective; randomized control trial – women enrolled at 20 wks	Non-validated questionnaire regarding UI symptoms; pelvic muscle strength device – assessed at 20 wks, 35 wks, 6 wks pp, 6 mths pp and 12 mths pp.	N=72 (high attrition with final N=46 – unclear sample size for treatment vs. control	PFMT	UI at 35 wks during pregnancy, at 6 wks pp, 6 mths pp and 12 mths pp.	1. Change in symptoms of UI from 20 wks to 35 wks (F=4.36, p=.043), 6 wks(F=4.94, p=.032 and 6 mths (F=4.29, p=.044) significantly different between intervention group and control group	Concluded that PFMT did improve symptoms of UI at 35 weeks of pregnancy, 6 weeks and 6 mths pp but not 12 mths post partum.

Legend: pp = postpartum; UI = urinary incontinence; FI = faecal incontinence; BMI = body mass index; mths = months; U/S = ultrasound

Table 3-2: Characteristics of included studies examining perineal massage.

Author & year	Design	Methods of data collection	Sample	Intervention	Outcomes	Incidence and/or prevalence of UI and/or FI	Conclusions
Eogan, Daly & O'Herlihy (2006)	Prospective observational – women recruited prior to 34 wks gestation	Wexner score, Likert scale for pain, Anal manometry, endoanal U/S at 3 days postpartum and 3 mths postpartum.	N=179; massage group N=100 vs. control group N=79	Perineal massage	FI, perineal pain, perineal defects	1. Incidence of FI similar between intervention and control groups at 3 mths pp.	No significant differences between groups for FI, manometry or sphincter defect.

Table 3-3: Critical appraisal of all included studies.

Author & year	Sample size	Groups	Methods of data collection for UI/FI	Statistical analysis	Interpretation and reporting of results	# of criteria met
Agur et al., 2008	Recruitment of sample from Reilly study; retrospective of 8 years; sample size did not meet power(n=164, 80% required n=256)	Heterogeneous group (multiparous – number of births per participant not mentioned; practice of PFMT) however, investigators did analyze primiparous data separately.	Self-reports using non-validated questionnaire	Appropriate	Sample size (n=164) did *not* meet power however, interpretation and reporting appropriate	3/5
Eogan et al., 2006	Convenience sample - prospective; no power mentioned; n= 136	Observational (due to difficulty with randomization) but appropriate; intervention group significantly older and experienced spontaneous onset of labour but otherwise similiar	Self-report using validated and standardized questionnaire	Appropriate	No power calculation done and non-randomized however, appropriate interpretation and reporting	4/5
Morkved et al., 2003	Convenience sample - prospective; power achieved (n=301, 85% power required n=290)	Randomly allocated; investigators and assessors blinded; groups similar at entry	Self-reports using non-validated questionnaires	Appropriate	Final sample size (n= 289) did *not* meet power therefore inappropriate interpretation and reporting	3/5
Reilly et al., 2002	Recruited sample - prospective; power achieved (n=268, 90% power required n=256)	Randomly allocated; investigators and assessors blinded; groups similiar at entry accept in bladder neck mobility	Self-reports using non-validated questionnaire; pad test at 3 mths pp	Appropriate	Final sample size (n= 230) did *not* meet power therefore inappropriate interpretation and reporting	4/5
Sampselle et al., 1998	No info provided re; recruitment (assume convenience) - prospective ; no power calculation done and ++ attrition with final n= 16	Randomly allocated; investigators and assessors blinded; groups similar at entry	Self-reports using non-validated questionnaire	Appropriate	Insufficient sample for significance therefore, inappropriate interpretation and reporting	2/5

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Appendix A: Quantitative Research Methodological Quality Assessment Form

TITLE:
AUTHORS:
JOURNAL: YEAR/VOL #/PAGES:

Name of reviewer: SP KH
Date: _____

Does the focus of the paper investigate the topic of interest for the systematic review?
____Yes
____No

Is there congruity between the research methodology and research question or objectives?
____Yes
____No

Was there a clear description of inclusion and exclusion criteria (e.g. type of birth injury)?
____Yes
____No

If comparisons are being made, was there sufficient description of the groups?
____Yes
____No

Are patients at a similar point in the course of their pregnancy/postpartum period during the study?
____Yes
____No

