A CLINICAL PREDICTION RULE FOR CLASSIFYING POSTPARTUM SUBJECTS WITH LOW BACK AND PELVIC GIRDLE PAIN WHO DEMONSTRATE SHORT-TERM IMPROVEMENT WITH MOBILIZATION OF THE SACROILIAC JOINT

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A CLINICAL PREDICTION RULE FOR CLASSIFYING POSTPARTUM SUBJECTS WITH LOW BACK AND PELVIC GIRDLE PAIN WHO DEMONSTRATE SHORT-TERM IMPROVEMENT WITH MOBILIZATION OF THE SACROILIAC JOINT

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Objective: develop a Clinical Prediction Rule (CPR) for identifying postpartum women with Low Back (LBP) or Pelvic Girdle Pain (PGP) who demonstrate short-term improvement with Sacroiliac Joint (SIJ) mobilization. **Significance:** Development of a CPR for classifying subject's a-prior would improve the clinical decision-making process and research. **Methods:** a prospective cohort of 69 postpartum women was conducted at the University of Pittsburgh Medical Center. Subjects were six weeks to one year postpartum and had a chief complaint of pain in the lower back, pelvic girdle, or thigh. Subjects completed several self-report measures, questionnaires and underwent a physical examination. Subjects then underwent a grade V mobilization to the SIJ. Success with treatment was determined using percent changes in disability scores after one mobilization and served as the reference standard for determining accuracy of the examination variables. Variables with univariate prediction of success and non-success were combined into multivariate CPR's**. Results:** Fifty-five subjects (80%) had success with the mobilization and 14 (20%) were categorized as non-success. A CPR for success with four variables (seated flexion test, prone knee bend test, negative posterior superior iliac spine symmetry test, and symptom location in the lower lumbar spine and/or SIJ areas only) was identified. The presence of 2/4 criteria (+LR=3.05) increased the probability of success with mobilization from 80% to 92%. A CPR for non-success with three variables (age > 35 years, visual analogue score-best > 3, and negative prone knee bend test) was identified. The presence

of 2/3 criteria (+LR=11.79) increased the probability of non-success with the mobilization from 20% to 75%. **Conclusion:** In our sample, 80% of subjects were successful after one mobilization without an attempt at prediction. This success rate was higher than the success rate of the general LBP population of a previously developed CPR. There is a low risk accompanying this intervention, it does not take long and benefits would be experienced after one session. The broad inclusion criteria of women with LBP or PGP allows clinicians to include women without a traditional diagnosis. Clinicians may opt to try the mobilization; an alternate approach can be used if it fails.

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1.0 PURPOSE

To some women, pregnancy may be a time of pain and suffering. Pelvic Girdle Pain (PGP) can be a most debilitating type of pain for pregnant and postpartum women as it prevents them from performing their everyday activities (Berg, Hammar, Moller-Nielsen, Linden, & Thorblad, 1988). It impacts the everyday lives of women all over the world and is costly to the healthcare systems that care for these women (Mens, Vleeming, Stoeckart, Stam, & Snijders, 1996; Hansen et al., 1999). There is a paucity of treatments proposed to address PGP and only a few have been researched for their effectiveness. A possible reason for this lack of evidence on the effectiveness of treatments may be the inability to classify patients with PGP into a homogenous group that may be likely to benefit from a specific intervention. Lumbosacral region manipulation (grade V mobilization) is a technique that has been used for the treatment of low back and pelvic pain (Cibulka, Delitto, & Koldehoff, 1988; Delitto, Erhard, & Bowling, 1995a; Cibulka & Koldehoff, 1999; Delitto, Cibulka, Erhard, Bowling, & Tenhula, 1993; Erhard, Delitto, & Cibulka, 1994; Meade, Dyer, Browne, Townsend, & Frank, 1990; Hawk et al., 1999). Flynn and collegues developed a clinical prediction rule that identified patients with low back pain most likely to benefit from spinal manipulation (Flynn et al., 2002). Patients who met at least four of the five criteria in the clinical prediction rule improved their chances of success with spinal manipulation from 45% to 95%. A 50% improvement on the Oswestry Disability Questionnaire (ODQ) was defined as a success. Developing a Clinical Prediction Rule (CPR) to identify postpartum

subjects who are likely to respond favorably to a mobilization procedure would aid clinicians in their decision-making process and possibly direct effective interventions to this population of PGP patients who have been largely neglected in the literature.

This study proposes to develop a CPR for identifying postpartum subjects with PGP who improve with SI mobilization. This will serve as my doctoral dissertation in health and rehabilitation science in the Department of Physical Therapy. The specific aims of this study are to: (1) determine the predictive ability of individual historic and physical examination variables in identifying positive response and non-response to treatment among subjects with PGP undergoing a mobilization of the SI joint, and (2) determine the best combination of historical and physical examination variables for predicting positive response and non-response to treatment among subjects with PGP undergoing a mobilization of the SI joint.

2.0 BACKGROUD AND SIGNIFICANCE

2.1 DEVELOPMENT OF PGP AND ITS RELATION TO PREGNANCY AND POSTPARTUM

Posterior pelvic pain is defined as pain arising from the SI joint that exhibits no demonstratable lesion, but which is presumed to have some type of biomechanical disorder that causes pain (Dreyfuss, Michaelsen, Pauza, McLarty, & Bogduk, 1996). The SI joints biomechanical disorder may be due to hypomobility of the joint's range of motion with subsequent altered positional relationships between the sacrum and ilium (Sturesson, Selvik, & Uden, 1989). In this study, PGP is defined as pain experienced after childbirth that originates from the SI joint extending into the lumbopelvic region, buttock, groin or posterior thigh.

For many years, pain from the SI joint has been described as a minor contributor of lower back, pelvic, and leg discomfort in many patient populations (Daum, 1995; Bernard, Jr. & Kirkaldy-Willis, 1987; DonTigny, 1985). Recently, however, SI joint pain has been given more attention as a major contributor with pain referral areas to the lower back, pelvic area, buttock, and legs (Kristiansson, Svardsudd, & von, 1996a; Ostgaard, 1991; Slipman et al., 2000). In some cases, PGP can be extremely debilitating, rendering the subject incapable of performing activities in the home, and workplace. According to Bernard et al., pain from the SI joint accounts for 22.6% of low back pain cases (Bernard, Jr. et al., 1987).

Low back pain (LBP) and pelvic pain during pregnancy is attributed to several mechanical and biological reasons such as altered postures, increased body weight, relaxation of ligamentus structures of the spine and pelvis, pressure changes in the abdominal cavity and intra uterine pressure (Sturesson, Uden, & Uden, 1997; Ireland & Ott, 2000). According to recent studies, 50% to 70% of women experience some type LBP during their pregnancy and women who experience severe LBP are at high risk for back pain for more than 3-10 years after the delivery (Kristiansson et al., 1996a; Ashkan, Casey, Powell, & Crockard, 1998; Berg et al., 1988; Heckman & Sassard, 1994; Mantle, Greenwood, & Currey, 1977). While the pelvis is not seen as a separate entity from the spine, several researchers have stressed the importance of differentiating between SI region pain and pain in the lumbar spine (Sturesson et al., 1997; Potter & Rothstein, 1985). Pelvic pain is common in women during pregnancy and postpartum (Damen et al., 2002; Sturesson et al., 1989). The majority of the patients recover from PGP shortly after delivery; however, pain may persist for prolonged periods in some patients ranging between 6-24 months in over 20% of the population (Ostgaard & Andersson, 1992; To & Wong, 2003).

2.2 THE IDENTIFICATION AND APPROPRIATE TREATMENT FOR PELVIC GIRDLE PAIN

While there may be many treatments used for PGP in pregnant and post partum women, few have been studied extensively for their effectiveness (Mens, Snijders, & Stam, 2000; Stuge, Laerum, Kirkesola, & Vollestad, 2004a). Nine controlled trials of physical therapy for women with pregnancy-related back pain and pelvic girdle pain were revealed by Stuge and colleagues through a systematic review (Stuge, Hilde, & Vollestad, 2003). However, because the trials in

the review were considered heterogeneous with regards to study population, outcome measures, and interventions, the studies were difficult to compare. Participants were different in terms of if whether they had pain or not, pain locations and whether they were still pregnant or not. There are a variety of conservative interventions for the treatment of PGP in pregnant and postpartum women including pelvic support, postural correction, pelvic tilts, physical agents (heat, cold, etc.), and strengthening of the abdominal, pelvic floor, and lumbar musculature (Berg et al., 1988; Ireland et al., 2000). None of these interventions have evidence to support their use.

2.2.1 Surgical treatment of Pelvic Girdle Pain

While a specific and optimal way to manage PGP has not been defined, there are several treatments proposed. These include injection of anesthetics and steroids into the joint which unfortunately only provide temporary relief lasting only a few hours (Fortin, Aprill, Ponthieux, & Pier, 1994), neural blockade through chemoneurolysis, cryolysis, and radiofrequency thermocoagulation, (Grabois, 2005) and on the rare occasion when trauma is not the cause, SIJ arthrodesis (Berthelot, Gouin, Glemarec, Maugars, & Prost, 2001; Belanger, 2001).

Yin et al. proposed the use of radiofrequencythermocoagulation of symptomatic sacral lateral branch nerves for the treatment of chronic SI joint complex pain. They found through a retrospective audit and examination that 64% of their subjects experienced a successful outcome. Success was defined as greater than 60% consistent subjective relief and greater than a 50% consistent decrease in visual integer pain score, maintained for at least 6 months after the procedure (Yin, Willard, Carreiro, & Dreyfuss, 2003).

Arthrodesis is the surgical option for SI joint pain. The joint is exposed, the cartilage on both joint surfaces is removed, bone grafting is performed and internally fixing with plates and

screws is done. Berthelot and colleagues stated that the use of arthrodesis in patients with aseptic sacroiliitis could be considered after careful selection and positive blocks in the SI joint coming to a conclusion that the pain is originating from the SI joint. They also note that arthrodesis should only be considered after the joint has been injected with steroids on several occasions with no lasting effect (Berthelot et al., 2001). Neuroaugmentation of the SI joint as a management for pain has been proposed by Calvillo et al. They found that through neuroaugmentation, peptides are released in the synovial fluid of the SI joint creating an analgesic response (Calvillo, 1998).

In some chronic cases it is thought that SI joint pain is due to hypermobility due to laxity of the ligaments. Prolotherapy is sometimes used in these cases. Prolotherapy consists of a series of saline and glucose injections that are applied to the weakened SI joint ligaments to cause an inflammatory reaction. The inflammatory reaction results in the formation of stronger fibers which tightens the ligaments and reduces the hypermobility of the joint and pain (Darrow, 2003). Unfortunately, there is conflicting evidence regarding the efficacy of these injections on reducing pain in chronic low back patients (Yelland, 2004).

2.2.2 Non-surgical treatment of Pelvic Girdle Pain

2.2.2.1 Exercise approaches

Many conservative interventions exist for PGP: pelvic support, postural correction, pelvic tilts, strengthening of the abdominal musculature along with lumbar musculature (Berg et al., 1988; Ireland et al., 2000)

Mens et al. conducted a study to evaluate the value of graded exercises of the diagonal trunk muscle system in post partum women. They found no differences among a group that

performed exercises specified at increasing the force of the diagonal trunk muscle system, a second group that performed training for the longitudinal trunk muscle system, and a control group that refrained from exercise (62.5%, 71.4%, and 57.1% respectively) in terms of better global improvement (Mens et al., 2000).

Stuge et al. conducted a randomized controlled trial to evaluate a treatment program focusing on whether specific stabilization exercises for pelvic girdle pain after pregnancy reduced pain. They found that an individualized program of specific training of the transverse abdominals with co-activation of lumbar muscles was more effective that physical therapy without specific training exercises for women with pelvic pain after pregnancy (Stuge et al., 2004a). They found minimal disability by means of the ODQ scores in 85% in the specific stabilization group compared to 47% in the control group after two years.

2.2.2.2 Manual therapy

The Guide to Physical Therapy Practice defines manipulation (Grade V mobilization) as a "manual therapy technique comprising a continuum of skilled passive movements to the joints and/or related soft tissues that are applied at varying speeds and amplitudes, including a small-amplitude/high-velocity therapeutic movement." In this study, mobilization will be considered a grade V mobilization. (American Physical Therapy Association., 2001). In general, mobilization is indicated when there is insufficient mobility in a structure and when there is a restriction in the movement of a joint (Harrison, Harrison, & Troyanovich, 1997; Beal, 1982; Lewit & Rosina, 1999). Several researchers have suggested that mobilization is effective in patients with pelvic pain (Cibulka et al., 1999; Delitto et al., 1993; Erhard et al., 1994; Hawk, 1999; Meade et al., 1990). It is thought that mobilization influences soft tissue structures such as the joint capsule, muscles, ligaments, tendons, and postural neuromuscular reflex patterns (Tullberg, Blomberg,

Branth, & Johnsson, 1998). It has been proposed to affect mechanical issues including the release of entrapped synovial or disc tissues reducing pain and restoring mobility; stretching and breaking of adhesions; and the dynamic stretching of musculature and myofascial tissues (Vernon, 1997). However, these theories remain highly speculative as there is a lack of adequate research on the topic. Another rationale is the restoration of joint motion or alignment; however, the means of restoring this function is unknown. There may be multiple joint movements which is a rationalization supported by the findings of Cibulka et al. who reported that a manipulative procedure specific to the SI joint changes innominate tilt bilaterally and in opposite directions (Cibulka et al., 1988).

Regardless of the proposed mechanism, there is increasing evidence of the effectiveness of manipulation, even when it is applied in a general fashion without regard to sub-grouping. Koes et al. performed a systematic review of randomized clinical trials to assess the efficacy of spinal mobilization for patients with low back pain. They found evidence that mobilization speeds the recovery of low back pain (Koes, 1996). Thirty six different randomized controlled trials were analyzed for quality and findings. They found that 53% of the trials reported better results for mobilization compared with the reference treatment such as short-wave diathermy, massage, exercise, analgesics, or a placebo treatment. They also found that five out of eight trials comparing mobilization focusing on patients with chronic or sub-acute low back pain indicated mobilization may be more effective for this patient population. The effectiveness of manipulation is further amplified when sub-grouping is taken into consideration. Childs et al. demonstrated the value of classification by demonstrating improvements in both pain and function in a group that was classified as positive on the CPR that received mobilization compared to a group that was classified as negative on the CPR that received mobilization, and

compared to a group that was classified as positive on the CPR that received a stabilization exercise (Childs, 2003).

While there is literature that supports the use of mobilization in the treatment of low back and pelvic pain, the use of this treatment technique is minimal. It may not be the technique of preference in clinics possibly due to the lack of skills some clinicians have or their fear of the risks accompanied with the techniques. Foster et al. found that a mere 2.8% of the therapists who responded to their questionnaire frequently used mobilization in the management of LBP and 76.6% did not use mobilization at all (Foster, 1999). According to Foster, reasons for this reduced percentage of therapists using mobilization may have been factors such as adequate training, resources, and the report that physical therapists did not have sufficient confidence with manipulative techniques. In a survey by Gracey and collegues, mobilization was found to be used in only 8.9% of treatments of LBP (Gracey, 2002). In a study by Cherkin et al. on the views of physicians on treating back pain, less than half of the physicians in the study believed that spinal mobilization was effective for back pain (Cherkin, Deyo, Wheeler, & Ciol, 1995).

The fact that clinicians may not use mobilization in the treatment of LBP due to the lack of skill may be true. Hurley et al. found in their study that the use of mobilization was considerably higher than reported by previous surveys and may reflect the postgraduate training of therapists in their trial (Hurley, McDonough, Baxter, Dempster, & Moore, 2005).

As with any type of treatment available, there are negative outcomes for their use. Senstad and colleagues performed a prospective clinic-based survey and found that the most common reactions to spinal mobilization/mobilization were local discomfort (53%), headache (12%), tiredness (11%), and radiating discomfort (10%) (Senstad, Leboeuf-Yde, & Borchgrevink, 1997). Reactions were characterized as mild or moderate (35%, 50%) respectively

and most reactions (64%) began within four hours and most (74%) disappeared within the first 24 hours. While the authors did not specify which area of the spine that was manipulated produced the most effect, they did specify that 75% of the recorded treatment sessions included treatment to the lumbar spine, 42% to the thoracic spine, and 33% to the cervical spine.

The most serious complication of mobilization of the lumbar spine is cauda equine syndrome. However, this has only been reported in a few cases according to a review of the literature by Haldeman in 1992 who found ten reports of cauda equine syndrome after mobilization of the lumbar spine over a 77 year period of the reported literature (Haldeman & Rubinstein, 1992). When compared to a common treatment for LBP, non-Steroidal anti-inflammatory drugs (NSAID's), the risks associated with mobilization are minimal. Approximately 30% of individuals exposed to NSAID's experience some side effects, most of which are gastrointestinal, especially when used for over four weeks (Hungin, Kean, Hungin, & Kean, 2001).

Mobilization may be an effective treatment choice for the treatment of PGP. It has been used in the past for the treatment of PGP in pregnant and non-pregnant women (Daly, Frame, & Rapoza, 1991; Golighty, 1982; Erhard et al., 1994). A 1991 study by Daly noted that mobilization relieved 91% of the pain the women were experiencing and had visible improvement in pelvic alignment (Daly et al., 1991). Though the study by Daly and colleagues does demonstrate some evidence for effectiveness of mobilization in patients with post-partum PGP, if is difficult to compare these results due to non-standardized outcome assessment. In addition, there was no attempt to sub-type the low back pain sample in this study. Sub-typing patients has been shown in the past to amplify the effect of manipulation and thus allow better targeting of this intervention strategy.

2.3 THE DIAGNOSIS OF PELVIC GIRDLE PAIN

Clinicians have relied on a variety of clinical tests to identify problems arising from the SI joint. These tests can be divided into tests that are designed to assess symmetry of bony landmarks in the static position (static symmetry tests), symmetry of bony landmarks during movement (movement symmetry tests), and tests that reproduce symptoms (provocation tests). Results from these tests are then used to help guide the clinician in the appropriate choice of treatment. Though purported to help identify those in whom manipulation might be indicated, the reliability of these tests and measures is equivocal (Riddle & Freburger, 2002).

2.3.1 Pathology-based vs. classification-based approaches to the diagnosis of Pelvic Girdle Pain

According to Ludwig, disease occurs when there is sufficient deviation from the normal and that disease is due to known or unknown natural causes. Ludwig also states that the elimination of these causes will result in the cure or improvement of the patient (Ludwig, 1975). Engel discusses the dominant biomedical model of disease as being the deviation from the norm of measurable biological variables and does not consider the social, psychological, or behavioral aspects of illness (Engel, 1977). If the physical approach to a disease depends on the illness being a physical pathology with the symptoms and disability being directly related to that physical pathology and psychological elements being unrelated, then according to Waddell, clinical recognition and diagnosis of the underlying pathology will provide the basis for a rational physical treatment of the illness. Waddell describes substantive or nominal diagnoses. Substantive having objective clinical features and investigations confirm a pathologic process

allowing a rational and successful treatment. Nominal diagnosis has been the preference of physicians and patients where a label can be given to the problem and treated (Waddell, 1987). If this concept is be applied to the diagnosis and treatment of PGP, a structural fault through diagnostic imaging or the identification of an underlying structure at fault by means of patient symptoms must be found.

When the mode of injury to the pelvis is traumatic and results in a fracture, the method to diagnose is straight forward. Imaging of the pelvis is performed, a diagnosis is found and a treatment is set forth. However when the mode of injury is not as clear cut, the process of diagnosis becomes more complicated. There is no physiologic test that has shown sufficient specificity to be used to diagnose the condition of PGP (Saal, 2002; Slipman, 1996; Tullberg et al., 1998; Slipman et al., 2000). Sacroiliac Joint (SIJ) pain is inconsistent with regards to radiologic findings as it occurs in supposedly morphologically normal joints (Beal, 1982; Schwarzer, Aprill, & Bogduk, 1995).

Imaging studies such as plain radiography, computed tomography, and magnetic resonance imaging do not demonstrate pain. Slipman et al. found very low sensitivity and high specificity of nuclear imaging in the diagnosis of SI joint syndrome (Slipman, Sterenfeld, Chou, Herzog, & Vresilovic, 1996). Elgafy and collegues also found a limited diagnostic value of computed tomography due to low sensitivity and specificity (Elgafy, Semaan, Ebraheim, & Coombs, 2001). Diagnostic injections or local anesthetic blocks provide objective means of diagnosing SI joint pain. However this method is invasive and requires fluoroscopic guidance (Schwarzer et al., 1995). The results of diagnostic blocks cannot be compared to a gold standard and thus there are no reliable data on the sensitivity and specificity of the test (Saal, 2002).

Diagnostic blocks are however, the only means to make a diagnosis of pain from the SI joint (Saal, 2002; Saal, 2002; Dreyfuss et al., 1996).

2.3.2 Clinical Tests for the Identification of Pelvic Girdle Pain

Although there is an abundance of studies on the different tests to identify SI region dysfunction, there has been no research to sufficiently conclude that these tests are reliable (Freburger & Riddle, 2001; Hestbaek & Leboeuf-Yde, 2000; van der, Hagmeijer, & Meyne, 2000). There has also been little research to demonstrate the validity of these tests (van der et al., 2000). Many of these tests are theoretically based on the existence of movement of the SI joint. Clinicians believe that a slight change in mobility of the SI joint is responsible for a variety of clinical conditions such as problems in the spine, pelvis and lower extremities (Beal, 1982). The few studies that have been done on the validity of these tests contest the existence of this movement (Sturesson et al., 1989; Sturesson, Uden, & Vleeming, 2000a; Tullberg et al., 1998; Sturesson, Uden, & Vleeming, 2000b). The lack of reliability and validity of these tests lead to contradictory results obtained by clinicians when testing for SI problems in patients. Some studies have indicated that these tests should be stopped altogether and alternative means of identifying SI region dysfunction be established (Harrison, Harrison, Troyanovich, & Harmon, 2000).