Were outcomes assessed using objective criteria?
____Yes
____No

Were the methods of statistical analysis described?
____Yes
____No

Overall appraisal: Include ____ Exclude ____ Seek Further Info. ____

Reviewer's Comments:
_____
_____
_____

Appendix B: Data Extraction Form

STUDY TITLE:
AUTHORS:
JOURNAL:
YEAR/VOL #/PAGES:

Name of reviewer: SP KH

Study Method: RCT Quasi-RCT Longitudinal
Retrospective Observational Other _____

If RCT: Investigators blinded? ____Yes ____No ____Unclear
Subjects blinded? ____Yes ____No ____Unclear

Setting: Acute Care ____ Clinic____ Home ____

Who Delivered: OB/Gyn ____FP____Midwife____Other____

Population: _____

N=	Age (range)	Age (mean)	Age (SD)	Gravida	Pre-pregnancy Incontinence (N)
Vaginal (V)					
C/S with labour (CwL)					
C/S no labour (CnL)					
Total					

Number enrolled (V/CwL/CnL): _____/_____/_____
Number completing the trial (V/CwL/CnL): _____/_____/_____
Dropouts/withdrawls: ***Vaginal***
Dropouts ____
Withdrawals ____
CwL
Dropouts ____
Withdrawals ____
CnL
Dropouts ____
Withdrawals ____

Inclusion Criteria	Exclusion Criteria

Interventions?

Intervention 1	
Intervention 2	
Intervention 3	

Clinical Outcome Measures

Outcome description	Scale/Measure
1. Continence/Incontinence	

Dichotomous Data

Outcome	Intervention ( ) Number/total number	Intervention ( ) Number/total number

Continuous Data

Outcome	Time One	Time Two	Time Three

Author's Conclusions:

_____

_____

Reviewer's Comments:

_____

_____

_____

Chapter 4

Discussion and proposal for future research.

Chapter Four

Through the process of reviewing the published literature specific to this thesis, we have concluded that further research is required in order to understand how continence is affected by both pregnancy and childbirth and how de novo childbirth incontinence can be prevented. There has been a great deal of attention paid to investigating the role of vaginal childbirth as a causal factor for urinary and faecal incontinence as our initial literature searches attest. However, the majority of studies did not meet our inclusion criteria because they failed to exclude or statistically adjust for participant's parity or continence status prior to pregnancy. The studies that were included were heterogeneous in many areas including the interventions utilized during labour and birth and, which interventions were selected for statistical analysis. Further, few of the studies included in the reviews presented in Chapters Two and Three described details of the approach to labour (active management, natural or some alternative). This lack of description made it difficult to establish which interventions were utilized during labour and birth and how they might have affected continence. Overall the published research included in our reviews was an inadequate base from which to develop clinical recommendations specific to our questions of interest.

Based on the studies that were included in the scoping study (Chapter Two) and systematic review (Chapter Three), several factors have been highlighted as potentially significant considerations:

- High pre-pregnancy BMI (>30) as a risk factor for de novo pregnancy or postpartum incontinence.
- De novo pregnancy incontinence as a risk factor for postpartum incontinence.

- Use of assistive devices during childbirth as a risk factor for de novo postpartum incontinence.
- Actively managed labour as a risk factor for de novo postpartum incontinence.

Each of these considerations has a demonstrated relationship to postpartum incontinence in nulliparous women. Further, pelvic floor muscle training has been shown to be a potentially useful preventive intervention for postpartum incontinence.

As mentioned previously and based on our reviews, the current published literature provides insufficient evidence to explain the relationships between pregnancy, childbirth and incontinence. The main reason for the lack of clarity of risk factors or causal factors is the variety of approaches to this type of research. The majority of studies involved some sort of intervention during labour. Interventions varied and included: induction; augmentation; epidural; directed pushing; use of assistive devices; episiotomy; Caesarean section (C/S). Further, it is evident that the published research reflects investigation of actively managed labour. The variety of interventions utilized with this approach and the intervention cascade that it causes (Patel, Peters & Murphy, 2005; Tracy, Sullivan, Wang, Black & Tracy, 2007) makes it difficult to clearly describe the relationships between pregnancy, childbirth and incontinence. For this reason, we suggest that further prospective research is required. In order to fully understand causality with respect to de novo pregnancy and postpartum incontinence and to develop clinical guidelines that are supported by well designed research, a program of study is suggested. This program of study will grow from the draft dissertation project outlined below which is a first step toward supporting women in their efforts to

protect continence during pregnancy and in the postpartum period. It is important to note that the dissertation project outlined below is an early draft for further development.