Clinicians have had little success in identifying specific faults in the SI region. Several researchers have suggested that by classifying subjects into subgroups that share similar characteristics would help guide the diagnosis, treatment, and overall decision making process in the management of LBP (Delitto et al., 1995a). Several studies on identifying characteristics of patients likely to benefit from a single manipulative intervention also suggest that many patients

with back pain may benefit from a single manipulative intervention (Delitto et al., 1993; Erhard et al., 1994; Flynn et al., 2002). This concept may be applied to pain arising from the SI joint.

Delitto and colleagues proposed a three level treatment-based classification approach for the management of patients with low back pain (Delitto et al., 1995a). The classification system is based on historical information, the behavior of symptoms, and clinical signs. First the patients are determined to be conservatively managed by physical therapists. The next level of classification is to stage their condition with regards to severity (stage I for the acute phase, stage II for the subacute phase, and stage III for patients returning to high physical demand activities). The final level of classification is for stage I patients who are then classified into distinct treatment-based categories that guide the conservative management of these patients. Delitto et al. proposed that in order to improve outcomes, classifying patients into categories and matching treatments with classifications will result in faster, efficient and more cost-effective care.

Since the Delitto et. al. publication, there have been a number of studies that have been conducted on sub-typing low back pain. Studies have reported that predictors of positive response to manipulation include patients with shorter duration of symptoms and the absence of leg pain (Skargren et al., 1998; Axen et al., 2005). Flynn et al. developed a CPR for manipulation classification for patients with non-radicular LBP (Flynn et al., 2002). The CPR consisted of: symptom duration less than 16 days, work subscale of the Fear Avoidance Beliefs Questionnaire less than 19, hypomobility of the lumbar spine, at least one hip with internal rotation greater than 35°, and symptoms not distal to the knee. If 4 of the 5 variables are positive (+LR = 24), patients are highly likely to improve with the manipulation procedure. Childs et al. followed up with a validity study by randomly assigning 131 patients to receive a standardized exercise program with or without manipulation (Childs, 2004). They examined the results in sub-groups based on

their status on the manipulation CPR developed by Flynn et al. Childs et al. found that patients who were positive on the CPR and received manipulation, experienced greater improvement in pain and disability than patients who were negative on the CPR and received the manipulation.

Hicks et al. developed a CPR for the stabilization classification sub-group of patients (Hicks et al., 2005). The CPR consisted of four variables: age less than 40 years, average straight leg raise range of motion (ROM) greater than 91°, aberrant movements during sagittal plane lumbar ROM, and a positive prone knee instability test. When 3 of the 4 variables are positive (+LR = 4.0), patients are likely to improve with the stabilization program. The accuracy of the stabilization CPR for success was not as strong as the CPR for manipulation. However, Hicks et al. did identify four predictive variables of failure with the stabilization program: negative prone instability test, absence of aberrant movements during sagittal plane ROM, absence of lumbar hypermobility, and a score of 9 or higher on the Fear Avoidance Beliefs Questionnaire (FABQ) physical activity subscale. The presence of 3 of the 4 variables was highly predictive of failure (+LR = 18.8). Stuge at al used five criteria to identify postpartum women with posterior pelvic girdle pain who are likely to benefit from a stabilization intervention (Stuge et al., 2004a; Stuge et al., 2004b). The criteria used were: posterior pelvic pain provocation test (PPPP), active straight leg raise test (ASLR), provocation of the long dorsal sacroiliac ligament, provocation of the pubic symphysis, and the modified Trendelenburg test.

2.4 CLINICAL PREDICTION RULES

A Clinical Prediction Rule (CPR) is a tool that quantifies individual contributions from different components of the history, physical examination, and laboratory findings to make a diagnosis,

prognosis, or likely response to a treatment in a patient (Guyatt & Rennie, 2002; Guyatt et al., 2002; Laupacis, Sekar, & Stiell, 1997; McGinn et al., 2000). CPRs aid in the classification and decision-making process of clinicians and help improve the accuracy in making a diagnosis and determining the prognosis of a patient (Laupacis et al., 1997). Such decisions include categorizing patients with suspected coronary artery disease into probability groups where decisions about appropriate diagnostic tests can be based (Morise, Haddad, & Beckner, 1997). CPRs have also been developed to risk stratify patients with suspected pulmonary embolisms (Moores, Collen, Woods, & Shorr, 2004). A developed CPR has also been shown to help clinicians predict the likelihood of a patient in developing cough from an angiotensin-converting enzyme inhibitor at the time of prescribing, and may also assist with subsequent clinical decisions (Morimoto & Gandhi, 2004). And recently, a spinal mobilization CPR was developed and shown to be useful in improving the decision making process for patients with low back pain (Childs, 2004).

The focus in this paper will be on developing a CPR to predict subjects likely to benefit from a specific intervention based on the outcome from treatment. The first step in developing a CPR is to create or derive the rule. This is done by constructing a list of potential predictors of the outcome of interest which may be found from the history and physical examination. The outcome of interest will serve as the reference or criterion standard. A successful outcome will then be judged using this reference criterion standard. The outcome being predicted by the rule should be clearly defined and clinically important (Laupacis et al., 1997). Any possible variables believed to be related to the outcome of interest are included as potential predictors and are selected based on previous research or clinical experience. Subjects are then exposed to the treatment and found to be either a success or non-success against the reference or criterion

standard. Statistical analysis will reveal which predictors are the most powerful and which can be omitted from the rule without loss of predictive power. Logistic regression is typically used in this process while others are available (Guyatt et al., 2002).

Due to the lack of evidence supporting the traditional methods of identifying SIJ causes of pain, a new method is warranted. The classification process is a process that is used to identify patients with similar characteristics who would likely benefit from a specific treatment procedure. A CPR can aid in the process of classifying these patients into a group that may benefit from a single treatment such as mobilization. Clinicians confirm the belief that patients improve dramatically after only one or two mobilization sessions. A CPR that combines information from the history and clinical examination could help guide clinicians further in the management of PGP in postpartum women.

2.5 SPECIAL CONSIDERATIONS RELATED TO PREGNANCY AND POST PARTUM

Low back and pelvic pain is a considerable problem in both pregnancy and postpartum and seems to be increasing. There have been several studies reporting the incidence as ranging between 14%-67% during pregnancy (Larsen et al., 1999; Albert, Godskesen, & Westergaard, 2000; Hansen et al., 1999; Wang et al., 2004; Berg et al., 1988; Daly et al., 1991). Postpartum low back and pelvic pain has also been shown to cause considerable disabilities with activities of daily living including housework, exercise, employment, hobbies and personal relationships (Hansen et al., 1999; MacLennan & MacLennan, 1997; Wang et al., 2004).

Lumbopelvic pain during pregnancy is said to diminish after delivery. A study by Larsen et al. found that the incidence of pregnancy related pelvic pain was 14% during pregnancy, 5% at 2 months postpartum, 4% at six months and 2% at 12 months postpartum (Larsen et al., 1999). However for some women this pain persists and diminishes the quality of their lives.

2.5.1 Hormonal Component

Contradiction surrounds the evidence that there is a relationship between serum relaxin levels and pelvic related symptoms in pregnant subjects (Hansen, 1996; MacLennan, Nicolson, Green, & Bath, 1986; Bjorklund, Bergstrom, Nordstrom, & Ulmsten, 2000; Marnach, 2003; Kristiansson, Svardsudd, & von, 1996b). In a study of 38 pregnant women with symptoms of pelvic girdle relaxation at the time of diagnosis, in the 30th and 38th week of pregnancy and two and six months post partum, Hansen et al. found that there were no differences in serum relaxin concentrations. They also found no differences in serum relaxin concentrations throughout pregnancy and after delivery in women with symptoms and positive clinical tests of pelvic girdle relaxation when compared to pregnant women without pelvic pain (Hansen, 1996). Bjorklund et al. studied the association between symphyseal distention, circulating relaxin levels and pelvic pain in pregnancy. They found that severe pelvic pain during pregnancy was strongly associated with an increased symphyseal distention. They did not however, find an association between serum relaxin levels and the degree of symphyseal distention or pelvic pain (Bjorklund et al., 2000). Contrary to these findings, Kristiansson et al. in their study of the relationship between serum relaxin levels and back pain during pregnancy suggested that relaxin may be involved in the development of pelvic pain in pregnancy (Kristiansson et al., 1996b). MacLennan et al. also

found a statistically significant association between relaxin levels and pelvic pain during late pregnancy (MacLennan et al., 1986).

2.5.2 Epidural Effects

There is little known about the long term effects of epidural analgesia on back pain. Some researchers have suggested an association between the use of epidurals during labor and back pain (Macarthur, Lewis, Knox, & Crawford, 1990b; Macarthur, 1993; Macleod, Macintyre, McClure, & Whitfield, 1995). Macarthur et al. first found through a questionnaire to 12,000 women who had delivered between 12 months and nine years that there may be a relationship between back pain and the use of epidural analgesia (Macarthur et al., 1990b). The results of this study however, were collected retrospectively and relied on the recall of these women several years later. Several prospective studies found no association between the use of epidurals and back pain after childbirth (To et al., 2003; Macarthur, Macarthur, & Weeks, 1995; Macarthur, Macarthur, & Weeks, 1997; Russell, Dundas, & Reynolds, 1996; Howell et al., 2002). A follow up after a randomized controlled trial by Howell et al. found that there were no differences in the incidence of long term low back pain, disability, or movement restriction between women who received epidurals and women who received other forms of pain relief. In the randomized controlled trial 369 women were included, 184 were randomized to an epidural group and 185 were randomized to a non-epidural group. The follow up study included 151 women from the epidural group and 155 from the non-epidural group (Howell et al., 2002).

2.5.3 Postpartum Depression

Postpartum depression affects approximately 10% of new mothers in the year after delivery (O'Hara, Zekoski, Philipps, & Wright, 1990). Up to 50% of cases go undetected (Yonkers & Chantilis, 1995). While previous research has found a correlation between depression and chronic low back pain (Middleton & Pollard, 2005), there has been no research on the link between postpartum depression and low back or pelvic pain. It has also been shown in previous research that depression does not affect treatment outcome in chronic back pain (Michaelson, 2004). However, this has not been studied in postpartum subjects.

The Edinburgh Postnatal Depression Scale (EPDS) has been developed to help health care providers detect postpartum depression. It consists of ten short statements related to mood, anxiety, guilt, and suicidal thoughts that are ranked from zero to three and can be completed by the new mother in less than five minutes. A score of 10 or more has been shown to be an indicator of a positive screen (Cox, Holden, & Sagovsky, 1987). Previous studies have shown that a score of 12 has a sensitivity of 86% and a positive predictive value of 73% for identifying postpartum depression (Georgiopoulos, 1999; Cox et al., 1987). The EPDS has also been validated in several countries including Sweden, Italy, and Portugal (Wickberg & Hwang, 1996; Areias, Kumar, Barros, & Figueiredo, 1996; Benvenuti, Ferrara, Niccolai, Valoriani, & Cox, 1999).

The EPDS will be administered in this study as part of the initial assessment. It will be completed by the subject on the first session along with the other questionnaires. If a positive screen is found with this questionnaire, the referring physician will be informed of the possibility of depressive findings.

3.0 DESIGN AND METHODS

3.1 DESIGN

This will be a prospective cohort study to create a CPR for identifying postpartum subjects with PGP who improve with SIJ mobilization. Subjects who meet the inclusion criteria and sign an informed consent will complete several self report measures related to pain, function and disability, and fear avoidance. They will then undergo a standardized history and physical examination and finally, a mobilization intervention to the SIJ. Each subject will be categorized as a success or non-success based on the criterion standard which will be 50% improvement in disability scores measured by the modified version of the Oswestry Disability Questionnaire (ODQ).

3.1.1 Study Flow

After completing the self report measures they will then undergo a physical examination by the primary physical therapy researcher. Next the subjects will receive the same intervention protocol, which will be a mobilization technique of the SI joint performed by the treating therapist followed by the hand-heel rock exercise. In the next visit which will take place 2-4 days later, each subject will complete a modified ODQ. Percentage improvement will be calculated by [(initial score – final score)/initial score X 100]. If the subject shows greater than a 50%

improvement, the subject will be categorized as a success and study participation will end. If the subject shows equal or less than 50% improvement, the therapist will repeat the examination and the mobilization procedure. In the third visit which will be 2-4 days later, the subject will again complete a modified ODQ questionnaire and the Edinburgh Postnatal Depression Scale (EPDS) questionnaire. If the subject shows greater than a 50% improvement, the subject will be categorized as a success and study participation will end. If the subject shows equal or less than 50% improvement, the subject will be categorized as a nonsuccess, study participation will end and further intervention will be administered as needed. (appendix 1 for study flow) All subjects will be given the opportunity to continue with physical therapy after participation in the study ends. Further intervention will be administered by the treating therapist and may consist of commonly used interventions such as modalities, exercise, and pelvic belts.

A maximum of three visits will be required from each subject. The subject will be given the opportunity to continue with physical therapy treatment as an outpatient at the Centers for Rehab Services. A 6-month follow up will be obtained over the telephone. Subjects will be contacted and asked to rate their disability using questions from the ODQ. They will be asked about the types of treatment they obtained for their PGP after their participation in the study, and they will be asked to rate their pain using a 10-point VAS (Appendix 13).

3.2 METHODS

3.2.1 Subjects and Sample Size

Postpartum subjects between six weeks and one year will be recruited (Stuge et al., 2004a). According to To et al., over 20% of women still experience persistent pain 24 months postpartum (To et al., 2003). They will be aged between 18 and 45 years and referred to physical therapy with a chief complaint of pain in the areas of the lower back, pelvic area, buttock, and legs. The baseline modified ODQ score will be at least 30%. Any subject complaining of nerve root compression signs in a radicular pattern (reduced SLR <45°, or reduced lower limb strength, reduced sensation, or reflex), lumbar/sacral spine surgery, pregnancy or spinal fractures will be excluded from this study. Seventy five women with PGP will be asked to participate. A sample size of 68 was chosen based on calculations from sensitivity and specificity values of 0.8 and a positive likelihood ratio of 2.0 using techniques described by Simel (Simel, Samsa, & Matchar, 1991). A 10% drop out rate will also be accounted for and thus a sample size of 75 was chosen. For the second aim of the study, sample size calculation was based on the condition that at least 10 subjects must be entered into the study for each predictor variable expected to remain in the logistic regression model. It is expected that no more than five to six predictors will remain in the final regression models for prediction of intervention outcome. Therefore, no more than 60 subjects will be required for the logistic regression analysis. Thus, a sample size of 75 was chosen to cover both aims of the study. A baseline score of the ODQ of at least 30% will be required for them to be eligible and the signing of an informed consent letter before any testing takes place will be required. Previous research has shown that an average ODQ score of 40% is seen for new patients referred to physical therapy, with a standard deviation (σ) of about 10%

(Fritz, 2000). Change in disability will be used as the reference criterion in this study and the minimum baseline level of 30% will insure that a wide range of individuals are included while extreme low scores of disability are excluded. Exclusion criteria will be nerve root compression signs in a radicular pattern (reduced SLR <45°, or reduced lower limb strength, reduced sensation, or reflex), lumbar/sacral spine surgery, pregnancy or spinal fractures.

3.2.2 Recruitment

Postpartum subjects diagnosed with SI region pain will be recruited from the OBGYN department of UPMC Magee Women's Hospital. Potential subjects will be identified by physicians who will refer the subjects to physical therapy. Potential subjects will be informed of the study by their care provider who will provide them with the investigators contact number. Information flyers will also be posted in the waiting rooms for patients to read through and ask their care providers about. Potential subjects will contact the primary investigator who will perform a phone screening for eligibility. If the subject is eligible to participate, arrangements will be made for an outpatient visit at the Physical Therapy department of Montefiore.

3.3 THERAPISTS

The primary investigator (PI), Nowall Hassan, will be responsible for physician recruitment, scheduling, telephone screening and will conduct the history and physical examination and the final follow up. The treating therapist, Carolyn Roberts, Susan George and Anthony Delitto will conduct the intervention.

3.4 INTERVENTION PROCEDURE

All subjects will receive the same mobilization procedure by the treating therapist. The subject will be positioned supine with the therapist standing on the opposite side to be mobilized. The side to be mobilized will be the side of pain reported by the subject. Cibulka et al. found that a manipulative procedure of the SIJ, changes innominate tilt bilaterally and in opposite directions (Cibulka et al., 1988). The subject will be passively side-bent to the opposite side (away from the therapist). The therapist will then passively rotate the subjects upper body opposite to the side bending and will then delivery a quick posterior and inferior thrust at a grade V through the ASIS (Stoddard, 1980). The therapist will record if a "pop" is heard or felt by the subject. If no pop is felt or heard, a second mobilization will be attempted. If no pop is heard, an attempt will be made to the opposite side. A maximum of two attempts per side will be permitted (Figure 1). According to Flynn et al., there is no relationship between an audible pop and improvement in range of motion, pain, or disability when performing a mobilization to the SIJ in individuals with non-radicular LBP (Flynn, Fritz, Wainner, & Whitman, 2003). Therefore, the treating therapist can be assured that the mobilization procedure was properly administered by the fourth attempt if no audible pop is heard.

The therapist will then instruct all the subjects to perform ten repetitions of the hand-heel rock exercise following the mobilization procedure. The subject is instructed to get on all fours on the bed or the floor and rest some of the weight on her hands and arms. The subject is asked to move her hands to just slightly higher than her shoulders. The forward rock is performed by transferring her weight more to her hands, not allowing her arms to bend. She is asked to allow her abdomen to sag towards the surface while she holds her head to look up. A pause is held towards the end of the range and then she is asked to return back towards neutral. The backward

rock is performed as if she were attempting to sit on her heels. She is asked to allow her back to round out while her hands drag along the surface in order to get the fully backward position. All the subjects will be advised to remain as active as possible within symptoms. A video clip of the mobilization intervention can be viewed by clicking on video clip. A video clip of the exercise can be viewed by clicking on video clip.

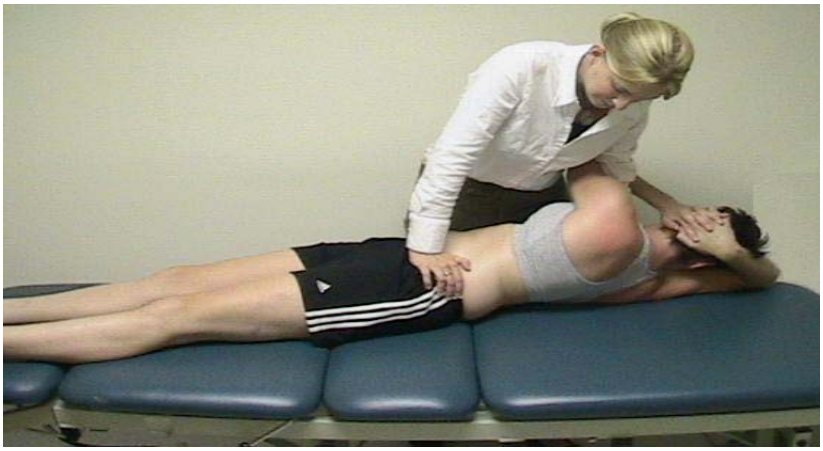

Figure 1 Mobilization Procedure

3.5 EXAMINATION PROCEDURES

All eligible subjects who consent to participate in the study will complete a series of self report measures, and a standardized history and physical examination. The self report measures and physical examination will be completed on the first and second visits by the examining physical therapist.

3.5.1 Self Report Measures

After completing a demographic information form, subjects will complete several self-report measures including a numeric pain rating using an 10-point scale, a pain diagram, the modified ODQ, the Fear-Avoidance Beliefs Questionnaire (FABQ), and the Edinburgh Postnatal Depresison Scale (EPDS).

- Demographic information: demographic information including age, height, weight before and after pregnancy, occupation, race, past medical history, number of pregnancies, number of children, epidural, and oral contraceptive use will be collected. Other questions asked will be related to mechanism of injury, onset of injury or pain location and nature of their symptoms, treatment for their previous pain and so on. This will be collected at baseline only. (Appendix 5)
- Visual Analogue Scale (VAS): subjects will rate their current level of pelvic pain intensity using a 10-point rating scale. This scale ranges from 0 (no pain) to 10 (worst pain imaginable). Pain intensity will be recorded for pain at present, at worst and at best. Jensen et al found that 10 and 21 point scales provide sufficient levels of discrimination to describe pain intensity (Jensen, Turner, & Romano, 1994). (Appendix 2)
- Pain diagram: subjects will indicate the location of their symptoms on a body diagram. This is used to categorize symptoms as lower back, pelvic area, buttock, or legs (Mann, III, Brown, Hertz, Enger, & Tompkins, 1993). In a study by Brynhildsen et al, pain over the region of the SI joint was most common (22 versus 13, $P<0.01$) (Brynhildsen, Hansson, Persson, & Hammar, 1998). (Appendix 2)
- Modified ODQ: disability due to SI region will be measured with a modified version of the ODQ. The ODQ questionnaire is a tool to help indicate the extent pain restricts a

person's functional level. Each item is scored from 0 to 5 giving a final score that is expressed as a percentage. A greater ODQ score indicates greater disability. Fritz et al showed that this questionnaire has high levels of test-retest reliability (ICC=.90) (Fritz & Irrgang, 2001). (Appendix 3)

- Fear-Avoidance Beliefs Questionnaire (FABQ): this questionnaire will help quantify the fear of pain the subject has and their beliefs about avoiding activity due to the SI region. There are 16 items, each with a score of 0 to 6 but not all items contribute to the score. The higher the score, the greater the fear-avoidance beliefs. The questionnaire also contains two subscales, a 7-item subscale concerning work, and a 4-item subscale concerning physical activity. Four items from the physical activity subscale are scored (numbers 2, 3, 4, and 5) and seven items from the work subscale (items 6, 7, 9, 10, 11, 12, and 15). Each subscale scores are summed giving possible ranges for the physical activity subscale of 0-24 and for the work subscale between 0-42. (Waddell, Newton, Henderson, Somerville, & Main, 1993). Jacob et al found high levels of test-retest reliability for the physical activity subscale and work subscale, ICC=0.77 and ICC=0.9, respectively (Jacob, Baras, Zeev, & Epstein, 2001). (Appendix 4)
- The Edinburgh Postnatal Depression Scale (EPDS): The EPDS has been developed to help health care providers detect postpartum depression. It consists of ten short statements related to mood, anxiety, guilt, and suicidal thoughts that are ranked from zero to three and can be completed by the new mother in less than five minutes. A score of 10 or more has been shown to be an indicator of a positive screen (Cox et al., 1987). Previous studies have shown that a score of 12 has a sensitivity of 86% and a positive predictive value of 73% for identifying postpartum depression (Georgiopoulos, 1999;

Cox et al., 1987). The mother is asked to underline the response which comes closest to how she has been feeling in the previous 7 days. Response categories are scored 0, 1, 2, and 3 according to increased severity of the symptoms. Items marked with an asterisk are reverse scored (i.e. 3, 2, 1, and 0). The total score is calculated by adding together the scores for each of the ten items (Morris-Rush & Bernstein, 2002). If a score of 12 or more is found, the subject's physician will be contacted and made aware of a possibility of depression. (Appendix 14)

3.5.2 History and Physical Examination

A history will then be obtained (age, height, weight, number of children, type of delivery, duration of current symptoms, mode of onset or mechanism of injury, if pain started during pregnancy or postpartum, nature of current symptoms, rank which is worst and best with respect to symptoms sitting, standing, or walking. They will then undergo a physical examination by the primary physical therapy researcher. The physical examination will include a neurological screening examination to rule out nerve root compression or radiculopathy, Waddell's nonorganic signs, Anterior Superior Iliac Spine (ASIS) symmetry in standing, iliac crest symmetry in standing, standing flexion test , Gillet test, palpation of posterior-superior iliac spine (PSIS) heights in sitting, the seated flexion test, supine long-sitting test, and the prone knee flexion test, Active Straight Leg Raise (ASLR) test, SIJ stiffness test, hip internal rotation ROM, long dorsal SI ligament pain test, posterior pelvic pain provocation test (PPPP), compression/distraction test, Patrick's fabere test.

- Neurological screening: subjects will be screened for evidence of nerve root compression. Screening will include pinprick testing for dermatomes from L1-S1, manual muscle

testing of major muscle groups for myotomes L1-S1, quadriceps and Achilles tendon reflex's, bilateral straight leg raise test, and prone knee flexion.

- Waddell's non-organic signs test: Waddell grouped eight signs into five groups. The five types or categories of signs are tenderness, simulation, distraction, regional disturbances, and. A non-organic sign observed during the physical exam is scored as positive and the presence of three or more types of signs indicates a positive result of the Waddell's non-organic signs test (Waddell, 1980).
- ASIS symmetry in standing: with the subject standing with feet about 12 inches apart, the ASIS are palpated and judged for symmetry. If one ASIS is judged to be higher than the other (1" at least), the test is positive (Flynn et al., 2002; Delitto et al., 1995a). Theoretically, differences in the ASIS heights indicate either an anteriorly or posteriorly rotated innominate.
- Iliac crest symmetry in standing: with the subject standing, the right and left iliac crests are palpated. If one iliac crest is judged to be higher than the other, the test is positive (Flynn et al., 2002). Theoretically, uneven iliac crests indicate a posteriorly or anteriorly rotated innominate.
- Standing flexion test: the subject is standing and the heights of the Posterior Superior Iliac Spines (PSIS) are assessed. The patient is then asked to flex forward as far as possible with the examiner continuing to palpate the PSIS. If a superior movement of one of the PSIS (1" at least) is sensed, the test is considered to be positive (Cibulka et al., 1999). Theoretically, the side with greater movement is the side of articular restriction (Potter et al., 1985; Beal, 1982).

- Gillet test (Stork test): with the subject standing with feet about 12 inches apart, the examiner places one thumb under the PSIS on the side being tested (flexed) and the other thumb over the S2 spinous process. The subject is then instructed to stand on the leg opposite the side being tested and flex the other hip and knee, bringing the leg toward the chest. A positive test in indicated when the PSIS fails to move posterior and inferior with respect to S2 spinous process (Flynn et al., 2002). Theoretically, the innominate should posteriorly rotate on the weight bearing side.
- Palpation of the PSIS in sitting: with the subject sitting on a level surface, the PSIS are palpated. A positive test is indicated when one PSIS appears lower when compared to the opposite side. Theoretically, the presence of a lower PSIS (1" at least) suggests that the ilium is rotated posteriorly on the sacrum and the opposite ilium may be anteriorly rotated. (Cibulka et al., 1999; Flynn et al., 2002).
- Seated flexion test: with the subject sitting, the relative heights of the PSIS are judged. The subject is asked to bend forward as far as possible while the tester continues to palpate the PSIS. A change in the relative relationship of the PSIS in the fully flexed position (1" at least) indicates a positive test (Flynn et al., 2002). Theoretically, a change in the relationship of the PSIS in the flexed position indicates an articular restriction on the side with more movement (Beal, 1982).
- Supine long sitting test: with the subject is in the supine position, a visual estimation of leg length is made by palpating the inferior aspects of the medial malleoli. The subject is asked to come to a long-sitting position. Any change in the relative position of the medial malleoli indicates a positive test (Cibulka et al., 1999; Flynn et al., 2002). Theoretically, when the subject is in the supine position, the finding of a shorter leg indicates a

posteriorly rotated innominate. When the subject is asked to sit up with legs straight, any lengthening of the short leg (1" at least) implies a posteriorly rotated innominate (Cibulka et al., 1999).

- Prone knee bend test: with the subject in the prone position, the relative leg lengths are assessed by looking at the soles of the heels (shoes on) with the knees fully extended. The examiner passively flexes the subjects knees to 90° and the relative leg lengths are assessed again. A change in the relative lengths between the two positions (1" at least) indicates a positive test. A positive finding from this test theoretically indicates a posteriorly rotated innominate (Flynn et al., 2002; Cibulka et al., 1999).
- Active Straight Leg Raise (ASLR): this test is performed in the supine position with the legs straight and the feet 20cm (8") apart. The subject is given the instructions to "Raise your leg above the table 8" without bending your knee". Their ability to raise their leg without rotation of the trunk and pelvic girdle is observed and their effort to do so is noted. Mens and collegues performed a cross-sectional analysis of a group of women with posterior pelvic pain since pregnancy. They found the sensitivity of the test as 0.87 and the specificity as 0.94.(Mens, Vleeming, Snijders, Koes, & Stam, 2001). In this study noting if the subject has difficulty lifting one leg as opposed to the other will be recorded.
- Sacroiliac Joint Stiffness Test: this test examines the ability of the SIJ to resist vertical and horizontal translation forces applied passively to the non-weight bearing joint. With the subject supine and the knees and hips flexed, the sacral sulcus just medial to the PSIS is palpated with the long and ring fingers while the index finger palpates the lumbosacral junction. The long and ring fingers monitor translation between the innominate and the sacrum while the index finger notes any movement between the pelvic girdle and the L5

vertebra. Anteroposterior translation is tested by applying a posterior pressure to the innominate through the iliac crest and the ASIS, and stiffness values are compared between the left and right sides. Vertical translation is tested by applying superior/inferior pressure to the innominate through the distal end of the femur, and stiffness is compared between the left and right sides (Lee & Vleeming, 2000). Any apparent discrepancy between either of the two motions will be considered as a positive test.

- Hip internal rotation ROM: rotation is tested in both the sitting and the prone position. In the sitting position, the patient is asked to place her hands on the table on either side of the knees to maintain the hips in a neutral abduction/adduction position. The tester then passively internally rotates both hips simultaneously by moving the ankles outwards. The relative ROM of the left and right hips are assessed visually by comparing the excursion of the lower legs. In the prone position, with the hips and knees bent at a 90° angle, the hips are aligned in neutral rotation and internal rotation is then assessed by moving the ankles outward. Cibulka et al found that internal rotation was limited from side to side in patients with SI region pain ($p<0.05$). They also stated that identifying hip ROM asymmetry in patients with low back pain may help in diagnosing SI region pain (Cibulka, Sinacore, Cromer, & Delitto, 1998).
- Long dorsal SI ligament pain test: this tests tenderness on bilateral palpation of the long dorsal ligament. With the subject prone or side lying, the long dorsal SI ligament is palpated. The test is positive if pain is produced with palpation (Vleeming, de Vries, Mens, & van Wingerden, 2002). Albert et al found sensitivity and specificity values of 0.49 and 1.0 with subjects who had pregnancy related pelvic pain (Albert, Godskesen, & Westergaard, 2000).

- Pain Provocation test (PPPP) (thigh thrust test/posterior shear test): the subject is supine. One leg is flexed to 90° at the hip and knee joint. With hands on the raised knee, pressure is exerted down the femur into the pelvis. The test is positive if the subject experiences pain in the pubic symphysis and/or the SIJ. The test is repeated to the other side. Albert et al found high sensitivity and specificity of this test, 0.90 and 0.98 respectively when evaluating pregnancy-related pelvic joint pain (Albert et al., 2000).
- Compression/Distraction test: with the subject supine, pressure is applied to the ASIS in a posterior and lateral direction to compress the joint. Next pressure is applied in an anterior and medial direction on the ASIS to distract the joint. A positive test is indicated when pain is reproduced in the SIJ region with either maneuver (Flynn et al., 2002). Albert et al found sensitivity and specificity values of 0.7 and 1.0 for the compression test and values of 0.4 and 1.0 for the separation test when used in subjects with pregnancy related pelvic joint pain (Albert et al., 2000).
- Fabere/Patrick's test: The subject is supine. One leg is flexed, abducted, and externally rotated so that the heel rests on the opposite knee. Over pressure is applied to the medial aspect of the knee while the pelvis is stabilized. Patrick's test of range of motion is tested by comparing both sides and noting a difference in the range of motion. If pain is experienced in the pelvic joints the Fabere test is considered to be positive. Albert et al found superior sensitivity with this test in the evaluation of pregnancy related pelvic joint pain with a sensitivity and specificity value of 0.7 and 0.99 (Albert et al., 2000).

4.0 DATA ANALYSIS

Descriptive statistics (mean, standard deviation) will be calculated for all baseline variables. Subjects will be dichotomized based on success or non-success with respect to the intervention.

4.1 SPECIFIC AIM1 AND ANALYSIS

The first specific aim is to determine the predictive ability of individual historic and physical examination variables in identifying positive response and non-response to intervention among subjects with PGP undergoing a mobilization of the SI joint. A meaningfully positive change is defined by determining individual changes in the modified ODQ score from baseline to the second or third visit. Success or non-success will be used as the reference or criterion standard. Subjects classified as non-success will have less than 50% improvement on the ODQ by the third visit. All other subjects will be classified as a success.

Each of the possible predictor variables measured at baseline will be investigated by calculating point and confidence interval values for test sensitivity, specificity and likelihood ratios using intervention response (individual change in the modified ODQ score) as the criterion standard. Test sensitivity is defined as the proportion of subjects with the target disorder who have a positive test result (Guyatt et al., 2002). Sensitivity in this study is the proportion of subjects with a positive response to the mobilization that had a positive test result. Test

specificity is defined as the proportion of subjects who are truly free of the target disorder and are identified by the test as negative. In this study, specificity will be the proportion of subjects with a non-response to intervention who had a negative test result. These probabilities will be calculated from a 2x2 contingency table (Figure 2).

		Reference Criterion	
		Intervention Outcome	
		Positive Response	**Non-Response**
Test Result	**Positive**	A	B
	Negative	C	D
		Sensitivity=A/A+C	**Specificity=D/B+D**

Figure 2 2X2 Contingency Table for Calculating Sensitivity and Specificity for Positive Response to Mobilization

Predictors of non-response to intervention will then be identified. The positive response and non-response columns under intervention outcome will be inverted so that non-response becomes the "typical positive state" of the criterion standard (Figure 3). Sensitivity will become the proportion of subjects who do not respond to mobilization but have a positive test result. Specificity will be the proportion of subjects who have positive response to mobilization with a negative test result. Calculation of all test properties using contingency table analysis will be done for prediction of positive response and non-response to intervention.

		Reference Criterion	
		Intervention Outcome	
		Non-Response	Response
Test Result	Positive	A	B
	Negative	C	D
		Sensitivity=A/A+C	Specificity=D/B+D

Figure 3 2X2 Contingency Table for Calculating Sensitivity and Specificity for Non-Response to Mobilization

For continuous independent variables such as age, weight, modified ODQ, number of episodes, and for categorical variables, a cut-point will be determined in order to dichotomize the variables for use in the 2x2 contingency table. This will be done by using a Receiver Operating Characteristic (ROC) curve that will plot sensitivity against 1-specificity for each possible cut-off value for the diagnostic test result (Crichton, 2002). To make the ROC graph, the X-axis is 1-specificity and the Y-axis is the sensitivity or true positive rate. A diagonal line from (0, 0) to (1, 1) reflects the characteristics of a test with no discriminating power. The point on the curve nearest to the upper left corner represents the value with the best diagnostic accuracy. This is where a true positive rate will be 1.0. If the area under the curve is only 0.5 for a certain cut-off point, then the test is non-discriminating.

For predicting positive response to the intervention, the likelihood ratio (LR) is the likelihood that a given result would be expected in a subject with a positive intervention outcome. The LR combines both sensitivity and specificity to tell how likely the subject is to have a positive intervention outcome as the result of the specific test performed. When using

sensitivity and specificity, important information is discarded or recalculation of the sensitivity and specificity for every cut-off point is needed. Likelihood ratios are more simple and efficient (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000). The positive LR will be calculated as sensitivity/(1-specificity) and will indicate the increase in the probability of success given a positive test result. The negative LR will be calculated as (1-sensitivity)/specificity. Likelihood ratios greater than 1.0 increase the probability that the target disorder is present and the higher the LR, the greater is this increase. Likelihood ratios smaller than 1.0 decrease the probability of the target disorder and the smaller the LR, the greater is the decrease in probability and the smaller is its final value. The positive LR is used to attempt to predict success with mobilization based on positive test results. Calculation of the post-test odds for a positive intervention outcome can also be performed by multiplying the LR by the pre-test odds (prevalence rate) predicted for a positive intervention outcome (online posttest probability calculator may be found at the following site (Probability Calculator, 2007)). The post-test probability can also be found using a LR nomogram which allows an easy transition from pretest to posttest probability (Guyatt et al., 2002). For example, if the probability of a subject having SI region is 50% and the LR is 5, the post-test probability is found by anchoring a ruler at 50% pretest probability and rotating it until it lines up with the LR of 5, then the posttest probability is found to be about 82% (Figure 4). A large positive LR indicates that the test is meaningful when the results are positive and helps in ruling in a positive intervention outcome. A small negative LR indicates that the test is meaningful when the test results are negative and helps in ruling out a positive intervention outcome.

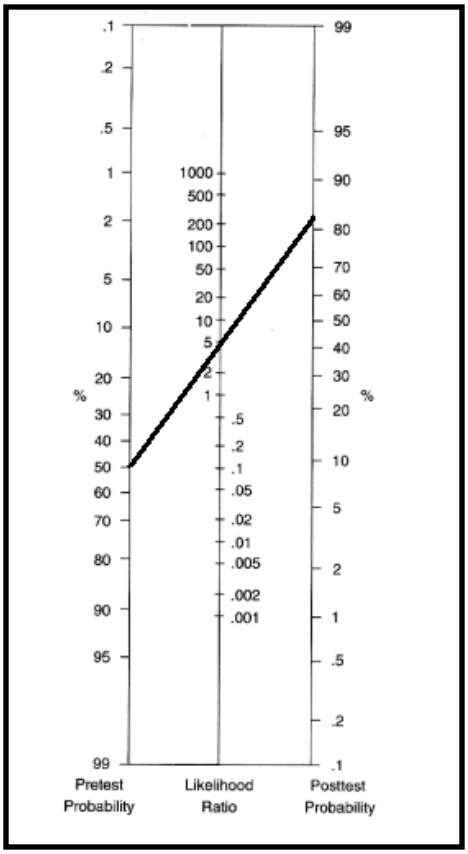

Figure 4 Nomogram of Pre-test and Post-test Probability

To determine which variables have predictive ability, criteria to demonstrate an acceptable level of predictive capacity will be established. A sensitivity and specificity values of 0.7 or greater will be used to ensure a minimum level of confidence that a specific condition can be ruled in or out. Based on previous research (Erhard et al., 1994; Delitto et al., 1993; Fritz, 2000), it is anticipated that about half of the subjects will be categorized as intervention successes. Given this prevalence, a sample size of 100 subjects will provide a 95% CI ranging between 0.7 and 0.9 for a true sensitivity or specificity value of 0.8. Therefore, to be certain that the CI would be sufficient enough to make the results definitive; the lower bound should not fall below 0.7 (Simel, Samsa, & Matchar, 1991).

Positive LR values of 2.0 or more and negative LR values of 0.5 or less will be considered acceptable. This is a small but possibly meaningful shift in probability. Likelihood ratios of >10 or <0.1 generate large and often conclusive changes from pre- to posttest probability; LR of 5-10 and 0.1-0.2 generate moderate shifts; LR of 2-5 and 0.5-0.2 generate small changes but sometimes important; and LR of 1-2 and 0.5-1 alter probability to a small degree (Guyatt et al., 2002). A confidence interval (CI) of 95% will be used to identify variables that have a definitive level of acceptability in terms of prediction. The lower bound of the 95% CI has to be at least 0.7 for both sensitivity and specificity and 2.0 for the positive LR. The upper bound of the 95% CI has to be less than 5.0 for the negative LR. The use of a CI makes the interpretation of the results more precise in regards to what the minimum predictive ability of the variable is in this sample.

4.2 SPECIFIC AIM2 AND ANALYSIS

The second aim is to determine the best combination of historical and physical examination variables for predicting positive response and non-response to intervention among subjects with PGP undergoing a mobilization of the SI joint. The possible predictors from the first aim will be entered into the final multivariate analysis to filter out the possible predictor variables. Sensitivity and specificity values calculated from the positive response portion of the previous aim will be used. Variables with a sensitivity or specificity value for which the lower bound of the 95% CI greater than .60 will be eligible for entry into the backward step-wise logistic regression model. Any variable with a p-value of 0.05 will be eligible for entry model and 0.15 to remove it. This will ensure that any potentially helpful variable will not be excluded due to

strict criteria. Two binary logistic regression models will be created for the two variable types (historical, physical examination). This will help identify the best cluster for each variable type. The best cluster that remains in the separate regression analyses will then be entered together with the same criteria for exiting the model as described earlier. All variables remaining in the final regression equation ($p<0.15$) will be considered significant predictors of a positive response to the mobilization technique of the SIJ when used as a cluster of tests.

When the final regression model is established, sensitivity, specificity and likelihood ratios will be calculated for the cluster of tests. Each cluster will be treated as one single variable, test properties will be examined at different levels of positive findings. For example, if there are five items in the final cluster of tests, a score of 1 will be given if one or more variables in the cluster are positive and a score of 0 will be given if there are no positive findings for any individual variable in the cluster. Calculation of sensitivity, specificity and likelihood ratios will then be performed for the cluster. In the next level of scoring, a score of 1 will be given of there are two or more positive findings and a score of 0 if there are less than two positive findings. The process will continue until all the appropriate levels have been examined. This will be repeated for the identification of clusters for non-response to mobilization. The variables entered into the model will be determined based on sensitivity and specificity values for prediction of non-response calculated in the first aim.

4.3 CODE GUIDE FOR SCORING OF VARIABLES

Table 1 Code Guide for Scoring of Demographic Variables

Variable	Type	Measurement

Age	Continuous *	Yrs (high=1, low=0)
BMI (Kg/m^2 x 100)	Continuous*	(high=1, low=0)
# children	Categorical * (multi-level)	1; 2; 3; ≥4; none (high=1, low=0)

- Variables will be dichotomized into high and low categories using ROC curve analysis.

Table 2 Code Guide for Scoring of Self-Report Variables

Variable	Type	Measurement
VAS	Continuous*	0-10 (high=1, low=0)
FABQ	Continuous*	(high=1, low=0)
EPDS	Continuous*	(high=1, low=0)

- Variables will be dichotomized into high and low categories using ROC curve analysis.

Table 3 Code Guide for Scoring of Historic Variables

Variable	Type	Measurement
Onset of Pain	Categorical* (multi-level)	1^{st} trim., 2^{nd}, 3^{rd}, <wk PP, > wk PP (high=1, low=0)
Traumatic onset	Categorical	Yes=1 No=0
Best position	Categorical* (multi-level)	Sit; stand; walk; lay down; uncertain (high=1, low=0)
Worst position	Categorical* (multi-level)	Sit; stand; walk; lay down; uncertain (high=1, low=0)
Best time	Categorical* (multi-level)	Morning; midday; evening; night; uncertain (high=1, low=0)
Worst time	Categorical* (multi-level)	Morning; midday; evening; night; uncertain (high=1, low=0)
Type Delivery	Categorical	Vaginal=1 C/S=0
Epidural	Categorical	Yes=1

		No=0
Oral Contraceptives	Categorical	Yes=1 No=0
Prior History	Categorical	Yes=1 No=0
Months Since Delivery	Categorical* (multi-level)	<3, 3-6, 6-9, >9 (high=1, low=0)
Multiple Gestation	Categorical	Yes=1 No=0
Breast feeding	Categorical	Yes=1 No=0
Symptom Location	Categorical* (multi-level)	upper and lower L/S; lower L/S and SIJ; Combined (high=1, low=0)
Episodes of pain	Categorical* (multi-level)	<3; 3-5; 6-10; >10 (high=1, low=0)
Duration of symptoms in weeks	Continuous*	Weeks (high=1, low=0)

- Variables will be dichotomized into high and low categories using ROC curve analysis.