The Dissertation Project

Purpose of the study

The purpose of the proposed study is to describe the relationships between pregnancy, natural childbirth and development of de novo incontinence (UI and/or FI) during pregnancy and /or postpartum period. To date, natural childbirth has not been the focus in the published literature specific to childbirth-related incontinence rather, reflecting labour and birth that involves interventions associated with actively managed labour and populations that are not homogenous with regards to parity or the presence of pre-pregnancy incontinence. For this reason, we suggest an observational study to begin to explore the relationships between normal pregnancy, natural childbirth and incontinence. This will be foundational work in the development of a program of research focused on understanding the influences on women's continence health during pregnancy and the postpartum period.

Research question:

1. What are the risk factors for de novo pregnancy urinary incontinence for nulliparous continent women?
2. What are the risk factors for de novo pregnancy faecal incontinence for nulliparous continent women?
3. What are the risk factors for de novo postpartum urinary incontinence for nulliparous women?

4. What are the risk factors for de novo postpartum faecal incontinence for nulliparous women?

Definition of terms

Normal pregnancy describes a pregnancy that is free of complications or risks to either the fetus or the pregnant woman as defined by the Alberta Association of Midwives.

Natural childbirth will involve natural onset of labour, no medical interventions to control contractions, no use of epidural for pain relief, no continuous monitoring, no directed pushing, and no use of episiotomy, forceps or vontouse (vacuum).

Labour supported by a midwife will involve care that is focused on the provision of support to women to birth in the manner that they choose. Many women who choose to birth with a midwife choose natural birth. Midwifery supported labour and birth can occur at home or in the hospital and delivery can occur in water or otherwise. Some midwives utilize natural methods to prepare and protect the perineum during childbirth and these interventions will be addressed through statistical analysis.

Actively managed labour is an approach to labour and birth that focuses on intervening to control for potential adverse events. The interventions utilized with this approach often include any or all of the following: induction, continuous monitoring, augmentation, epidural, directed pushing, episiotomy, use of forceps, vontouse or C/S. Interventions are, in some institutions, standard protocol.

Study Design

This prospective descriptive study will be conducted in Edmonton Alberta.

Sample

Recruitment of nulliparous continent women accessing midwifery services will occur at their pre-pregnancy appointment or at first prenatal appointment as long as this appointment occurs prior to 12 weeks gestation (as per last menstrual period). Follow up for this study will continue to three mths postpartum. Anticipated sample size is 100 women. This sample size was determined using the formula for an adjusted R^2 outlined by (Munro, 2005) where 10 participants are required per independent variable in regression analysis (Munro, 2005). Considering that the proposed study will involve regression analysis with eight independent variables, a minimum of 80 participants would be required. In order to allow for loss of participants, 100 participants will be recruited.

As the focus of this study is to examine the relationships between normal pregnancy, natural childbirth and incontinence, the sample will be recruited from midwifery practices in Edmonton Alberta. Women who require transfer to a physician at any time during their pregnancy or labour may be included in the study but any confounding variable (medical interventions) will be addressed through statistical analysis.

Methods and instruments

Participant data (both subjective and objective) will be collected at the first prenatal appointment, at the 36 week midwifery care visit, and at the 6 week postpartum visit. At 3 mths postpartum, participant data collection will be done via mailed out questionnaire. A demographic questionnaire developed for the study will be utilized to collect demographic data as well as data regarding health history, pre-pregnancy and prenatal exercise history (including use of PFMT), and pregnancy data (Appendix A). Information about urinary and faecal continence will be collected

using standardized, validated questionnaires for faecal incontinence (The Manchester Health Questionnaire) and urinary incontinence (ICIQ-UI Short Form – Appendix B). This battery of demographic and standardized questionnaires will be pilot tested with a small sample of two nulliparous pregnant continent women accessing midwifery services. The results of the pilot test will provide the opportunity to evaluate the adequacy of the questionnaires in eliciting the desired information.