Table 4 Code Guide for Scoring of Physical Examination Variables

Variable	Type	Measurement
ASIS Symm.	Categorical	Positive = 1 Negative = 0
Iliac Crest	Categorical	Positive = 1 Negative = 0
Stand Flex.	Categorical	Positive = 1 Negative = 0
Gillet	Categorical	Positive = 1 Negative = 0
PSIS symm.	Categorical	Positive = 1 Negative = 0
Seated Flex.	Categorical	Positive = 1 Negative = 0
Hip IR	Categorical	Positive = 1 Negative = 0
ASLR	Categorical	Positive = 1 Negative = 0
Supine long sit	Categorical	Positive = 1 Negative = 0
SIJ Stiffness	Categorical	Positive = 1 Negative = 0
PPPP	Categorical	Positive = 1 Negative = 0

Compression	Categorical	Positive = 1 Negative = 0
Distraction	Categorical	Positive = 1 Negative = 0
Patrick's/FABER	Categorical	Positive = 1 Negative = 0
Prone knee bend	Categorical	Positive = 1 Negative = 0
Long dorsal lig.	Categorical	Positive = 1 Negative = 0

4.4 REFERENCE CRITERION

The outcome from the mobilization procedure will be used as the reference criterion to identify subjects categorized as success or non-success. The outcome will be measured by change in disability scores of the ODQ. Any subject with more than 50% improvement of the ODQ will be categorized as a intervention success, all others will be categorized as non-success.

In previous research by Fritz et al., it was shown that the minimum clinically important difference (MCID) for the ODQ is six points (Fritz et al., 2001). With a baseline of 30% on the ODQ, a 50% improvement corresponds to approximately a 15-point improvement in disability. This change will give the clinician confidence that the improvement is due to the mobilization and not just the natural healing history of back pain. With higher baseline levels of disability, a 50% improvement will demonstrate an even greater degree of improvement.

Previous research that used this same mobilization intervention found that a 50% improvement in the ODQ was able to distinguish between subjects who responded to the mobilization versus subjects who just benefited from the natural history of back pain (Delitto et al., 1993; Erhard et al., 1994; Fritz, 2000). Patients that were matched to this intervention

experienced mean improvements in ODQ scores from 57% to 83%. Patients that were not matched to interventions experienced mean improvements between 20% and 38%. This was over a 1-4 week period. Therefore, a 50% improvement over a 2-4 day period should be adequate to distinguish between response to the intervention rather than just the natural history of back pain (Flynn et al., 2002).

5.0 EXPECTED RESULTS

5.1 CAN INDIVIDUAL HISTORIC AND PHYSICAL EXAMINATION VARIABLES IDENTIFY PATIENTS WITH PGP WHO POSITIVELY RESPOND OR DO NOT RESPOND TO MOBILIZATION OF THE SIJ?

It is anticipated that approximately five historic variables and ten physical examination variables will demonstrate predictive ability in this study. Previous research by Flynn and colleagues found that among the self-reported variables, the FABQ work subscale less than 19, the presence of symptoms in the back only, and no symptoms distal to the knee were retained as potential prediction variables. In this study, it is anticipated that the FABQ, no symptoms distal to the knee, and presence of symptoms in the lumbar region and over the PSIS will be retained as possible predictors. Previous research demonstrated that the majority of patients reported pain involving the lower lumbar region and buttocks, 72% and 94% respectively (Slipman et al., 2000).

Variables from the history retained by Flynn et al. were duration of symptoms less than 16 days, increasing episode frequency, and ranking standing as the worst position were retained. In this study, it is thought that dynamic positions increase SI pain and therefore walking may be ranked as worst position. variables such as body mass index (BMI), number of pregnancies and children, type of delivery, use of epidural, age, and the use of oral contraception's were included.

A study by Endresen et al. found that BMI and number of children were both associated with pelvic pain in pregnant women (Endresen, 1995). While Breen and colleagues did not find an association between type of delivery (vaginal versus c-section) and the use of an epidural during delivery with pain, it is felt that the inclusion of these in the list of variables is justified as a confirmation of the previous findings (Breen, Ransil, Groves, & Oriol, 1994). Breen et al. also found an association between age and pain with younger women experiencing more pain than older women, 58% versus 35% respectively. To et al. found after studying back pain in pregnant and postpartum women that the main risk factors associated with the persistence of back pain at 24 months appeared to be the onset of pain during pregnancy (To et al., 2003). It is anticipated that this variable will be a possible predictor in this study.

Variables retained from the physical examination of the Flynn et al. study included hip internal rotation range of motion, hypomobility and pain with spring testing of the lumbar spine. They also retained compression and distraction as possible predictors. In this study, it is anticipated that hip internal rotation will remain as a predictor. Flynn et al. did not investigate some of the variables being included in this study. These variables include the ASLR, SIJ stiffness test, and palpation of the long dorsal SI ligament. It is anticipated that ASLR, PPPP test, compression, distraction and palpation of the long dorsal SI ligament will remain as predictors. Mens and colleagues found high sensitivity and specificity values for the ASLR in a cross sectional analysis of women with posterior pelvic pain since pregnancy (Mens et al., 2001). Albert et al. found the PPPP test as being both sensitive and specific (0.90, 0.98) and low sensitivity but high specificity values of palpation of the long dorsal SI ligament test (0.49, 1.00) when used in pregnancy related pelvic joint pain (Albert et al., 2000).

While several variables included in this study were found to be non-predictors in the spinal mobilization CPR by Flynn et al., it is believed the outcomes may differ in this study due to the unique population being tested (i.e. postpartum women). Therefore, these variables will be included in the study.

5.2 WHAT IS THE BEST COMBINATION OF HISTORIC AND PHYSICAL EXAMINATION VARIABLES FOR PREDICTING POSITIVE RESPONSE AND NON-RESPONSE TO THE INTERVENTION?

Flynn et al. developed a spinal mobilization CPR that included five variables; symptom duration, FABQ, hypomobility, hip internal rotation and the pain diagram (Flynn et al., 2002). They found that duration of symptoms that were less than 16 days, at least one hip with greater than 35º of internal rotation, hypomobility with lumbar spring testing, FABQ work subscale score less than 19, and no symptoms distal to the knee were predictors of positive response to the intervention. The presence of four of five of these variables increased the probability of success with mobilization from 45% to 95%. In this study it is anticipated that 5-6 variables will remain in the rule and that subjects having 4/5 positive predictors will increase the probability of success with the mobilization by at least half.

6.0 RESULTS

A total of 70 subjects were recruited and gave consent for participation in this study. All recruitment occurred between January 2006 and December 2006. One subject was ineligible for the study after signing an informed consent due to nerve root compression signs in a radicular pattern found during the neurological examination. As a result of the drop-out, primary analyses are based on 69 subjects.

Baseline characteristics of the study sample including demographics, historic and self-report variables are listed in Table 5. The mean age of the study population was 31 years (SD=6), 73.9% were Caucasian. The mean BMI was 28.9 (SD=7.54) and 43.47% of this sample had a BMI above 29kg/m^2. The mean number of children for this sample was 1 (SD=1), 33.3% of the subjects had one child, 42% had two children, and 23.2% had three or more children, only 1.4% had a full term miscarriage. Fifty one subjects (73.9%) of this sample had an epidural, and gave birth vaginally and 21 subjects (30.4%) started to experience pain in the third trimester. Only 3 subjects (4.3%) started to experience pain in their first trimester, 17 (24.6%) in their second trimester and 14 (20.3%) started to experience pain less than one week postpartum and 14 (20.3%) after one week postpartum. Fifty two subjects (75.4%) reported that they experienced pain in the lower lumbar and SIJ areas only.

Table 5 Baseline Characteristics of Study Participants

Variable	Mean (σ) n=69
Age (years)	31 (6)
Body Mass Index; (Kg/m^2)	28.9 (7.5)
Ethnicity; (# of Caucasian subjects (%))	51 (73.9%)
Number of Children	1 (1)
Epidural Used; (# Epidurals (%))	51 (74%)
Type of Delivery; (# of vaginal births (%))	51 (74%)
Months Since Delivery; (# (%))	
- Less than 3 months	27 (39%)
Onset of Pain; (# Per category (%))	
- 1st Trimester	3 (4%)
- 2nd Trimester	17 (25%)
- 3rd Trimester	21 (31%)
- < 1 Week Postpartum	14 (20%)
- > 1 Week Postpartum	14 (20%)
Multiple Gestation; [# multiple gest. (%)]	3 (4%)
Breast Feeding; [# Breastfeeding (%)]	28 (41%)
Using Oral Contraceptives; [# using (%)]	9 (13%)
Visual Analog Scale (0-10)	
- Pain at present	4.7 (2.1)
- Pain at worst	6.7 (2.2)
- Pain at best	3.4 (2.5)
Fear Avoidance Beliefs	
- Work	13.1 (9.7)
- Physical Activity	15.4 (4.3)
Edinburgh Postpartum Depression Quest.	6.0 (4.5)
Oswestry Disability Questionnaire (ODQ)	42.3 (9.2)
Traumatic Onset of pain; [# traumatic onset (%)]	4 (5.8%)
Prior History of pain; [# With prior history (%)]	22 (32%)
Symptom Location; [# (%)]	
- Lower lumbar &/or SIJ area only	52 (75.4%)

- Values are means (σ) unless otherwise indicated

The analysis was initially planned after two physical therapy visits; however, after post-hoc analysis, it was determined to be more parsimonious to look at the data after one visit. We observed an unexpectedly high improvement in ODQ after the first visit and results from the

second visit were not more informative than results from the first visit because only five subjects showed additional improvement after the second visit. Therefore, the following analysis is after one physical therapy visit.

The mean ODQ score at baseline was 42.26 ± 9.21, and after the first intervention it was 13.54 ± 11.47. The mean percent improvement in the ODQ over the study period was 69 ± 25.25% (range 10.5 – 100%). Fifty five (80%) were categorized as intervention successes, and 14 (20%) were categorized as non-successes. Subjects classified as non-success had less than 50% improvement in the ODQ after the first visit. The mean improvement in the success group was 33.2 ± 8.78 points, with a mean % improvement of 79 ± 11.64%. The mean improvement in non-success group was 11.71 ± 5.37 points, with a mean % improvement of 27.14 ± 11%. The initial ODQ score in the success group was 42.18 (39.71, 44.65) and ODQ2 was 8.98 (7.17, 10.79). The initial ODQ in the non-success group was 43.14 (37.77, 48.52) and ODQ2 was 31.43 (26.60, 36.25) (Figure 6).

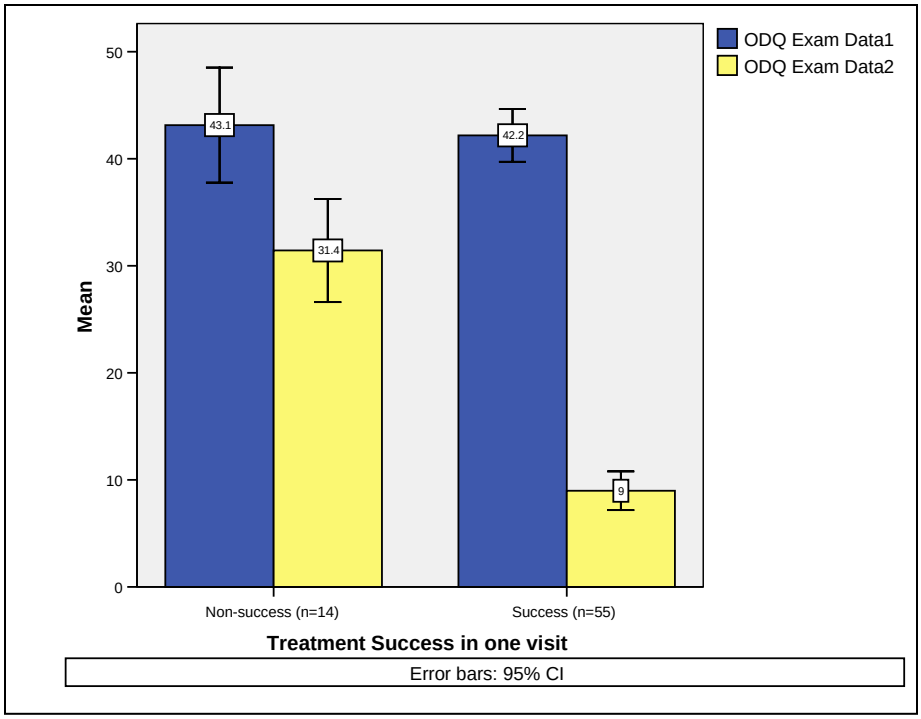

Figure 5 Initial and Final Oswestry Disability Questionnaire (ODQ) Scores for the Success and Non-Success Groups

‡ Subjects classified as non-success had less than 50% improvement in the ODQ after the first visit

7.0 SPECIFIC AIM1

The first aim was to determine the predictive ability of individual historic and physical examination variables in identifying positive response and non-response to intervention among subjects with PGP undergoing a mobilization of the SIJ. Subjects classified as non-success had less than 50% improvement on the ODQ after the first visit. All other subjects were classified as intervention success.

7.1 UNIVARIATE PREDICTION OF POSITIVE RESPONSE TO THE MOBILIZATION INTERVENTION

Of the 69 participants in the study, 55 were classified as positively responding to the intervention. The prevalence of positive response to the intervention in this population was 80%. ROC analysis was used to establish cut-off points for the following continuous or multi-level categorical variables: age, BMI, number of children, VAS, FABQ, EPDS, onset of pain, best position, worst position, best time, worst time, months since delivery, symptom location, episodes of pain, and duration of symptoms. Cut-off points were established for the FABQ-W, onset of pain, best position, worst position, best time, symptom location and number of episodes of pain. For the other variables, no potentially useful cut-off points were established due to the lower bound of the 95% CI for each variable's area under the curve (AUC) being less than .50. If

the area under the curve is only 0.5 for a certain cut-off point, then the test is non-discriminating (Crichton, 2002). The AUC for FABQ-W was .56, onset of pain was .54, best position was .5, worst position was .52, best time was .55, symptom location was .56, and the AUC for number of episodes of pain was .51. ROC curve analysis provided a cut point of 10 for FABQ-W, onset of pain in the 3rd trimester or less than one week postpartum, standing as best position, laying down as worst position, midday for best time, lower lumbar spine and/or SIJ area for symptom location, and increasing number of episodes of pain.

Table 6 provides the diagnostic test properties of the historic and self-report variables. Table 7 provides the diagnostic test properties of the physical examination variables. Only nine variables from both tables met the criteria to be considered definitively acceptable: symptom location, best position, worst position, best-time, traumatic onset of pain, seated flexion, iliac crest symmetry, standing flexion, and prone knee bend. Symptom location, seated flexion, iliac crest symmetry, standing flexion, and prone knee bend had definitively acceptable levels of sensitivity while best position, worst position, best-time, and traumatic onset of pain had definitively acceptable levels of specificity. No variables had definitively acceptable levels of +LR or –LR. For a variable to be considered definitively acceptable, the lower bound of the 95% CI has to be at least 0.7 for sensitivity and specificity and 2.0 for the positive LR, and the upper bound of the 95% CI has to be less than 5.0 for the negative LR. Symptom location was the only variable with a definitively acceptable level of sensitivity.

Table 6 Diagnostic Test Properties of Historic and Self-Report Variables Used for Prediction of Positive Response to Mobilization

Variable*	% of Responders	SN (95% CI)	SP (95% CI)	-LR (95% CI)	+LR (95% CI)

Onset of pain (during 3rd trimester or <1 week postpartum)	47.27	.47 (.34, .61)	.36 (.14, .64)	1.48 (.89, 2.44)	.74 (.46, 1.19)
Epidural Used	76.36	**.76** (.63, .86)	.29 (.1, .58)	.83 (.36, 1.89)	1.07 (.74, 1.54)
Symptom Location (Lower L/S &/or SIJ area only)	83.64	**.84** (.71, .92)	.57 (.3, .81)	**.29** (.14, .58)	1.95 (1.05, 3.61)
FABQ-W (> 10)	60	.6 (.46, .73)	.57 (.30, .81)	.7 (.46, 1.1)	1.4 (.74, 2.66)
Best Position (Standing)	9.09	.01 (.03, .21)	**1** (.73, 1)	.91 (.84)	-
Worst Position (Laying Down)	7.27	.07 (.02, .18)	**1** (.73, 1)	.93 (.86, .99)	-
Best Time (Midday)	10.91	.11 (.05, .23)	**1** (.73, 1)	.89 (.81, .98)	-
Prior History of LBP	30.91	.31 (.19, .45)	**.71** (.42, .90)	.97 (.77, 1.22)	1.08 (.43, 2.71)
Vaginal Delivery	76.36	**.76** (.63, .86)	.36 (.14, .64)	.66 (.32, 1.37)	1.19 (.78, 1.8)
Pain Episodes (Increasing)	25.45	.25 (.15, .39)	**.79** (.49, .94)	.95 (.78, 1.15)	1.19 (.39, 3.57)
Pain onset (During Pregnancy)	65.45	.65 (.51, .77)	.43 (.19, .70)	.81 (.46, 1.39)	1.15(.69, 1.87)
Traumatic Onset	7.27	.07 (.02, .18)	**1** (.73, 1)	.93 (.86, .99)	-
Use of Oral Contraceptives	16.36	.16 (.08, .29)	**.93** (.64, .99)	.90 (.79, 1.02)	**2.29**(.32,16.61)
Multiple Gestation	3.64	.04 (.01, .14)	**.93** (.64, .99)	1.04 (.98, 1.1)	.51 (.05, 5.22)
Breast Feeding	40	.4 (.27, .54)	.64 (.36, .86)	.93 (.69, 1.25)	1.12(.52, 2.43)

SN= Sensitivity, **SP**= Specificity, **-LR**= Negative Likelihood Ratio, **+LR**= Positive Likelihood Ratio, **95% CI**= 95% Confidence Interval

§ Lower Lumbar Spine (L/S) &/or Sacroiliac Joint (SIJ) area only; Fear Avoidance Beliefs Questionnaire-Work subscale (FABQ-W);

‡ Positive state of the variable for this analysis is enclosed in parenthesis following the variable name.

Table 7 Diagnostic Test Properties of Physical Examination Variables Used for Prediciton of Positive Response to Mobilization

+ Variable*	% of Responders	SN (95% CI)	SP (95% CI)	-LR (95% CI)	+LR (95% CI)
ASIS Symm.	34.55	.36 (.23, .49)	.5 (.24, .76)	1.31 (.94, 1.82)	.69 (.37, 1.41)
Iliac Crest Symm.	90.91	**.91** (.79, .97)	.14 (.03, .44)	.64 (.12, 3.39)	1.06 (.84, 1.33)
Standing Flexion Test	89.09	**.89** (.77, .95)	.14 (.03, .44)	.76 (.15, 3.76)	1.04 (.82, 1.31)
Gillet Test	76.36	**.76** (.63, .86)	.29 (.1, .58)	.83 (.36, 1.89)	1.07 (.74, 1.54)
PSIS Symm. (negative test)	29.09	.29 (.18, .43)	**.93** (.64, .99)	.76 (.64, .91)	**4.07** (.59, 28.15)
Seated Flexion Test	85.45	**.85** (.72, .93)	.4 (.17, .67)	**.37** (.16, .85)	1.42 (.93, 2.83)
Hip IR	74.55	**.75** (.61, .85)	.14 (.03, .44)	1.78 (.49, 6.49)	.87 (.67, 1.13)
ASLR	78.18	**.78** (.65, .88)	.07 (0, .36)	3.05 (.3, 31.09	.84 (.69, 1.03)
Supine Long Sit	65.45	.65 (.51, .77)	.21 (.06, .51)	1.61 (.67, 3.88)	.83 (.6, 1.16)
SIJ Stiffness	70.91	**.71** (.57, .82)	.07 (0, .36)	4.07(.44, 37.97)	.76 (.61, .95)
PPPP	72.73	**.72** (.59, .83)	.29 (.10, .58)	.95 (.44, 2.09)	1.02 (.70, 1.47)
Compression	34.55	.35 (.23, .49)	.64 (.36, .86)	1.02 (.78, 1.33)	.97 (.44, 2.13)
Distraction	18.18	.18 (.10, .31)	**.86** (.56, .97)	.95 (.82, 1.11)	1.27 (.31, 5.16)
Patricks	72.73	**.73** (.59, .83)	.07 (0, .36)	3.82 (.40, 36.28	.78 (.63, .97)
FABER	43.64	.44 (.31, .58)	.43 (.19, .70)	1.32 (.86, 2.0)	.76 (.44, 1.32)
Prone Knee Bend Test	80	**.79** (.70, .89)	.6 (.38, .83)	**.34** (.18, .63)	1.99(1.06, 3.75)
Long Dorsal Lig.	67.27	.67 (.53, .79)	.14 (.03, .44)	2.3 (.68, 7.75)	.78 (.59, 1.04)

SN= Sensitivity, **SP**= Specificity, **-LR**= Negative Likelihood Ratio, **+LR**= Positive Likelihood Ratio, **95% CI**= 95% Confidence Interval

‡ Anterior Superior Iliac Spines (ASIS); Posterior Superior Iliac Spine (PSIS); Internal Rotation (IR); Active Straight Leg Raise (ASLR); Sacroiliac Joint (SIJ); Posterior Pelvic Pain Provocation (PPPP)

7.2 UNIVARIATE PREDICTION OF NON-RESPONSE TO THE MOBILIZATION INTERVENTION

Of the 69 participants in the study, 14 were classified into the non-response to the intervention outcome group. The prevalence of non-response to intervention in this study population was 20%. ROC analysis was used to establish cut-off points for the following continuous variables: age, BMI, number of children, VAS, FABQ-PA, EPDS, worst time and duration of symptoms in weeks. The AUC for age was .70, BMI was .58, number of children was .60, VAS-present was .70, VAS-worst was .68, VAS-best was .76, FABQ-PA was .63, EPDS was .57, worst time was .58, and the cut-point for duration of symptoms in weeks was .51. The ROC curve analysis provided cut points of 35 for age, 26 for BMI, one child for number of children, five for VAS-present, seven for VAS-worst, three for VAS-best, 16 for FABQ-PA, seven for EPDS, worst time not night and 25 weeks or more for duration of symptoms.

Table 8 provides the diagnostic test properties of the historic and self-report variables. Table 9 provides the diagnostic test properties of the physical examination variables. Five variables met the criteria to be considered definitively acceptable in terms of sensitivity, specificity or likelihood ratios: age, oral contraceptive use, multiple-gestation, FABQ-PA and the distraction test. FABQ-PA and the distraction test both had definitively acceptable levels of sensitivity while age, the use of oral contraceptives and multiple gestations had definitively acceptable levels of specificity. No variables had definitively acceptable levels of +LR or –LR.

Table 8 Diagnostic Test Properties of Historic and Self-Report Variables Used for Prediction of Non-Response to Mobilization

Variable*	% of Non-Responders	SN (95% CI)	SP (95% CI)	-LR (95% CI)	+LR (95% CI)
Age (> 35 years)	50	.5 (.24, .76)	**.84** (.71, .92)	.6 (.35, 1.0)	**3.06** (1.38, 6.67)
BMI (≥26)	71.43	**.71** (.42, .90)	.49 (.36, .63)	.58 (.25, 1.38)	1.4 (.92, 2.14)
# of Children (More than one)	5.71	**.79** (.49, .94)	.42 (.29, .56)	.51 (.18, 1.47)	1.35 (.94, 1.92)
VAS-Present (≥5)	71.43	**.71** (.42, .90)	.51 (.37, .64)	.56 (.24, 1.33)	1.46 (.95, 2.23)
VAS-Worst (≥7)	92.86	**.93** (.64, 1)	.44 (.31, .58)	.16 (.02, 1.13)	1.65 (1.25, 2.17)
VAS-Best (>3)	85.71	**.86** (.60, .97)	.67 (.53, .79)	**.21** (.05, .78)	**2.62** (1.7, 4.05)
FABQ-PA (≥16)	71.43	**.71** (.42, .90)	.49 (.36, .63)	.58 (.25, 1.38)	1.4 (.9, 2.14)
EPDS (≥7)	57.14	.57 (.30, .81)	.56 (.42, .69)	.76 (.4, 1.43)	1.31 (.76, 2.26)
Worst Time of day (not night)	71.43	**.71** (.42, .90)	.42 (.29, .56)	.68 (.28, 1.64)	1.23 (.82, 1.83
Vaginal Delivery	64.29	.64 (.36, .86)	.24 (.14, .37)	1.51 (.67, .42)	.84 (.55, 1.28)
Epidural Used	71.43	**.71** (.42, .90)	.24 (.14, .37)	1.21 (.47, 3.1)	394 (.65, 1.34)
Oral Contraceptives Used	7.14	.07 (0, .36)	**.84** (.71, .92)	1.11(.95, 1.29)	.44 (.06, 3.16)
Prior history of pain	28.57	.29 (.1, .58)	.69 (.55, .80)	1.03(.73, 1.46)	.92 (.37, 2.31)
Multiple Gestation	7.14	.07(.003, .36)	**.96** (.86, .99)	.96 (.83, 1.11)	1.96 (.19, 20.14)
Duration of Symptoms (≥25 weeks)	50	.5 (.24, .76)	.5 (.36, .63)	1.02(.58, 1.78)	.98 (.55, 1.76)

SN= Sensitivity, **SP**= Specificity, **-LR**= Negative Likelihood Ratio, **+LR**= Positive Likelihood Ratio, **95% CI**= 95% Confidence Interval

§ Body Mass Index in Kg/m^2x100 (BMI); Visual Analogue Scale (VAS); Fear Avoidance Beliefs Questionnaire-Physical Activity subscale (FABQ-PA); Edinburgh Postnatal Depression Scale (EPDS)

‡ Positive state of the variable for this analysis is enclosed in parenthesis following the variable name.

Table 9 Diagnostic Test Properties of Physical Examination Variables Used for Prediction of Non-Response to Mobilization

Variable*	% of Non-Responders	SN (95% CI)	SP (95% CI)	-LR (95% CI)	+LR (95% CI)
ASIS	50	.65 (.51, .77)	.5 (.24, .76)	.69 (.42, 1.43)	1.31 (.75, 2.29)
Iliac Crest Symm.	85.71	.09 (.03, .21)	**.86** (.56, .97)	1.06 (.95, 1.18)	.64 (.14, 2.94)
Standing Flex	85.71	.11 (.05, .23)	**.86** (.56, .97)	1.04 (.93, 1.17)	.76 (.17, 3.38)
Gillet	71.43	.24 (.14, .37)	**.71** (.42, .90)	1.07 (.87, 1.31)	.83 (.32, 2.15)
PSIS/Seated	92.86	.29 (.18, .43)	**.93** (.64, .99)	.76 (.64, .91)	**4.1** (.59, 28.15)
Seated Flexion	64.29	.15 (.07, .27)	.64 (.36, .86)	1.33 (1.1, 1.6)	.41 (.16, 1.05)
Hip IR	85.71	.25 (.15, .39)	**.86** (.60, .97)	.87 (.73, 1.04)	1.8 (.46, 6.95)
ASLR	92.86	.22 (.12, .35)	**.93** (.64, .99)	.84 (.72, .98)	**3.05**(.43, 21.55)
Supine Long Sit	78.57	.35 (.23, .49)	**.97** (.49, .94)	.83 (.66, 1.05)	1.61 (.55, 1.69)
SIJ Stiffness	92.86	.29 (.18, .43)	**.93** (.64, .99)	.76 (.64, .91)	**4.1** (.59, 28.15)
PPPP	71.43	.27 (.17, .41)	**.71** (.42, .90)	1.02 (.82, 1.27)	.95 (.38, 2.42)
Compression Test	35.71	.65 (.51, .77)	.36 (.14, .64)	.97 (.52, 1.79)	1.02 (.66, 1.57)
Distraction	14.29	**.82** (.7, .9)	.14 (.03, .44)	1.27 (.31, 5.16)	.95 (.75, 1.22)
Patrick Test	92.86	.27 (.17, .41)	**.93** (.64, .99)	.78 (.66, .93)	**3.82** (.55, 26.5)
Faber	57.14	.56 (.42, .69)	.57 (.3, .81)	.76 (.51, 1.15)	1.32 (.69, 2.51)
Negative Prone Knee Bend	57.14	.57 (.3, .81)	**.8** (.67, .89)	.54 (.29, .99)	**2.86**(1.42,5.73)
Long Dorsal Lig.	85.71	.33 (.21, .47)	**.86** (.60, .97)	.78 (.64, .97)	**2.3** (.60, 8.73)

SN= Sensitivity, **SP**= Specificity, **-LR**= Negative Likelihood Ratio, **+LR**= Positive Likelihood Ratio, **95% CI**= 95% Confidence Interval

‡ Anterior Superior Iliac Spines (ASIS); Posterior Superior Iliac Spine (PSIS); Internal Rotation (IR); Active Straight Leg Raise (ASLR); Sacroiliac Joint (SIJ); Posterior Pelvic Pain Provocation (PPPP)

8.0 SPECIFIC AIM2

The second aim was to determine the best combination of historical and physical examination variables for predicting positive response and non-response to intervention.

8.1 TEST CLUSTER FOR POSITIVE RESPONSE TO MOBILIZATION

A filtering step to eliminate the large number of variables for prediction of positive response was needed. The filtering step eliminated any variables that would likely offer no additional predictive value to the test cluster. Any variables from the first aim with test sensitivity and specificity values for which the lower bound of the 95% CI was less than .60 were eliminated. This approach was used so that any helpful variables would not be excluded due to criteria that were too stringent. After the filtering process, eleven historic variables and twelve physical examination variables (Table 10) were entered into the two separate binary logistic regression models. The analysis was performed to identify the best cluster of historic and physical examination variables.

Table 10 Variables Entered into the Logistic Regression Model as Predictors of Positive Response to Mobilization

Historic Variables
Epidural used
Symptom location
Best position
Worst position
Best time
Prior history
Vaginal delivery
Pain episodes increasing
Traumatic onset of pain
Oral contraceptives used
Multiple gestation
Physical Examination Variables
Iliac crest symmetry
Standing flexion
Gillet test
PSIS symmetry
Seated flexion
Hip IR
ASLR
SIJ stiffness
PPPP
Distraction
Patrick's test
Prone knee bend

One historic variable and three physical examination variables remained in their respective final regression models (Tables 11 and 12). The Hosemer-Lemeshow goodness of fit test was used to assess how well the data fit the model. Both models fit the data ($p>.05$). The best cluster of variables for predicting positive response to the intervention are shown in Table 13.

Table 11 Best Subset of Historic Variables for Prediction of Positive Response to Mobilization

	BETA	Standard Error	SIG.	Negelkerke R Square Statistic
Historic Variable				
1. Symptom location	1.63	.65	.01	.14
Constant	.25	.50	.62	

Table 12 Best Subset of Physical Examination Variables for Prediction of Positive Response to Mobilization

Physical Examination Variables				
1. Seated Flexion	2.77	.96	.00	.42
2. Prone Knee Bend	2.67	.83	00	
3. Negative PSIS	3.07	1.31	.02	
Constant	-2.89	1.1	.01	

Table 13 Test Cluster for Positive Response to Mobilization: Final Variables Remaining in the Logistic Regression Model

	BETA	Standard Error	SIG.	Negelkerke R Square Statistic
Physical Examination Variables				
1. Seated Flexion	3.23	1.12	.00	.53
2. Prone Knee Bend	2.84	.94	.00	
3. Negative PSIS	4.32	1.79	.02	
Historic Variable				
4. Symptom location	2.32	.96	.02	
Constant	-4.98	1.66	.00	

The variables in Table 13 represent the most appropriate cluster for prediction of positive response to the intervention outcome and were used to form the clinical prediction rule. Table 14 shows the number of subjects in each group at each level of the CPR. Only six subjects were positive for all four variables in the CPR and they were in the success group.

Table 14 Number of Subjects in the Success and Non-Success Groups at Each Level of the Clinical Prediction Rule

# of Predictor Variables Present	# of Subjects in the Mobilization Success Group	# of Subjects in the Mobilization Non-Success Group
0	***0***	***0***
1	***1***	***6***
2	***19***	***4***
3	***32***	***1***
4	***6***	***0***

Table 15 shows the test properties for the four different levels of positive findings in the cluster. There were no false positive cases in the contingency table formulated for the presence of three and four positive test items and so 0.5 was added to all cell values in the table so no zero cells would be available (Agresti, 2002).

Table 15 Cluster for Prediction of Positive Response to Mobilization

Minimum Number of Positive Findings	SN (95% CI)	SP (95% CI)	-LR (95% CI)	+LR (95% CI)
Zero	**.97** (.7, 1)	.01 (0, .09)	3.73 (.01,2772.31)	.98 (.89, 1.07)
One	**.85** (.73, .93)	.36 (.14, .64)	.41 (.17, .99)	**1.33** (.89, 1.99)
Two	.65 (.51, .77)	.79 (.49, .94)	.44 (.29, .66)	**3.05** (1.1, 8.48)
Three	.12 (.05, .24)	**.97** (.7, 1)	.91 (.83, 1.01)	**3.48** (.21, 58.39)
Four	.12 (.05, .24)	**.97** (.7, 1)	.91 (.83, 1.01)	**3.48** (.21, 58.39)
Cluster	1. Seated flexion, 2. Prone knee bend, 3. Negative PSIS, and 4. Symptom location in the lower L/S &/or SIJ areas only			

SN= Sensitivity, **SP**= Specificity, **-LR**= Negative Likelihood Ratio, **+LR**= Positive Likelihood Ratio, **95% CI**= 95% Confidence Interval

To determine if any specific grouping was more predictive of positive response, different combinations of variables in the cluster were examined. Test properties of all possible combinations of the four variables in the cluster were calculated and are shown in Table 16.

Table 16 Different Combinations of the Cluster for Prediction of Positive Response to Mobilization

Variable	SN (95% CI)	SP (95% CI)	-LR (95% CI)	+LR (95% CI)
1. Seated Flexion	**.85** (.73, .93)	.36 (.14, .64)	.41 (.17, .99)	**1.33** (.89, 1.99)
2. Prone Knee	**.79** (.70, .89)	.6 (.38, .83)	**.34** (.18, .63)	1.99(1.06, 3.75)
3. (-) PSIS	.29 (.18, .43)	**.93** (.64, .99)	.76 (.64, .91)	**4.07** (.59, 28.15)
4.Symptom location	**.84** (.71, .92)	.57 (.3, .81)	**.29** (.14, .58)	1.95 (1.05, 3.61)
Variables 1 & 2	.65 (.51, .77)	**.79** (.49, .94)	.44 (.29, .66)	**3.05** (1.1, 8.48)
Variables 1 & 3	.21 (.11, .34)	**.97** (.7, 1)	.82 (.72, .94)	**6.16** (.38, 98.66)
Variables 1 & 4	**.73** (.59, .83)	**.71** (.42, .9)	.38 (.23, .62)	**2.55** (1.09, 5.92)
Variable 2 & 3	.21 (.11, .34)	**.97** (.7, 1)	.82 (.72, .94)	**6.16** (.38, 98.66)
Variables 2 & 4	.67 (.53, .79)	**.79** (.49, .94)	.42 (.27, .63)	**3.14** (1.13, 8.7)
Variables 3 & 4	.24 (.14, .38)	**.97** (7, .1)	.79 (.67, .91)	**7.23** (.46, 111.79)
All 4 Variables	.12 (.05, .24)	**.97** (.7, 1)	.91 (.83, 1.01)	**3.48** (.21, 58.39)

SN= Sensitivity, **SP**= Specificity, **-LR**= Negative Likelihood Ratio, **+LR**= Positive Likelihood Ratio, **95% CI**= 95% Confidence Interval

Accuracy statistics were calculated for each level of the clinical prediction rule (i.e. when one variable was present in the CPR, when two variables were present, when three variables were present…etc.). Based on the pretest probability of success with mobilization found in this study (80%), and the positive likelihood ratio values calculated, a subject with four variables present at baseline increases her probability of success with the mobilization from 80% to 93%. If two or more variables are present, the probability of success was increased from 80% to 92% (Table 17).

Table 17 Clinical Prediction Rule for Positive Response to Mobilization

# of Predictor Variables Present	Sensitivity	Specificity	Positive LR	Probability of Success (%)
4+	.12 (.05, .24)	**.97** (.7, 1)	**3.48** (.21, 58.39)	93
3+	.12 (.05, .24)	**.97** (.7, 1)	**3.48** (.21, 58.39)	93
2+	.65 (.51, .77)	.79 (.49, .94)	**3.05** (1.1, 8.48)	92
1+	**.85** (.73, .93)	.36 (.14, .64)	**1.33** (.89, 1.99)	84

Accuracy statistics with 95% CI for individual variables for predicting positive response.

8.2 TEST CLUSTER FOR NON-RESPONSE TO MOBILIZATION

A filtering process to eliminate the large number of variables for prediction of non-response was performed. The same criteria to eliminate variables from the previous step were used in this step as well. After the filtering process, five historical variables and twelve physical examination variables were entered into their respective regression models (Table 18).

Table 18 Variable Entered into the Logistic Regression Models as Predictors of Non-Response to Mobilization

Historic Variables
Age
VAS –worst
VAS –best
Oral contraceptives used
Multiple gestation
Physical Examination Variables
Iliac crest symmetry
Standing flexion
Gillet
PSIS
Hip IR
ASLR
Supine long sit
SIJ stiffness
PPPP
Distraction
Patrick's test
Negative prone knee bend test
Long dorsal SI ligament

Two historic variables remained in the historic variables regression analysis and one physical examination variable remained in the physical examination regression analysis (Tables 19 and 20). The Hosemer-Lemeshow goodness of fit test was used to assess how well the data fit the model. The model fits the data presented in each regression analysis ($p>.05$).

Table 19 Best Subset of Historic Variables for Prediction of Non-Response to Mobilization

	BETA	Standard Error	SIG.	Negelkerke R Square Statistic
Historic Variables				
Age > 35 years	1.9	.79	.02	.39
VAS at Best > 3	2.7	.88	.00	
Constant	-3.63	.87	.00	

Table 20 Best Subset of Physical Examination Variables for Prediction of Non-Response to Mobilization

	BETA	Standard Error	SIG.	Negelkerke R Square Statistic
Physical Examination Variable				
Negative Prone Knee Bend Test	1.67	.64	.01	.12
Constant	-1.99	.44	.00	

The variables in Table 21 represent the most appropriate cluster for prediction of non-response to the intervention outcome and were used to form the clinical prediction rule. No subjects in the success group were positive for all three retained prediction variables at baseline. Three subjects in the non-success group were positive for all three variables (Table 22).

Table 21 Test Cluster for Non-Response to Mobilizaiton: Final Variables Remaining in the Logistic Regression Model

	BETA	Standard Error	SIG.	Negelkerke R Square Statistic
Historic Variables				
1. Age > 35 years	1.98	.86	.02	.51
2. VAS-Best > 3	3.11	1.01	.00	
Physical Examination Variable				
3. Negative Prone Knee Bend Test	2.14	.85	.01	
Constant	-4.76	1.16	.00	

Table 22 Number of Subjects in the Success and Non-Success Groups at Each Level of the Model

# of Predictor Variables Present	# of Subjects in the Mobilization Success Group	# of Subjects in the Mobilization Non-Success Group
0	***24***	***0***
1	***24***	***4***
2	***7***	***7***
3	***0***	***3***

The variables in Table 23 represent the most appropriate cluster for prediction of non-response to the intervention outcome. Sensitivity, specificity and likelihood ratios were established for the cluster using contingency table analysis. Test properties were calculated for different levels of non-response in the cluster.

Table 23 Different Combinations of the Clinical Prediction Rule for Prediction of Non-Response to the Mobilization

Variable	SN (95% CI)	SP (95% CI)	-LR (95% CI)	+LR (95% CI)
1. Age > 35 years	.5 (.24, .76)	**.84** (.71, .92)	.6 (.35, 1.02)	**3.05** (1.38, 6.76)
2. VAS-Best > 3	**.86** (.56, .97)	.67 (.53, .79)	**.21** (.06, .79)	**2.62** (1.7, 4.05)
3. Negative Prone Knee Bend Test	.57 (.3, .81)	**.8** (.7, .89)	.54 (.3, .99)	**2.86** (1.42, 5.73)
Variables 1 & 2	.43 (.19, .7)	**.96** (.86, .99)	.59 (.38, .93)	**11.79**(2.66,52.24)
Variables 1 & 3	.21 (.06, .51)	**.95** (.84, .99)	.83 (.63, 1.09)	**3.93** (.89, 17.41)
Variables 2 & 3	.5 (.24, .76)	**.96** (.86, .99)	.52 (.31, .88)	**13.75** (3.2, 59.08)

SN= Sensitivity, **SP**= Specificity, **-LR**= Negative Likelihood Ratio, **+LR**= Positive Likelihood Ratio, **95% CI**= 95% Confidence Interval

Table 24 shows the test properties for the two different levels of positive findings in the cluster. There were no false positive cases in the contingency table formulated for the presence of none and three positive test items and so 0.5 was added to all cell values in the table so no zero cells would be available (Agresti, 2002).

Table 24 Cluster for Prediction of Non-Response to Mobilization

Minimum Number of	SN (95% CI)	SP (95% CI)	-LR (95% CI)	+LR (95% CI)

Positive Findings				
Zero	.03 (0, .3)	.56 (.42, .69)	1.72 (1.52,1.94)	.08 (0, 1.18)
One	.5 (.24, .76)	**.84** (.71, .92)	.6 (.35, 1.02)	**3.06** (1.38, 6.76)
Two	.43 (.19, .7)	**.96** (.86, .99)	.59 (.38, .93)	**11.79** (2.66, 52.24)
Three	.23 (.07, .52)	**.99** (.91, 1)	.77 (.58, 1.02)	**26.1** (1.43,478.71)
Cluster	1. Age > 35 years, 2. VAS-Best > 3, 3. Negative Prone Knee Bend Test			

SN= Sensitivity, **SP**= Specificity, **-LR**= Negative Likelihood Ratio, **+LR**= Positive Likelihood Ratio, **95% CI**= 95% Confidence Interval

Accuracy statistics were calculated for each level of the clinical prediction rule for non-response to the intervention. Based on the pretest probability of non-success with mobilization found in this study (20%), and the positive likelihood ratio values calculated, subjects with three variables present at baseline increased their probability of non-success from 20 to 87%, while subjects with two variables only, increased their probability of non-success to 75% and subjects with one variable at baseline increased their probability of non-success to 43% (Table 25).