The Manchester Health Questionnaire

The Manchester Health Questionnaire is adapted from the King's Health Questionnaire which is "a condition-specific health-related quality of life questionnaire for the assessment of urinary incontinence" (Bugg, Kiff, & Hosker, 2001, pg. 1058). The adapted faecal incontinence version (The Manchester Health Questionnaire) utilizes a five-point scoring system with items focused on several domains including: impact of incontinence, physical function and others (see Appendix B). This 31-item questionnaire has acceptable reliability (Cronbach's alpha exceeded 0.81 for all domains; mean internal consistency, 0.81; mean test retest, 0.87) and validity (mean criterion validity, -0.56; mean convergent validity, 0.51) (Bugg et al., 2001). Overall, this questionnaire is considered to be a clinically effective tool of measurement for the presence and impact of faecal incontinence for women (Bugg et al., 2001). Unfortunately, this tool has not yet been validated for the pregnant or postpartum woman.

The ICIQ-UI Short Form

The International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI Short Form) (Appendix B) was awarded a grade A recommendation by the Third

International Consultation on Incontinence 2004. Such a recommendation means that this tool has "undergone rigorous psychometric testing…and has published evidence regarding the validity, reliability and responsiveness of the instrument…" (Abrams et al., 2006, pg. 1064). This tool has been shown to be reliable (Cronbach's alpha of 0.95) and valid (convergent validity as Spearman's r_s, range 0.24 to 0.86) (Avery et al., 2004). It has been utilized with a variety of populations and has demonstrated its strength as a subjective measure for evaluating urinary incontinence even when compared to objective measures such as urodynamic examination (Seckiner et al., 2007). Further this tool has been compared with the 24-hour pad test and found to demonstrate statistically significant correlation (Karantanic, et al., 2004).

The 24-hour weighed pad test

The 24-hour pad test will be utilized as an objective measure of urinary continence prenatally when possible as well as during pregnancy and in the postpartum period. This measure is important in order to quantify any urinary incontinence. Urinary incontinence is generally defined as greater than 8 gram of urine lost on 24 pad test for women (Groutz, Blaivas, & Rosenthal, 2000; Lose, Jorgensen, & Thunedborg, 1989; Versi et al., 1996). The pad test has been shown to be reproducible (Karantanis et al., 2005; Versi et al., 1996), and a single 24 hour test is considered sufficient to determine severity of urine leakage (Karantanis et al., 2005). For the pad test, pre-weighed pads will be provided to participants to be worn and changed as necessary for a 24-hour period. At the end of the test period, the pads will be collected in sealed plastic bags and weighed. The pad tests will occur at recruitment, at the 36-week midwifery visit, at the 6-week postpartum midwifery visit (if lochia has stopped), and at 3 mths postpartum.

Data analysis

Data will coded then entered and analyzed using SPSS statistical software. Descriptive statistics will be used to summarize demographic data, health history, exercise history, pregnancy data and labour and birth variables of interest. Data collected from questionnaires will be scored summarized as descriptive statistics. ANOVA will be undertaken to compare participant's reported continence status at the four time periods that data are collected (1st trimester, 3rd trimester 6 weeks postpartum and 3 mths postpartum). Multiple regression analysis will be undertaken to identify risk factors associated with change in continence status between the four time periods. As this is a prospective study, both Odds Ratio (OR) and Relative Risk (RR) can be calculated.

Regressions:

1. Type: Multiple

- Outcome (dependent) variable: change in urinary continence status during pregnancy (as measured by pad test).
- Independent variables: age, pre-pregnancy BMI, exercise during pregnancy, practice of PFMT during pregnancy.

2. Type: Multiple

- Outcome (dependent) variable: change in faecal continence status during pregnancy.
- Independent variables: age, pre-pregnancy BMI, exercise during pregnancy, practice of PFMT during pregnancy, use of midwifery techniques to prepare perineum.

3. Type: Multiple

- Outcome (dependent) variable: change in urinary continence status in the

postpartum period (as measured by pad test).

- Independent variables: de novo pregnancy incontinence, midwifery interventions to initiate labour, midwifery techniques to protect perineum, medical interventions to initiate labour, medical interventions during labour (e.g. epidural, directed pushing), medical interventions during birth (e.g. episiotomy, forceps, vontouse), presence of perineal laceration.

4. Type: Multiple

- Outcome (dependent) variable: change in faecal continence status in the postpartum period.
- Independent variables: de novo pregnancy incontinence, midwifery interventions to initiate labour, midwifery techniques to protect perineum, medical interventions to initiate labour, medical interventions during labour (e.g. epidural, directed pushing), medical interventions during birth (e.g. episiotomy, forceps, vontouse), presence of perineal laceration.

Ethical considerations

Prior to initiation of the study, the Health Research Ethics Board will be approached with a request for ethical review of the proposed study. Prior to consenting to participate in this study, participants will be informed of the purpose of the study, procedures involved, risks, benefits, voluntary participation, and confidentiality (see Appendix C for Participant Information Sheet and Consent Form). No monetary compensation will be provided to the participants. It will be stressed that the participant is under no obligation to participate and may withdraw at any time and further,

that withdrawal from the study will not influence care given. An information sheet will be provided outlining all of the details as mentioned above.

There are no risks to participant health associated with completion of the questionnaires or pad tests that are part of this study. Involvement in this study may however, make participants more aware of the risks associated with certain interventions during labour and birth which may influence their decisions to choose for, or against, some options. The midwives that have agreed to be involved as recruitment sites have also committed to providing information and support to women that may result from involvement in this study.

Conclusion

To date, no study has been undertaken to specifically examine the relationships between natural labour and vaginal birth and incontinence. Only through prospective observation of pregnancy with comparison of natural vaginal birth versus actively managed labour and delivery, and long-term follow up of objectively assessed continence can any relationships be defined. The proposed study is suggested as a first step toward understanding how pregnancy and/or natural vaginal birth influence the continence status of women postpartum. Further, this study will act as a springboard from which a program of study will develop that is focused on examining the many influences on health during pregnancy, childbirth and in the postpartum period.

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APPENDICES

Appendix A: Study Demographic Questionnaire

The Relationships between Pregnancy, Natural Childbirth and Incontinence.

Demographic Questionnaire

ID #: _____

Date: _____

Thank you for agreeing to participate in our research study. In order to be eligible to participate in this study, you must be planning or experiencing your first pregnancy.

Please complete the following questionnaire. This questionnaire will provide us information about you and your health history. All information collected is kept strictly confidential.

General Information:

1. What is your age?
- 16-20 yrs ☐
- 21-25 yrs ☐
- 26-30 yrs ☐
- 31-35 yrs ☐
- 36-40 yrs ☐
- 41-45 yrs ☐
- 46-50 yrs ☐

2. What is your highest level of education completed?
- Highschool diploma ☐
- College diploma ☐
- Undergraduate degree ☐
- Postgraduate degree ☐

3. Is this your first pregnancy?
- Yes ☐
- No ☐

4. How many weeks pregnant are you today?
- <12wks ☐
- >12wks ☐

5. Have you ever experienced uncontrolled leakage of urine or stool? Yes ☐

No ☐

If you answered "no" to question # 5, please go on to question # 8.

6. When you were incontinent of urine/stool, was it related to this pregnancy? Yes ☐

No ☐

7. When you were incontinent of urine/stool, was it related to a medical condition other than pregnancy?

Yes ☐

No ☐

8. Do you live with any of the following chronic health conditions?

Irritable bowel syndrome	Yes ☐	No ☐
Crohn's Disease	Yes ☐	No ☐
Colitis	Yes ☐	No ☐
Incontinence	Yes ☐	No ☐

9. Have you ever had a surgery that involved your reproductive, urinary or faecal organs? Yes ☐

No ☐

If you answered "yes" to question # 10, please indicate what surgery you experienced:

_____

10. Where are you planning on having your baby? Home ☐

Hospital ☐

11. Are you planning on a water birth? Yes ☐

No ☐

12. Are you planning on utilizing any of the following interventions during your labour and/or birth?

Epidural	Yes ☐	No ☐
Caesarean section	Yes ☐	No ☐

13. What is your weight today? _____ kg.

14. What is your height? _____ cm.

15. If you are pregnant today, what was your weight prior to this pregnancy? _____kg.

16. Since you have become pregnant, have you been practicing Kegel exercise (pelvic floor muscle training)?

Yes ☐

No ☐

If you answered no to question # 16, please move to question # 18.

17. How often do you practice your Kegel exercises?

☐ Once per day

☐ 2-3 times per day

☐ >3 times per day

18. In the year before you became pregnant, how often did you participate in physical activity?

☐ Never

☐ 1-2 times per week

☐ 3-5 times per week

☐ > 5 times per week

19. What type of physical exercise did you participate in regularly?

☐ Walking

☐ Yoga

☐ Aerobic exercise (e.g. running, group exercise class)

☐ Biking

☐ Other _____

20. Now that you are pregnant, how often do you participate in physical activity?

☐ Never

☐ 1-2 times per week

☐ 3-5 times per week

☐ > 5 times per week

Thank you for taking the time to complete this questionnaire.