Table 25 Clinical Prediction Rule for Non-Response to Mobilization

# of Predictor Variables Present	***Sensitivity***	***Specificity***	***Positive LR***	***Probability of Non-Success (%)***
3	.23 (.07, .52)	**.99** (.91, 1)	**26.13** (1.43,478.71)	87
2+	.43 (.19, .7)	**.96** (.86, .99)	**11.79** (2.66, 52.24)	75
1+	.5 (.24, .76)	**.84** (.71, .92)	**3.06** (1.38, 6.76)	43
Cluster	1. Age > 35 years, 2. VAS-Best > 3, 3. Negative Prone Knee Bend Test			

9.0 DISCUSSION

The following discussion section is divided into chapters that will cover both aims of the study, reliability of the SIJ stiffness test and adverse events. A CPR was developed for both success and non-success from the mobilization intervention. By using these CPR's, a clinician is better able to determine a-priori if the patient will benefit or not from the mobilization intervention.

When we first started this project, obstetricians we contacted were not very enthusiastic about the intervention of choice for the study. They would not offer reasons for their lack of enthusiasm. We summarize one possible reason might be due to high serum relaxin levels and resultant joint laxity during pregnancy and shortly after delivery as a possible concern to a manual therapy thrust procedure. Clinicians who routinely use SIJ mobilization for postpartum pelvic girdle pain have anecdotally offered that they find remarkable improvements in their patients. However, these same clinicians admitted that they use thrust procedures without any rules for who will most likely benefit from the intervention, noting further that some patients do not respond to the intervention forcing them to use alternate treatments such as stabilization and strengthening.

The CPR developed in this study is a way to predict a-priori what reaction the patient will have to mobilization of the SIJ. This is beneficial to clinicians and physicians alike. It is known that no one specific SIJ test is reliable enough to predict when mobilization should be used for PGP (Freburger & Riddle, 1999; Potter et al., 1985); however, studies have shown that

combining some of the SIJ tests are beneficial in identifying dysfunction (Cibulka et al., 1999; Broadhurst & Bond, 1998; Kokmeyer, van der, Aufdemkampe, & Fickenscher, 2002). By combining historic and physical examination variables, we were able to develop a CPR that may be useful for clinicians in classifying patients who are likely to respond to mobilization.

The prevalence of positive response to mobilization of the SIJ in this study was 80% (55 out of 69). This prevalence rate was higher than we expected based on previous reports in the literature. Flynn et al. found a 45% prevalence rate in their prospective cohort study of patients with non-radicular low back pain who received the same intervention to the SIJ (Flynn et al., 2002). The discrepancy in positive response notes the unique patient population group in this study (i.e. postpartum women).

Spectrum bias could be another possible explanation for the high positive response rate. Spectrum bias is the systematic error in the estimate of a study parameter that results when the study population includes only selected subgroups of the clinically relevant population (Glossary of Medical Decision Making Terms, 2007). However, evaluation of subjects occurred after consent to participate was obtained. This made it impossible for the therapist to enroll participants whom she believed would positively respond to the intervention. Replicating this study in a different sample may give us a better idea if this prevalence rate is representative of this population group. Of course the ultimate verification of this CPR will be a validation study conducted in a similar manner as that of Childs and his colleagues (Childs et. al., 2004)

9.1 SPECIFIC AIM1: IDENTIFYING PREDICTORS OF POSITIVE RESPONSE AND NON-RESPONSE TO MOBILIZATION OF THE SIJ

9.1.1 Univariate Prediction of Positive Response to Mobilization

Determining variables with univariate prediction of positive response to the mobilization was a step performed to help aid in the creation of the CPR. Clinicians rarely use one testing procedure or variable from the history to determine the intervention suited for that patient. Therefore, any variables found in this study with univariate prediction of response to the mobilization should be used alone with caution. Cibulka et al. found that combining tests of the SIJ is useful in identifying SIJ dysfunction in patients with LBP (Cibulka et al., 1999).

Eleven historic and self report variables had acceptable diagnostic test properties (Table 6). Epidural used during delivery, symptom location in the lower L/S and/or SIJ areas only, and vaginal deliveries had acceptable levels of sensitivity. A negative response to these questions means that the woman is less likely to respond to the mobilization. Epidurals have been blamed by many women for causing their LBP. However, research published on this topic is contradictory (Howell et al., 2002; Macarthur, Lewis, Knox, & Crawford, 1990a). While the use of an epidural had acceptable sensitivity, the confidence interval around the sensitivity value was not sufficiently narrow to allow classification as definitively acceptable. Clinicians choosing the mobilization intervention based on this result alone should do so with caution. For a variable to be considered definitively acceptable, the lower bound of the 95% CI has to be at least 0.7 for sensitivity and specificity and 2.0 for the positive LR, and the upper bound of the 95% CI has to be less than 5.0 for the negative LR (Jaeschke et al., 1994). Symptom location was the only variable with a definitively acceptable level of sensitivity. Theoretically it makes sense that a

vaginal delivery may result in the misalignment of the pelvis during the birthing process. Garagiola et al. found that normal changes in the pelvis after uncomplicated vaginal delivery include widening of the symphysis and SIJ's (Garagiola, Tarver, Gibson, Rogers, & Wass, 1989). Vaginal deliveries had acceptable level of sensitivity, however the 95% CI around the sensitivity value was not sufficiently narrow to allow classification as definitively acceptable.

Best position, worst position, best time, prior history of back pain, traumatic onset of pain, pain episodes increasing and use of oral contraceptives all had acceptable levels of specificity. These questions are useful for ruling in a positive response to the mobilization. Therefore, a positive response to these questions means that the woman is likely to positively respond to the mobilization. Only symptom location, best position, worst position, best time and traumatic onset of pain had confidence intervals around sensitivity or specificity values sufficiently narrow to allow classification as definitively acceptable. Best and worst positions and best time of day with no or less pain for postpartum women have not been documented in the literature. While these variables did show high levels of specificity for standing as the best position, laying down as the worst position and midday as the best time of day with no or the least amount of pain, only a minimal number of subjects fell in these categories and all were in the success group. Sitting was ranked as the best position of choice for those in the success category (15 subjects in the success group, 27.3%) and walking was the worst position of choice in the success group (26 subjects in the success group, 47.3%). The best time of day selected by the majority of subjects in the success group was morning (28 subjects in the success group, 50.9%).

Prior history of back pain was common in women who have had previous pregnancies, which is supported by findings from a previous study (Ostgaard, 1991). Of those women with

previous back pain, the pain resolved naturally over time or by way of different treatments including chiropractic, physical therapy, medication, or massage therapy. Traumatic onset of pain in this study was reported by four subjects, all in the success group. All four subjects reported lifting car seats out of their vehicles as the cause of their pain. Flexion and rotation of the trunk while lifting are all risk factors for LBP, especially when repeated throughout the day (Hoogendoorn et al., 2000).

Wreje et al. concluded that an increased risk for LBP is associated with current or prior use of oral contraceptives (Wreje et al., 1997), while Vassey et al. found no association (Vessey et al., 1999). Findings from this study found a relationship between the use of oral contraceptives and mobilization outcome. However, the 95% CI around the sensitivity of this variable was too wide to be conclusive.

Symptom location had an acceptable negative likelihood ratio. The negative likelihood ratio represents the change in odds favoring the condition of interest when the diagnostic test result is negative. If a patient has a pre-test probability of positively responding to the mobilization of 80% (based on the prevalence rate of positive response to mobilization) and she reports having pain in areas other than her lower L/S and/or SIJ areas only (-LR = .29), the clinician can calculate her post-test probability of positive response as 54% based on the methodology described by Sackett et al. (Sackett et al., 2000). Calculating post-test probability may also be performed online using pre-test probability and likelihood ratios (Posttest Probability Calculator, 2007). The reduction found in the post-test probability may indicate to the clinician that this person would not be an appropriate candidate for mobilization.

Positive likelihood ratios represent the odds favoring the condition of interest when the diagnostic test is positive. A large positive likelihood ratio indicates a big shift in probability

towards a positive response to the mobilization. This can be calculated in the same way as described above. A patient reporting pain in the areas of the lower L/S and/or the SIJ areas only (+LR = 1.95) would have a post-test probability of positive response of 89%. This finding is supported by the fact that the mobilization technique is not specific to the SIJ only but impacts the lumbar spine as well. Flynn et al. also retained this variable in the CPR created for the general population with LBP (Flynn et al., 2002). The increase in probability of success from the mobilization from 80% to 89% using symptom location as a predictor indicates that the patient is likely to benefit from the mobilization intervention. Symptom location appears to be the only historic variable with univariate prediction of response to the mobilization. The majority of women in the success group reported pain in the lower L/S and SIJ areas only (83.64%).

Twelve of the 17 physical examination variables had acceptable diagnostic test properties (Table 7). Iliac crest symmetry, standing flexion test, Gillet test, seated flexion test, hip IR, ASLR, SIJ stiffness test, PPPP test, Patrick's test, and prone knee bend test all had acceptable levels of sensitivity which is useful for ruling out patients who will positively respond to the stabilization when the diagnostic test is negative. Seated flexion and prone knee bend had acceptable levels of negative LRs. If a patient has a pre-test probability of positively responding to the mobilization of 80% (based on the prevalence rate of positive response to mobilization) and the prone knee bend test was negative (-LR = .34), the clinician can calculate her post-test probability of positive response as 58%. The distraction test and a negative PSIS symmetry test both had acceptable levels of specificity. The negative PSIS test had a positive LR greater than one (+LR= 4.07; 95% CI .59, 28.15).

Only four physical examination variables had confidence intervals around their perspective sensitivity values sufficiently narrow to allow classification as definitively

acceptable; iliac crest symmetry, standing flexion, seated flexion, and prone knee bend, all of which are based on symmetry in the pelvis. The only physical examination variable that had definitively acceptable levels of sensitivity and – LR was the prone knee bend which also had a +LR that was statistically greater than 1.0. There is a pattern noted in these tests. The majority of SIJ tests are based on the theory behind SIJ motion. With this patient population group, SIJ joint motion may be a key factor. According to findings by Kristiansson et al., there is more joint motion in postpartum women due to serum relaxin levels during pregnancy (Kristiansson, Svardsudd, & von, 1996b). Shortly after delivery, serum relaxin levels return to their normal levels and theoretically, the joints of the pelvis should tighten. However, in some women, tightening occurs with the pelvis in a misaligned position, which was apparent with tests of symmetry performed in this study. Symmetry tests were only considered to be positive if apparent differences were found between right and left sides (at least 1").

9.1.2 Univariate Prediction of non-Response to Mobilization

Eight of the 15 historical/self report variables used for prediction of non-response had acceptable levels of test sensitivity (BMI ≥ 26, more than one child, VAS-present ≥ 5, VAS-worst ≥ 7, VAS-best > 3, FABQ-PA ≥ 16, worst time of day not night, and epidural used) (Table 8). If a patient does not have a BMI ≥ 26, did not have more than one child, does not have a VAS-present ≥ 5, does not have a VAS-worst ≥ 7, does not have a VAS-best > 3, does not have a FABQ-PA ≥ 16, worst time of day is night, and did not have an epidural, then she is less likely to be non-responsive to the mobilization. None of these variables had definitive levels of acceptability as defined by its 95% CI.

"Normal weight" individuals are considered to have BMI's between 18.5-24.9, according to the National Heart Lung and Blood Institute (NHLBI, 2007). In this study, a BMI greater than 26 was found to have an acceptable sensitivity for univariate prediction of non-response to the mobilization intervention. The mean BMI for subjects older than 35 years in this study was 31.03 (6.44). Mirtz et al. found a lack in the relationship between BMI and LBP (Mirtz & Greene, 1936).

Multiparous women are reported to have increased risk of back pain (Ostgaard, 1991). Results from this study indicate that the majority of non-responders indeed had two or more children. Multiparity may be the causative factor, as more deliveries correspond with more traumas to the pelvic structures. However, another explanation may be age rather than multiparity. Older women tend to have more children than younger women. Older women in this study responded less favorably to the mobilization intervention.

Visual Analogue Scales provide a descriptor of perceived pain intensity. In this study, VAS at present, worst and best all had acceptable sensitivity values. In this study, the younger women had slightly higher levels of pain at worst than the older group of women while pain at best was slightly lower in the younger group. Higher intensity of pain at the time of the intervention visit may have responded more favorably to the intervention than lower intensities of pain. Women with higher intensities of pain at best in this sample experienced less improvement than those with less intensities of pain at best.

The FABQ-PA quantifies a patient's fear of pain and subsequent avoidance of activity. Higher FABQ-PA scores were associated with non-response in this study. Previous research on the general population of LBP has found that patients with high levels of fear-avoidance beliefs about work activities are unlikely to respond to the mobilization intervention (Flynn et al., 2002).

Fear-avoidance beliefs about physical activity may be unique to this specific patient population group. The majority of subjects in the success group reported having the worst pain during the night time (41.8%). Therefore, this variable as a univariate predictor of non-response makes sense.

Epidural used was found to have acceptable sensitivity for both success and non-success to the mobilization intervention. However, in both cases the 95% CI was too wide to be conclusive and caution should be used when interpreting this result. Approximately the same percent of responders and non-responders had epidurals (76.36% and 71.43%). Some researchers have suggested an association between epidural use during labor and back pain while others have found no association (Macarthur, Lewis, Knox, & Crawford, 1990b; Macleod, Macintyre, McClure, & Whitfield, 1995; Howell et al., 2002).

Three variables had definitively acceptable specificity (age > 35 years, use of oral contraceptives, and multiple gestations). If a patient is over the age of 35, is on oral contraceptives, or had a multiple gestation, then she is less likely to respond to the mobilization intervention. The results from this study suggest that women who are older than 35 years are less likely to respond to the intervention. Previous research has shown that younger women had an increased risk of back pain during pregnancy and had higher intensity of pain during their first trimester than older women (Ostgaard, 1991). It may be that older women are more adapted to the stresses of pregnancy and delivery. Ostgaard et al. also found that previous back pain is a strong risk factor with respect to pain intensity. Older women in general, have had more babies than younger women and may have already experienced some back pain during their prior pregnancies and so may just well be more tolerant of the pain. There were no strong bivariate correlations found between age and pain intensity at best or between any other variable

remaining in the CPR's in this study. The lack of correlation could be due to the fact that pain intensity is not significant until age is accounted for. It may also be that older women are less likely to respond to the intervention regardless of their pain intensity. The small number of non-responders (n=14) may also weaken the correlation between age and pain intensity. A different sample may identify more non-responders which may allow an additional test to enter the logistic regression model increasing sensitivity and specificity by a few points. A previously damaged pelvis from earlier pregnancies may be more sensitive to the influence of hormones during pregnancy. This could be a reason why older women are less likely to respond to the mobilization intervention.

Wreje et al. concluded that an increased risk for LBP is associated with current or prior use of oral contraceptives (Wreje et al., 1997). Findings from this study found a relationship between the use of oral contraceptives and non-response to the mobilization. Twin pregnancies have been associated with postpartum pelvic pain (Mens et al., 1996). In this study, multiple gestations had a definitively acceptable specificity value.

The only variable with a definitively acceptable negative LR was VAS-best > 3. Age > 35 years and VAS-best > 3 both had acceptable positive LR's 3.06 and 2.62 respectively. If a patient's pre-test probability of non-response to the mobilization is 20% (based on prevalence rate of non-response to mobilization) and she reports that her VAS-best is greater than three, the clinician can calculate her post-test probability of non-response as 40% based on the methodology described earlier. If a patient indicates that she is older than 35 years of age, her post-test probability of non-success is only increased to 43%. The small increase in post-test probability for non-success with the univariate predictors is not surprising. Clinicians in general do not rely on one finding alone to determine the intervention of choice for PGP in this

population group. Rather, they use a multitude of findings from the history and physical examination to help guide them in the appropriate choice.

The women in the non-success group had ages that ranged between 26 and 40 years with the majority (21.4%) aged 40. Hicks et al. reported that individuals who are likely to benefit from a stabilization program rather than a mobilization program are individuals younger than 40 years of age (Hicks et al., 2005). It may be that the older subjects found in this study to be non-responders to the mobilization may benefit from a stabilization program instead. Shibata et al. found that degeneration of the SIJ was markedly more frequent in individuals aged 40 or more (Shibata et al., 2002). This degeneration may be a reason why the women in this study did not respond to the mobilization intervention.

Thirteen of the 17 physical examination variables had acceptable diagnostic test properties (Table 9). All but the distraction test had acceptable levels of specificity. Positive test results for these variables are useful for ruling in the possibility of a non-response to the intervention. The distraction test had an acceptable level of sensitivity and was also definitively acceptable in terms of the 95% CI. In other words, if the patient had a negative distraction test, she would less likely respond to the mobilization. The Posterior Superior Iliac Spine symmetry test, ASLR, SIJ stiffness test, Patrick's test, negative prone knee bend test, and the long dorsal SI ligament test all had acceptable +LRs. However, none were definitively acceptable.

The univariate association between asymmetric hip rotation and non-success with the mobilization found in this study is supported by findings of Cibulka et al. who found that subjects with evidence of SIJ dysfunction had unilateral hip rotation asymmetry (Cibulka et al., 1998). The Active Straight Leg Raise (ASLR) was found to be a suitable diagnostic instrument to discriminate between patients with PGP and healthy patients (Mens et al., 2001). A specificity

of 100% and specificity of 93% was found in the Mens et al. study. The 95% CI around the specificity found for the ASLR test in this study were too wide to be conclusive and clinicians using this test as a univariate predictor of non-response to the mobilization intervention should proceed with caution. Confidence intervals were not reported in the study by Mens et al. and therefore cannot be compared with the results of this study.

The SIJ stiffness test theoretically examines the ability of the SIJ to resist vertical and horizontal translation forces applied passively to the non-weight bearing joint. In this study, SIJ stiffness had acceptable specificity and +LR. Unfortunately, no studies are available that report SIJ stiffness as a predictor for mobilization outcome.

The Posterior Pelvic Pain Provocation test was previously found to have high sensitivity and specificity values (.9, and .98) for pregnancy related pelvic joint pain (Albert et al., 2000). However, confidence intervals were not reported. Acceptable specificity was found in this study for the PPPP, but the 95% CI were too wide to be considered definitively acceptable.

The Patrick/Faber tests were also found to have sensitivity and specificity values of .7 and .99 (Albert et al., 2000). In this study, only the Patrick test showed high levels of specificity. However, the 95% CI was too wide to be considered definitively acceptable. With tests of pain provocation, the goal is to provoke the SIJ and stress the structures, thus attempting to reproduce the patient's symptoms. SIJ pain provocation tests have been documented as being the only tests that yield the required objectivity and reproducibility (Laslett & Williams, 1994; Ostgaard, Zetherstrom, & Roos-Hansson, 1994). Previous studies on postpartum women with PGP reported that the ilium rotates slightly anteriorly causing increased tension in the long dorsal sacroiliac ligament thus causing tenderness to palpation (Mens, Vleeming, Snijders, Stam, & Ginai, 1999).

9.2 SPECIFIC AIM2: IDENTIFYING TEST CLUSTERS FOR PREDICTION OF RESPONSE AND NON-RESPONSE TO MOBILIZATION

9.2.1 CPR for Prediction of Positive Response to Mobilization

Two separate logistic regression models were built to identify the best cluster of historic and physical examination variables. One historic variable remained from the 11 that were entered (symptom location in the lower L/S and/or SIJ areas only) (Table 11). According to the Nagelkerke R-square statistic for this model, this variable explained 14% of the variability in patient response to the mobilization. It is a reasonable assumption that this variable would remain in the model because the intervention used in this study purportedly affects the SIJ as well as the lumbar spine (Delitto, Erhard, & Bowling, 1995b).

Three physical examination variables remained from the 12 that were entered into the model (negative PSIS symmetry test in the seated position, seated flexion test, and prone knee bend test) explaining 42% of the variability in response to the mobilization (Table 12). The theory behind asymmetry in the position of bony landmarks such as in the PSIS test is that it indicates an asymmetry in the position of the innominate bones, which is considered to be a sign of SIJ problems (Cibulka et al., 1988; Cibulka et al., 1998; DonTigny, 1985). Inter-tester reliability of the PSIS symmetry test was found to be poor (Potter, 1985; Riddle et al., 2002), which may be due to the differences between the bony landmarks being too small to detect visually. In this study the differences had to be apparent and obvious (at least 1") to be considered a positive test. Potter et al. studied the general low back population while this study looked at a unique population (i.e. postpartum women).

The seated flexion test supposedly indicates articular restriction when a positive test is found. This occurs when one PSIS moves more superiorly than the other. Potter and Rothstein also found poor inter-tester reliability with this test with only 50% agreement (Potter et al., 1985). The prone knee bend test is supposedly a SIJ test that compares apparent leg lengths with the patient in the prone position when both knees are flexed to 90° to fully extended. An observable difference between the flexed and extended position theoretically indicates a posteriorly rotated innominate (Cibulka et al., 1999). Cibulka and colleagues found that SIJ dysfunction can be identified reliably in patients with LBP if 3 out of 4 of the tests used in their study are positive using the same treatment procedure as was used in this study (Cibulka et al., 1988; Cibulka et al., 1988; Erhard et al., 1994). They found sensitivity, specificity and predictive values of at least 0.8, however, confidence intervals were not reported in that study. Tests used by Cibulka et al. were the standing flexion, sitting PSIS symmetry, supine long sit and prone knee bend. The CPR developed in this study retained two of the four tests used by Cibulka et al. In this study, when 3 of the 4 tests in the CPR are positive, post-test probability increased from 80 to 93% while one positive finding only increased post-test probability 84%.

When the one historic and three physical examination variables were placed into the same logistic regression equation, the final model for this study (seated flexion, prone knee bend, negative PSIS symmetry test, and symptom location in the lower L/S and SIJ areas only) explained 53% of the variability in the intervention outcome. This final model represents the most reasonable cluster for prediction of positive response to mobilization (Table 13).

After examining the diagnostic test properties of the cluster at different levels of positive findings, it was found that as the number of positive findings increased, the positive LR increased (Table 15). The presence of one or more positive findings in the CPR has a high level

of sensitivity with the 95% CI within the definitive range. If there are no positive findings in the CPR, it is less likely that the patient will respond to the mobilization. After looking at different combinations of pairs of tests from the CPR, a positive seated flexion test and pain in the areas of the lower L/S and/or SIJ areas only had high levels of specificity, and positive likelihood ratio (Table 16). However, the 95% CI for the specificity did not fall within the definitively acceptable range.

Two positive findings in the CPR seem to be the best cut-off point for ruling in a positive response to the mobilization. With a combination of an acceptable specificity and positive LR, a patient with two positive findings and a pre-test probability of 80%, the post-test probability of positive response to the mobilization increases to 92% (Table 17). However, the 95% CI for the specificity did not fall within the definitively acceptable range (SP= .79, 95% CI, .49, .94). This wide confidence interval could be due to the large number of responders in this study. In the study by Cibulka et al., 95% CI's were not reported and thus the specificity found in this study cannot be compared with the specificity found by Cibulka et al.

The positive LR indicates the increase in the probability of success given a positive test result. The positive LR is the primary statistic of interest in this study which expresses the change in odds favoring the outcome when the patient meets the prediction rule criteria (Sackett & Sackett, 1992). In this study, 80% of the subjects were successful without an attempt at prediction. Using a criteria of 4/4 variables present at baseline (+LR=3.48), the probability of success is raised to 93%; thus these individuals should be mobilized. Even when two or three out of four variables are present in the CPR with positive LR's of 3.05 and 3.48, post-test probability of success is raised from 80% to 92 and 93% respectively. The aim of the CPR is to increase post-test probability of success and this is found with the +LR. Steurer et al. found that

presenting test accuracy as the positive LR seemed to be more effective in eliciting correct estimates of disease than presenting it in sensitivity and specificity when presented to general practitioners (Steurer 2002). This is an important goal for this study, to give the practitioner, especially the obstetrician an understanding of the use of this intervention for postpartum women. For clinicians, not only does the CPR provide an estimate of post-test probability of success, but also improves the decision making process with this unique patient population group (i.e. postpartum women). However, these predictors do not hold up after the second intervention procedure.

9.2.2 CPR for Prediction of Non-Response to Mobilization

Two separate logistic regression models were built to identify the best cluster of historic and physical examination variables such as was done in the positive response CPR. Two historic variables remained (age > 35 years, and VAS-best > 3). According to the Nagelkerke R-square statistic for this model, these variables explained 39% of the variability in patient non-response to the mobilization (Table 19). The mean age of individuals in the success group was 30.27 ± 5.65 while the mean age of the subjects in the non-success group was 34.36 ± 5.24. Our results suggest that women who are older than 35 years are less likely to respond to the intervention. Fifty percent of the non-responders in this study were over the age of 35. Previous research has shown that younger women had an increased risk of back pain during pregnancy and had higher intensity of pain during their first trimester than older women (Ostgaard, 1991). This may be due to the fact that older women may have already had children and are aware of the pain associated with pregnancy. It is common for women to think that these aches and pains are “normal” and will go away eventually. Older women who have already had children may have experienced

pain in their previous pregnancies and remember that at some point the pain disappeared which may cause them to be more tolerant of the pain. Previous research has also shown that younger women had an increased risk of back pain during pregnancy and had higher intensity of pain during their first trimester than older women (Ostgaard, 1991). In this study, the younger women had slightly higher levels of pain at worst than the older group of women while pain at best was slightly lower in the younger group. Higher intensity of pain may respond more favorably to the intervention than lower intensity of pain. Women with higher intensities of pain at best in this population experienced less improvements than those with less intensities of pain at best. Therefore, the two variables (age > 35, and VAS-best > 3) that remained in the CPR for non-response to the intervention are reasonable.

One physical examination variable remained (negative prone knee bend test). According to the Nagelkerke R-square statistic for this model, this variable explained 12% of the variability in patient non-response to the mobilization (Table 20). As mentioned earlier in the positive response section of the discussion, a positive prone knee bend test supposedly indicates a posteriorly rotated innominate (Cibulka et al., 1999). According to the CPR for non-response to the mobilization, a negative prone knee bend test is a predictor of non-response to the mobilization. This is reasonable to assume based on the theory behind this test.

When the two historic and one physical examination variables were placed into the same logistic regression equation, the final model (Age > 35 years, VAS-Best > 3, and Negative prone knee bend test) explained 51% of the variability in the intervention outcome. This model represents the most reasonable cluster for prediction of non-response to mobilization (Table 21).

After examining the diagnostic test properties of the CPR at different the levels, it was found that as the number of positive findings increased, specificity and positive LR's increased.

All three levels of the CPR had definitively acceptable levels of specificity and positive LR's. If there is one positive variable in the CPR, it is less likely that the patient will respond to the mobilization. The presence of two or more variables in the CPR appeared to be the best cut-point for prediction of non-response to the mobilization (+LR= 11.79, 95% CI, 2.66, 52.24). Therefore, in a patient with two positive variables and a pre-test probability of non-success of 20%, the post-test probability of non-success to the mobilization increases to 75%, indicating that these patients may benefit from an alternate intervention (Table 25). A patient with all three variables present in the CPR (+LR = 26.13) increases her post-test probability of non-success from 20% to 87% (Table 22). It is apparent from the findings of this study that there is a link between age and pain intensity as was found in previous research (Ostgaard, 1991). Older women tend to respond less favorably than younger women and women with higher intensities of pain at best tend to respond less favorably than women with lower intensities at best. As noted in the section on adverse events, age and pain intensity may indicate a risk to performing the mobilization intervention. While only two subjects reported a slight increase in ODQ scores after their second intervention visit, a larger sample may have found more non-responders and subsequently more increases in disability scores.

After analyzing the different combinations of pairs of tests from the CPR, it was found that the combination of age with VAS, and VAS with prone knee bend test both had definitively acceptable levels of specificity and positive LR's (Table 23). The presence of these findings results in a post-test probability of non-success of 75% and 77% respectively, indicating that these patients should not be mobilized and alternate treatment should be considered. Previous research has demonstrated the value of classification by demonstrating improvements in both pain and function in a group that was classified as positive on the CPR that received mobilization

compared to a group that was classified as negative on the CPR that received mobilization. (Childs, 2003). Therefore, when found to be positive with regards to the CPR, mobilization is the intervention of choice. This supports the importance of classifying patients a priori in order to identify patients who may or may not benefit from the mobilization procedure.

Two of the 14 non-responders (Subject-A, and Subject-B) experienced a slight increase in disability scores after the second mobilization visit with a mean percent increase in ODQ score of -10.63 (6.19). Subject-A was 40 years old, she had two children and was experiencing pain in her upper and lower L/S. She reported a pain intensity of 0/10 on the VAS-Best and was positive on the prone knee bend test for both examination sessions. Subject-B was 26 years old, she had one child and was experiencing pain in both her upper and lower L/S and SIJ areas. She reported a pain intensity of 8/10 on the VAS-Best and was positive on the prone knee bend test for both examination sessions. Both subjects were positive for only one variable related to the CPR for non-success with the mobilization. Subject-A was over 35 years and Subject-B had a VAS-Best > 3. Each variable alone in the CPR does not increase post-test probability of non-success to over 43%. However, it is possible that these two variables may suggest a relative contraindication to the mobilization. When both variables are present in the CPR, post-test probability of non-success increases from 20% to 75%. It may take 1-2 sessions to return the patient to the level they were before the mobilization which increased their disability scores and an alternate approach would be initiated. Time is of the essence with this specific population group. Postpartum women would rather care for their families than to take the extra time for themselves. If a clinician is able to predict a-priori that their patient may not benefit from this intervention, an alternate approach may be initiated with out wasting the time on the mobilization. None of the variables from the CPR for non-response to the mobilization remained

after the second intervention visit. This may be the result of the small number of non-responders in the study.

For the benefit of the clinician, the following table provides a summary of variables of interest to determine if the patient is appropriate for the mobilization intervention (Table 26). Due to the high mobilization success rate, the clinician can choose to mobilize immediately unless at least two of the three criteria in the following CPR are met. Criteria from the CPR for success are not presented due to the high success rate before an attempt at prediction.

Table 26 Criteria for Determining Appropriateness of the use of SIJ Mobilization

Predictor Variable	Probability of Non-Response
1+ Age > 35 years	43%
2+ VAS-Best > 3	75%
3+ Negative Prone Knee Bend Test	87%

- Based on a pre-test probability of non-success with mobilization of 20%.

10.0 LIMITATIONS AND BIASES

The high prevalence rate of success (80%) in this study was not expected. This could be coincidental to this specific sample. However, the patients participating in this study should represent those postpartum women seeking physical therapy in a large metropolitan area due to the recruitment procedures and availability of intervention to a wide range of women. The methods of recruitment were such that subjects were recruited from high to low socioeconomic statuses.

The small sample size of this study may have been a study limitation. The larger the sample, the more sure one can be that the answers truly reflect the population. For a given confidence interval, the larger the sample size, the smaller the confidence interval (Davies, 2001). Some individual tests in this study had acceptable diagnostic properties; however, they also had wide confidence intervals suggesting a vagueness of the diagnostic value. A larger sample size may have provided more accurate sensitivity, specificity and likelihood values. Only 14 non-responders were identified in this study. A small number of non-responders may have weakened the correlation between variables because any one test is not specific. A larger sample size may have found more non-responders and correlations may have been found between variables including age and pain intensity. However, an a-priori sample size calculation was performed. Using techniques described by Simel et al., a sample size of 68 was chosen based on

calculations from sensitivity and specificity values of 0.8 and a positive likelihood ratio of 2.0 (Simel et al., 1991). However, we did underestimate the success rate.

Generalizability and bias is another question in this study that may be affected by both assessment and intervention. Only one therapist performed all the testing procedures on all the study subjects. Some SIJ tests require the ability of the therapist to see and feel a change in symmetry. This ability may vary from therapist to therapist. However, the testing procedures used in this study have been described in detail as to how to determine a positive test result. For example, with the PSIS symmetry test, a difference in the relative relationship of the PSIS in the seated position (1" at least) indicates a positive test. This large difference in position of the PSIS is obvious enough to be seen by any trained therapist using this test routinely in the clinic. If a therapist has any doubt as to whether he/she noticed a change, then the test is considered negative. In addition to this, with this specific sample, the difference seen in symmetry was dramatically obvious, making it easy for the therapist to determine if the test was positive or not. The testing therapist also was blinded to the self-report variables at the time of testing. Three therapists performed the intervention in this study. However, the mobilization technique used in this study is a standard technique taught in physical therapy education programs. Therefore, the results should be generalizable.

The study design was also a limitation. A Randomized Controlled Trial (RCT) would have limited bias by randomly assigning patients, thus minimizing the chance that the incidence of confounding variables will differ between the groups. The lack of a control group was also a limitation. A control group allows for the discrimination of patient outcome caused by the intervention from outcomes caused by other factors such as the natural history of back pain. However, the main goal of this study was to develop the CPR. The next step would be to validate

the CPR by means of a confirmatory RCT that would randomize subjects to a treatment group and a control group. It is also possible that recovery for a small percentage (25-30%) of subjects may have been due to the placebo effect because this effect is part of the hands on approach and the expectation of the subject (Childs et al., 2003; Licciardone et al., 2005). However, the clinical effect (50%) does exceed the placebo effect and some subjects in this study were skeptical of the effectiveness of the treatment.

11.0 FUTURE RESEARCH

Replication of this study on a different sample can confirm the results found in this study. A larger sample size may also be merited. This study is the first step in the development and testing of a CPR for identifying postpartum women who benefit from a mobilization of the SIJ. The next step will be to validate the rule by means of a randomized clinical trial. The findings from this study indicate a CPR can identify a-priori the individuals that may benefit from mobilization of the SIJ and the individuals who most likely do not benefit from this intervention. To determine if this CPR does indeed help in classifying these patients, a validation study is warranted. A validation study would help to incorporate the rule into the clinics. A validation study where the control group will receive a competing intervention protocol such as a pelvic girdle stabilization program (Stuge et al., 2004a) can determine if the subjects who met the criteria of the CPR may have benefited from a variety of other interventions or simply from the natural history of back and pelvic pain. The design of the follow up validation study would be similar to the study conducted by Childs and colleagues (Childs et al., 2003). However, a sham mobilization group will be included to determine the placebo effect. The sham mobilization group will be followed up with a real mobilization at the one week follow up period. To avoid an age imbalance in the study groups without sacrificing the advantages of randomization, stratification can ensure that the numbers of participants receiving each intervention are closely balanced within each stratum.

Future clinical trials can be developed later to test the implementation of the CPR in clinical practice on patterns of practice, outcome of care, and cost of care.

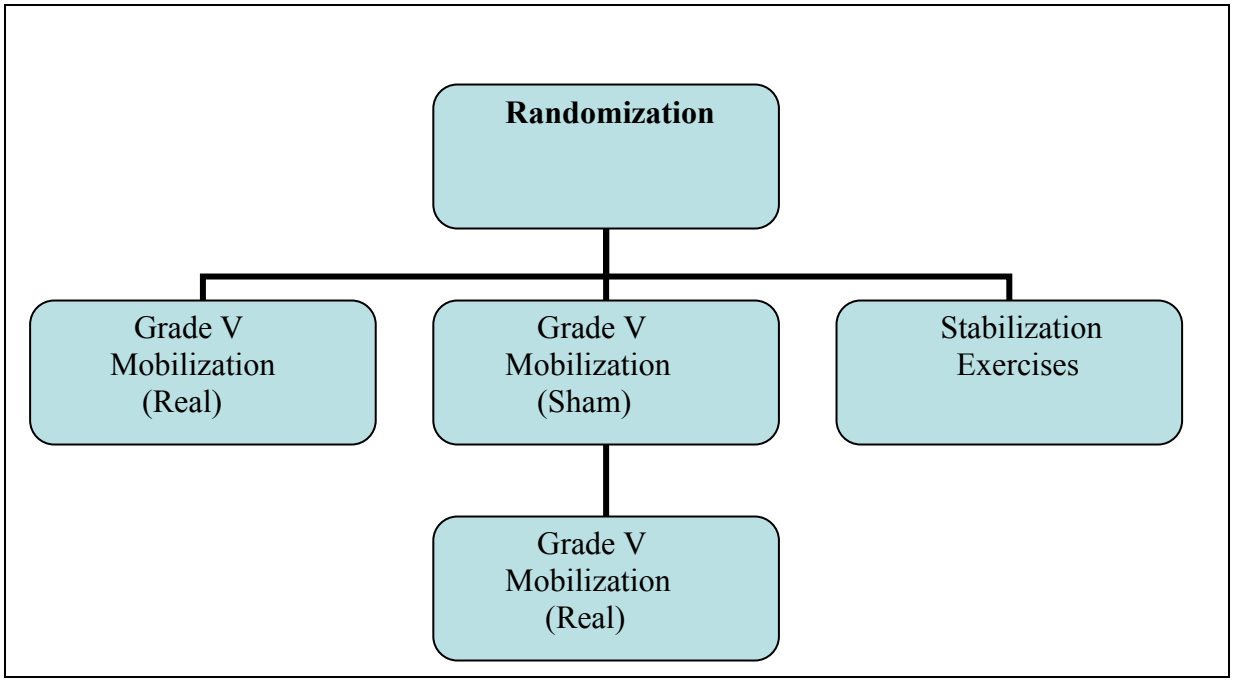

Figure 6 Randomization Diagram

12.0 CONCLUSION

Based on the probability of chance alone, postpartum women with LBP or PGP would likely benefit from the mobilization regardless of the CPR for success. In our sample, 80% of subjects were successful after one mobilization without an attempt at prediction. This success rate was higher than the success rate of the general LBP population that Flynn and his colleagues found. There is a low risk accompanying this intervention choice, benefits would be experienced after one intervention session and the mobilization itself does not take long. The broad inclusion criteria of women with LBP or PGP allows clinicians to include women without a traditional diagnosis. Some clinicians may opt to try the mobilization, and if it fails, an alternate approach can be used.

The results of prediction of non-response in this study are also a beneficial tool for clinicians. The pre-test probability of success (80%) in this patient population group is great enough to put the clinicians mind at ease with the immediate decision of mobilizing the patient unless 2/3 criteria are met in the CPR for non-response. The mobilization technique still may be a choice for clinicians, however, a description to the patient about the likelihood of improvement with the mobilization when 2/3 criteria are met in the CPR for non-success should be addressed. Further research is needed to address an alternative intervention for patients who are less likely to improve with the mobilization technique.

The initial recruitment procedure of this study was to rely on physicians to refer patients with postpartum PGP. Unfortunately, there was a low referral rate and alternate methods of recruitment were imposed. The low referral rate from physician offices indicates that these women are being missed. It is not known whether the women in this study would have recovered without the study intervention. It is known however that there is an effective intervention for this type of pain for this population and there is no reason for new mothers to have to deal with unnecessary pain.

This prospective cohort study was the first step in the development and testing of a CPR to identify postpartum women with pelvic girdle pain who would likely benefit from a mobilization to the SIJ. An important part of physical therapy is the adequate way of gathering historical and examination findings, organizing these findings and determining an effective intervention strategy. Using treatment outcome as the reference-standard helps the clinician reach such a goal.

Four historic variables (best position, worst position, best time, and traumatic onset of pain) had definitively acceptable levels of specificity for prediction of positive response to mobilization of the SIJ. One historic variable (symptom location in the lower L/S &/or SIJ area only) and four physical examination variables (seated flexion, iliac crest symmetry, standing flexion, and prone knee bend) had definitively acceptable levels of sensitivity. Symptom location had definitively acceptable levels of –LR. A CPR (symptom location in the lower L/S and/or SIJ area only, positive PSIS symmetry test, positive seated flexion test, and positive prone knee bend test) to identify positive response to mobilization of the SIJ was established with acceptable positive LR when three or more positive findings are present. Using a criteria of at least 3 of 4 variables present at baseline (+LR = 2.55), the probability of success is raised to 91% indicating

that these women should be mobilized. This level of certainty seems to be adequate to influence decision-making, and even if there is a decrease in posttest probability in a validation study, we do not believe the decrease will be too great that the accuracy will not matter. A decrease in posttest probability in a validation study will most likely be due to the increased generalizability as was seen with Childs et al. (91.2% post-test probability) in the validation of Flynns' et al. (95% post-test probability) CPR as 13 examiners were used in the validation study (Flynn et al., 2002; Childs, 2003). Results from other studies advocating Grade V mobilization and results from this study do not indicate that this is the only intervention suitable for this patient group. Patients will likely need other interventions that accompany mobilization to improve the effects of the mobilization if this was the intervention of choice. The CPR is developed to identify patients who may or may not improve in the short term but does not identify patients who will improve in the long term. This is being addressed by an ongoing gathering of ODQ scores by phone at a six month follow up period.

For non-response to intervention a CPR (age > 35 years, VAS-Best > 3, and negative prone knee bend test) had definitively acceptable +LR's and specificities. According to the findings of this study, the majority (80%) of postpartum women with PGP will benefit from mobilization of the SIJ. However, a CPR consisting of three questions can determine if the patient will be a non-responder to the intervention. These three questions can be of tremendous help to the practitioner when determining the appropriate intervention for this patient population. If the patient is positive for two variables (+LR = 11.79), her post-test probability of non-success increases to 75%, indicating that these patients may benefit from an alternate intervention program.