Appendix B: The ICIQ-UI Short Form

Initial number

ICIQ-UI Short Form

CONFIDENTIAL

DAY MONTH YEAR

Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth:

DAY MONTH YEAR

2 Are you *(tick one)*: Female ☐ Male ☐

3 How often do you leak urine? *(Tick one box)*

never ☐	0
about once a week or less often ☐	1
two or three times a week ☐	2
about once a day ☐	3
several times a day ☐	4
all the time ☐	5

4 We would like to know how much urine <u>you think</u> leaks.
How much urine do you <u>usually</u> leak (whether you wear protection or not)?
(Tick one box)

none ☐	0
a small amount ☐	2
a moderate amount ☐	4
a large amount ☐	6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all a great deal

ICIQ score: sum scores 3+4+5 ☐☐

6 When does urine leak? *(Please tick all that apply to you)*

never – urine does not leak	☐
leaks before you can get to the toilet	☐
leaks when you cough or sneeze	☐
leaks when you are asleep	☐
leaks when you are physically active/exercising	☐
leaks when you have finished urinating and are dressed	☐
leaks for no obvious reason	☐
leaks all the time	☐

Thank you very much for answering these questions.

Appendix C: Participant Information Sheet and Consent Form

INFORMATION SHEET

Pregnancy, Natural Childbirth and Incontinence

Principal Investigator: Kathleen Hunter, PhD RN NP, Assistant Professor
Co-Investigator: Susan Prendergast, MN RN NP

Congratulations on your decision to become pregnant! We would like you to participate in a research study that is looking at the links between pregnancy, childbirth and incontinence. We require 100 women to take part in this study.

During the childbearing years, many women experience incontinence (uncontrolled loss of urine or stool). There is not a clear understanding about how pregnancy and childbirth are related to incontinence. Some think that perhaps being pregnant puts women at risk for incontinence, while others believe that vaginal childbirth is the cause. We would like to learn about natural childbirth – birth allowed to proceed without medical intervention.

If you agree to take part, we will ask you to complete a survey about bowel and bladder control. This survey will be provided to you by your midwife and you can complete it during your midwifery visits if you choose. The survey will ask you to describe how your pregnancy and/or childbirth affect your bladder and bowel control. You will complete the same survey at four points (1st trimester, 3rd trimester, 6 weeks postpartum and 3 months postpartum) during your pregnancy and postpartum period.

At the same time that you fill out the survey, you will be asked wear sanitary napkins for the next 24 hours. These sanitary napkins will act as a measure of urine leakage. You will be asked to mail these napkins to the investigator. All supplies will be provided to you at no cost.

Your involvement (or your decision not to participate) will not affect your care in any way. You don't have to take part in the study at all, and you can quit at any time. You should tell your midwife that you want to quit should you decide.

Your involvement in this study is strictly confidential. No one except your midwife will know you're taking part in the study unless you want to tell them. Your name and your chart won't be seen by anyone except the midwife and the nurse practitioner researcher.

If you have any questions about this study, you can contact the principle investigator directly at: (780) XXX-XXXX. If you have any concerns about the study, you can contact the Faculty of Nursing Associate Dean of Research at XXXXXXX

If you agree to take part in this study, we ask that you sign the consent form attached.

PARTICIPANT CONSENT FORM

Title of Project: **Pregnancy, natural childbirth and incontinence.**

Principal Investigator: Dr. Kathleen Hunter PhD RN NP Phone Number: 780 XXX-XXXX
Co-Investigator: Susan Prendergast MN RN NP

Do you understand that you have been asked to participate in a research study? YES NO

Have you read and received a copy of the attached Information Sheet? YES NO

Do you understand the benefits and risks involved in taking part in this research study? YES NO

Have you had an opportunity to ask questions and discuss this study? YES NO

Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future care? YES NO

Do you understand who will have access to your records, including personally identifiable health information? YES NO

Do you want the investigator(s) to inform your family doctor you are participating in this research study? If yes, please provide us with your Doctor's Name: _____
Who explained this study to you? _____

I agree to take part in this study: YES NO

Your Signature: _____ Date & Time _____

(Printed Name): _____

Signature of Witness: _____
Date & Time:_____ _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate in the research.

Signature of Investigator or Designee: _____
Date & Time: _____ _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE PARTICIPANT OF THE RESEARCH SUBJECT