APPENDICES

APPENDIX A

STUDY FLOW DIAGRAM

APPENDIX B

PAIN DIAGRAM AND VISUAL ANALOGUE SCALE

APPENDIX C

OSWESTRY DISABILITY QUESTIONNAIRE

APPENDIX D

FEAR AVOIDANCE BELIEFS QUESTIONNAIRE

APPENDIX E

BASELINE DEMOGRAPHIC FORM (TO PATIENT)

APPENDIX F

BASELINE EXAMINATION FORM (TO THERAPIST)

APPENDIX G

SCREENING FORM

APPENDIX H

EXAGGERATED WADDELL SIGNS FOR NON-ORGANIC PAIN BEHAVIOUR

APPENDIX I

TREATMENT FORM

APPENDIX J

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RECRUITMENT SCRIPT

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PATIENT BROCHURE

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APPENDIX N

EDINBURGH POSTPARTUM DEPRESSION SCALE

APPENDIX O

SACROILIAC JOINT STIFFNESS FORM

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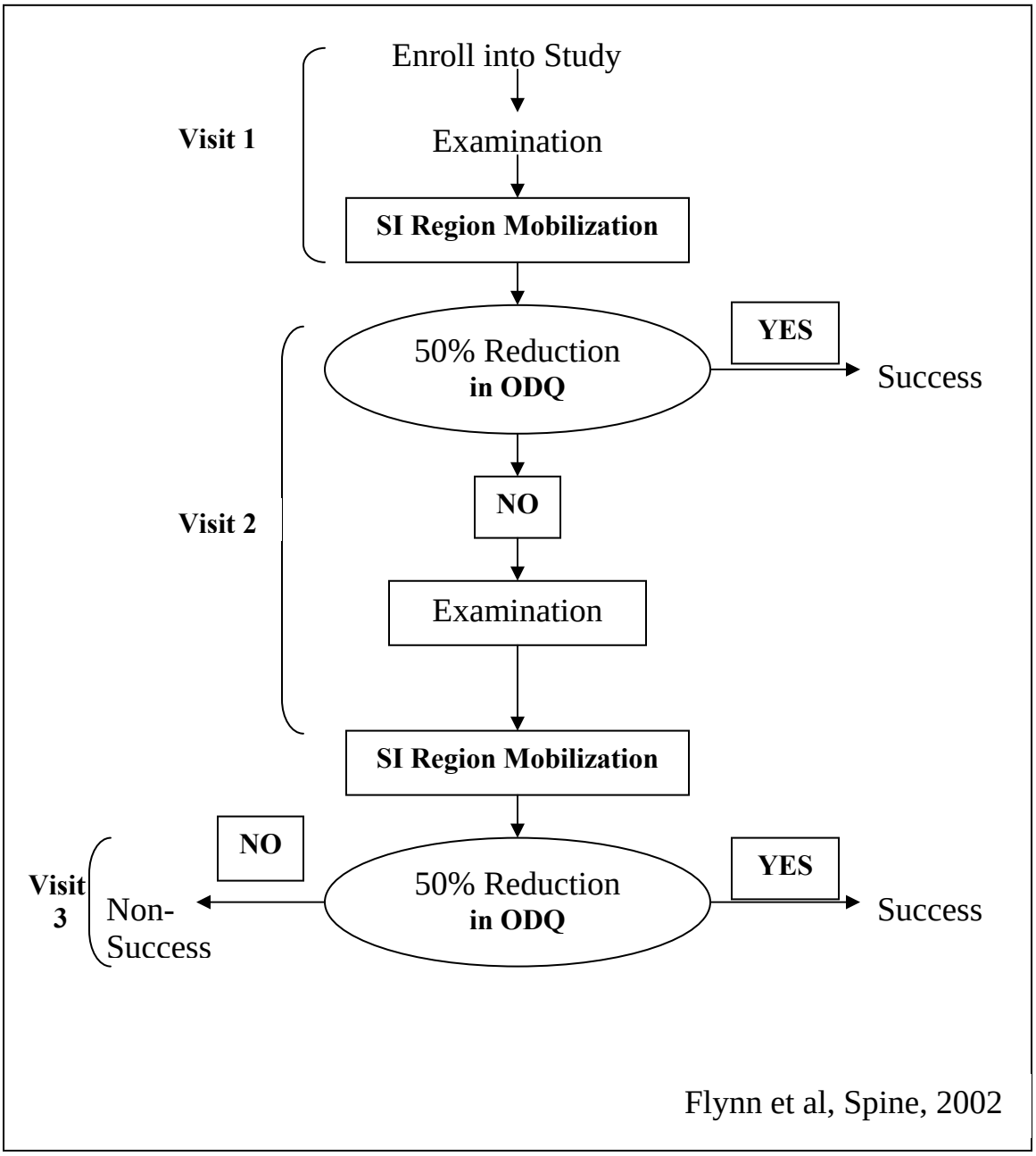
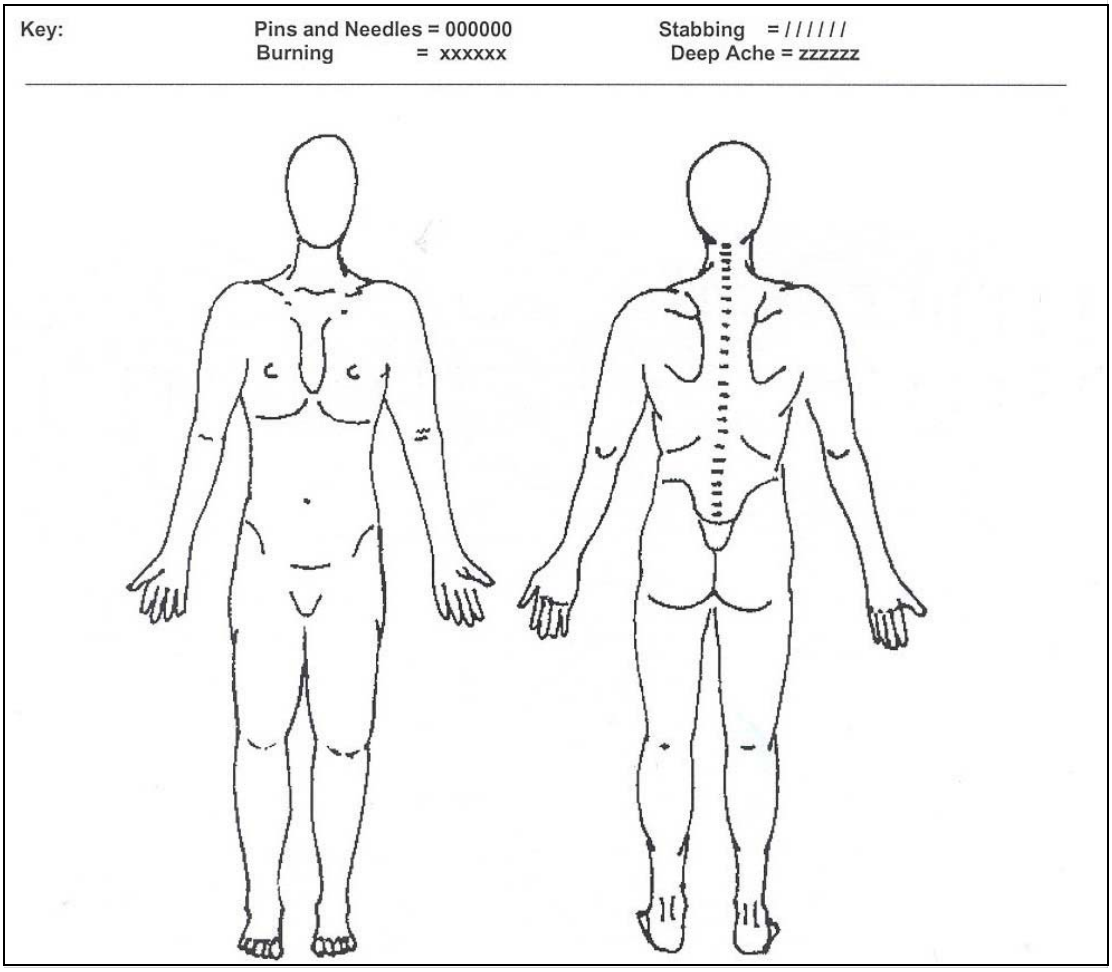


Flynn et al, Spine, 2002

Pain Diagram and Rating

Name: _____ **Date:** ____/____/____
mm dd yy

Please use the following diagram to indicate the symptoms you have experienced over the past 24 hours. Use the key to indicate the type of symptoms.



Please use the three scales below to rate your pain over the past 24 hours.
Rate your pain **0 = no pain** **10 = Extremely intense pain**

Rate your current level of pain (please check one):

○0 ○1 ○2 ○3 ○4 ○5 ○6 ○7 ○8 ○9 ○10

Rate your worst level of pain in the past 24 hours (please check one):

○0 ○1 ○2 ○3 ○4 ○5 ○6 ○7 ○8 ○9 ○10

Rate your best level of pain in the past 24 hours (please check one):

○0 ○1 ○2 ○3 ○4 ○5 ○6 ○7 ○8 ○9 ○10

Name:_____ Date: ___/___/___
mm dd yy

This questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to manage in every day life. Please answer every question by placing a mark in the one box that best describes your condition today. We realize you may feel that two of the statements may describe your condition, but please mark only the box which most closely describes your current condition.

Pain Intensity

I can tolerate the pain I have without having to use pain medication.
The pain is bad but I can manage without having to take pain medication.
Pain medication provides me complete relief from pain.
Pain medication provides me with moderate relief from pain.
Pain medication provides me with little relief from pain.
Pain medication has no affect on my pain.

Personal Care (Washing, Dressing etc.)

I can take care of myself normally without causing increased pain.
I can take care of myself normally but it increases my pain.
It is painful to take care of myself and I am slow and careful.
I need help but I am able to manage most of my personal care
I need help every day in most aspects of my care.
I do not get dressed, wash with difficulty and stay in bed.

Lifting

I can lift heavy weights without increased pain.
I can lift heavy weights but it causes increased pain.
Pain prevents me from lifting heavy weights off the floor, but I can manage if the weights are conveniently positioned (ex. on a table).
Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
I can lift only very light weights.
I can not lift or carry anything at all.

Walking

Pain does not prevent me from walking any distance.
Pain prevents me from walking more than 1 mile.
Pain prevents me from walking more than ½ mile
Pain prevents me from walking more than ¼ mile.
I can only walk with crutches or a cane.
I am in bed most of the time and have to crawl to the toilet.

Sitting

I can sit in any chair as long as I like.
I can only sit in my favorite chair as long as I like.
Pain prevents me from sitting for more than 1 hour.
Pain prevents me from sitting for more than ½ hour.
Pain prevents me from sitting for more than 10 minutes.
Pain prevents me from sitting at all.

Standing

I can stand as long as I want without increased pain.
I can stand as long as I want but increases my pain.
Pain prevents me from standing more than 1 hour.
Pain prevents me from standing more than ½ hour.
Pain prevents me from standing more than 10 minutes.
Pain prevents me from standing at all.

Sleeping

Pain does not prevent me from sleeping well.
I can sleep well only by using pain medication.
Even when I take pain medication, I sleep less than 6 hours.
Even when I take pain medication, I sleep less than 4 hours.
Evens when I take pain medication, I sleep less than 2 hours.
Pain prevents me from sleeping at all.

Social Life

My social life is normal and does not increase my pain.
My social life is normal, but it increases my level of pain.
Pain prevents me from participating in more energetic activities (ex. sports, dancing etc.)
Pain prevents me from going out very often.
Pain has restricted my social life to my home.
I have hardly any social life because of my pain.

Traveling

I can travel anywhere without increased pain.
I can travel anywhere but it increases my pain.
My pain restricts travel over 2 hours.
My pain restricts my travel over 1 hour.
My pain restricts my travel to short necessary journeys under ½ hour.
My pain prevents all travel except for visits to the doctor/therapist or hospital.

Employment/Homemaking

My normal homemaking/job activities do not cause pain.
My normal homemaking/job activities increase my pain, but I can still perform all that is required of me.
I can perform most of my homemaking/job duties, but pain prevents me from performing more physically stressful activities (ex. lifting, vacuuming)
Pain prevents me from doing anything but light duties.
Pan prevents me from doing even light duties.
Pain prevents me from performing any job or homemaking chores.

Fear-Avoidance Beliefs Questionnaire (FABQ)

Here are some of the things which other patients told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain.

	Completely Disagree			Unsure			Completely agree
1. My pain was caused by physical activity……..	0	1	2	3	4	5	6
2. Physical activity makes my pain worse……	0	1	2	3	4	5	6
3. Physical activity might harm my back……..	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse……	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse……	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your back pain.

	Completely Disagree			Unsure			Completely agree
6. My pain was caused by my work or by an accident at work……	0	1	2	3	4	5	6
7. My work aggravates my pain…….	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain…….	0	1	2	3	4	5	6
9. My work is too heavy for me…….	0	1	2	3	4	5	6
10.My work makes or would make my pain worse……	0	1	2	3	4	5	6
11.My work might harm my back……..	0	1	2	3	4	5	6
12.I should not do my normal work with my present pain	0	1	2	3	4	5	6
13.I cannot do my normal work with my present pain…	0	1	2	3	4	5	6
14.I cannot do my normal work till my pain is treated…	0	1	2	3	4	5	6
15.I do not think that I will be back to my normal work within 3 months…….	0	1	2	3	4	5	6
16.I do not think that I will be able to go back to that work	0	1	2	3	4	5	6

Scoring

Scale 1: fear-avoidance beliefs about work – items 6, 7, 9, 10, 11, 12, 15.

Scale 2: fear-avoidance beliefs about physical activity – items 2, 3, 4, 5.

Baseline Examination (To subject)
Thank you for participating in this study. This questionnaire will help us better understand your general health and any problems related to bone and muscle conditions. All the answers you provide will be held in strict confidentiality. Please answer all of the question. There is no right or wrong answer. Just give the best answer you can to any questions you are not sure of. Thank you again for participating.

Demographic Information:

Name: _____ **Date: _____/_____/_____**
mm dd yy

Age: ____ **Height: _____** **Weight (now): _____** **Occupation: _____**

Weight (before pregnancy): _____

Race:

American Indian
Asian
Black or African American
Hispanic
Pacific Islander
White or Caucasian
Other _____

Number of Children: _____ **Type of Delivery:** □ Vaginal □ Cesarean Section

Did you have an epidural? □ Yes □ No

Are you currently pregnant? □ Yes □ No □ I am not sure

Are you currently breast-feeding? □ Yes □ No

Are you currently taking oral contraceptives (birth control pills)? □ Yes □ No

1. □ Prior history of pelvic pain □ No prior history of pelvic pain
2. Approximate date of first episode if there was a prior history: _____
3. When did your pain first start? □ During Pregnancy □ After Delivery
4. Number of prior episodes: □ Less than 3 □ 3-5 □ 6-10 □ More than 10
5. Events causing prior episodes: □ Heavy lifting □ Moderate/light lifting
   □ Twisting □ Bending to the floor
   □ Other _____
   □ No precipitating event
6. Treatment for prior episodes: Response to Treatments

Medication	□ Not attempted	□ Improved	□ Worsened	□ No effect

Reduced work/activity	□ Not attempted	□ Improved	□ Worsened	□ No effect
Traction	□ Not attempted	□ Improved	□ Worsened	□ No effect
Manipulation/Mobilization	□ Not attempted	□ Improved	□ Worsened	□ No effect
Self-manipulation	□ Not attempted	□ Improved	□ Worsened	□ No effect
Brace/Pelvic belt	□ Not attempted	□ Improved	□ Worsened	□ No effect

7. Mode of onset of current episode Comments

- □ Gradual _____
- □ Sudden (minimal/no perturbation)_____
  Traumatic
  - □ Lifting _____
  - □ Twisting _____
  - □ Direct Blow _____
  - □ Pulling/Pushing _____
  - □ Fall _____
  - □ Other _____

8. Ordering of symptoms

Worst:	Best:
□ Sitting	□ Sitting
□ Standing	□ Standing
□ Walking	□ Walking
□ Uncertain	□ Uncertain

9. Please indicate whether you suffer from or experienced any of the following:

- □ Osteoporosis
- □ Spinal fracture
- □ Spinal surgery (indicate type) _____
- □ Cancer (indicate type) _____

Baseline Examination (Therapist)

Physical Examination:

Name: _____ **Date:** ____/____/____
mm dd yy

Date of onset of current symptoms: ___/___/___ **Date of delivery:** ___/___/___
mm dd yy

mm dd yy

History:

Mode of onset		Comments
Gradual	○Yes ○No	
Sudden	○Yes ○No	
Missed step	○Yes ○No	
Traumatic:		
Lifting	○Yes ○No	
Twisting	○Yes ○No	
Direct blow	○Yes ○No	
Pulling	○Yes ○No	
Fall	○Yes ○No	
Other	○Yes ○No	

Distribution of Symptoms:

	Symptoms	Location		Nature
Lumbar Spine	○Pain ○Stiffness ○Pain and Stiffness	○Central ○Bilateral ○Right ○Left		○Constant ○Intermittent ○Variable
Buttock/SIJ region	○Pain ○Paresthesia ○Pain and Paresthesia	○Central ○Bilateral ○Right ○Left		○Constant ○Intermittent ○Variable
Groin	○Pain ○Paresthesia ○Pain and Paresthesia	○Bilateral ○Right ○Left		○Constant ○Intermittent ○Variable
Thigh	○Pain ○Paresthesia ○Pain and Paresthesia	○Bilateral ○Right ○Left	○Anterior ○Posterior ○Both A/P	○Constant ○Intermittent ○Variable
Lower leg/foot	○Pain ○Paresthesia ○Pain and Paresthesia	○Bilateral ○Right ○Left	○Anterior ○Posterior ○Both A/P	○Constant ○Intermittent ○Variable

Temporal Ordering of Symptoms:

Worst	Best
○ Morning	○ Morning
○ Midday	○ Midday
○ Evening	○ Evening
○Night	○Night
○ Uncertain	○ Uncertain

Neurological Screening:

Sensory Examination (Pin Prick)

	Right			Left		
Level	Normal	Dimin.	Absent	Normal	Dimin.	Absent
L1 (Inguinal)						
L2 (Ant. Mid. Thigh)						
L3 (Distal ant. Thigh)						
L4 (Med. Lower leg/foot)						
L5 (Lat. Leg/foot)						
S1 (Lat. Side Foot)						

Motor Examination

	Right			Left		
Muscle Test	Normal	Dimin.	Pain	Normal	Dimin.	Pain
Hip Flex (L2-3)						
Knee Ext. (L3-4)						
Dorsiflexion (L4)						
Hallux Ext. (L5)						
Ankle Eversion (S1-2)						

Deep Tendon Reflexes

	Normal	Dimin.	Absent
Right-Quad			
Left-Quad			
Right-Ankle			
Left-Ankle			

Tension Signs

	Neg.	Pos.
Right SLR <45°		
Left SLR <45°		
Right FNS		
Left FNS		

Standing Examination:

Test	Positive	Negative
ASIS symmetry		
Iliac crest symmetry		
Standing flexion	○Right ○Left	
Gillet test	○Right ○Left	

Seated Examination:

Test	Positive	Negative
Palpation of PSIS		
Seated flexion test	○Right ○Left	
Hip IR ROM symmetry	○↓Right ○↓Left	○Symmetrical

Supine Examination:

1. Straight Leg Raise(estimate): Right: _____° Left: _____°

Test	Position	Right	Left	
Supine log sitting test	Supine	○Short right	○Short left	○Symm.
	Sitting	○Longer right ○Equally short right ○Shorter right	○Longer left ○Equally short left ○Shorter left	○Symm.

Test	Right	Left
ASLR	○Difficulty	○Difficulty

Test	Symmetrical	Asymmetrical
SIJ Stiffness (see other form)		

Test	Right	Left
PPPP test (thigh thrust)	○Pain	○Pain
Compression	○Pain	○Pain
Distraction	○Pain	○Pain
Patricks test (ROM)	○ Symmetrical ○ Asymmetrical	
Fabere test (Pain)	○Pain	○Pain

Prone Examination:

Test	Position	Right	Left	
Prone knee flexion (shoes on)	Knees extended	○Short right	○Short left	○Symm.
	Knees flexed 90°	○Longer right ○Equally short right ○Shorter right	○Longer left ○Equally short left ○Shorter left	○Symm.

Test	Positive	Negative
Hip IR ROM symmetry	○↓Right ○↓Left	○Symmetrical
Long dorsal SI ligament (or side lying)		

Screening Examination Form
Name: _____ Age: _____

Date: ____/____/____
mm dd yy

Fill out before asking subject to complete baseline questionnaires. This will ensure the subject is eligible for the study before she is asked to fill out all the questionnaires.

Inclusion Criteria (All answers should be marked "YES"):

1. Does the subject have a chief complaint of pain in the posterior pelvic region, buttock, and/or lower extremity? ○Yes ○No
2. Did the pain start during pregnancy or postpartum? ○Yes ○No
3 Does the subject have a baseline OSW of at least 30%? ○Yes ○No
4 Is the subject between 18 and 45 years old? ○Yes ○No
5 Is the subject between 6 weeks to one year postpartum? ○Yes ○No

Exclusion Criteria: (All should be marked "NO"):

1. Red flags:
   a. Tumor (self report): ○Yes ○No
   b. Osteoporosis (self report): ○Yes ○No
   c. Spinal fracture (self report): ○Yes ○No

2. Signs consistent with nerve root compression:
   a. Reproduction of LBP or leg pain with SLR <45° (phys exam): ○Yes ○No
   b. Myotomal weakness of the lower extremity (phys exam): ○Yes ○No
   c. Quadriceps or Achilles tendon stretch reflex diminished (phys exam): ○Yes ○No
   d. Diminished myotomal sensation of the lower limbs (phys exam): ○Yes ○No

3. Did the pain start before pregnancy? ○Yes ○No
4. Is the subject pregnant? ○Yes ○No

5. Is the patient going to be available for the next 2 weeks to complete the study? (Should be marked "Yes") ○Yes ○No

Waddell's Nonorganic Signs Test

Sign	Description	Result
Superficial tenderness	◆Skin discomfort on light palpation. ◆Physical back pain does not make the skin tender to light touch.	
Nonanatomic tenderness	◆Tenderness that crosses multiple somatic boundaries ◆Any pain or tenderness that crosses anatomic lines without a reasonable explanation is considered positive.	
Axial loading	◆Pressing down on the top of the head of a standing patient. ◆This maneuver should not produce low back pain.	
Simulated rotation	◆In a standing position, when the shoulders and pelvis are rotated in unison, the structures in the back are not stressed.	
Distracted straight-leg raise	◆Patient may complain of pain or limitation in range in a supine straight leg raising test. ◆Lack of pain when examiner extends the knee with the patient seated, and looking at the foot for pulses, Babinski or reflex testing.	
Regional sensory change	◆"Stocking" or global distribution of numbness ◆Any widespread numbness that involves an entire extremity or side of the body.	
Regional weakness	◆In patients with normal strength, the sudden letting go of a muscle may be described as "cogwheeling," "giving way," "breakaway" weakness, or "dithering." ◆In patients with physical weakness, the muscle is smoothly overpowered with no jerking, and the response throughout a resisted range-of-motion maneuver remains smooth and constant. ◆This smooth weakness is nearly impossible for a patient with nonorganic weakness to duplicate.	
Overreaction	◆Exaggerated, nonreproducible response to stimulus ◆A patient may be hypersensitive to light touch at one point during examination but later give no response to touching of the same area. ◆A disproportionate grimace, tremor, exaggerated verbalizations, sweating, or collapse.	
◆The predictive value is greatly improved when three or more positive signs are present.		

Physical Therapy Treatment Form

Name: _____ **Date:** ____/____/____
mm dd yy

Have the subject lay supine, therapist stands on the opposite side to be mobilized. The side to be mobilized will be the side of pain reported by the subject. Passively side-bend the subject away from you. Therapist passively rotate the subjects upper body opposite to the side bending, delivery a quick posterior and inferior thrust at a grade V through the ASIS . Record if a "pop" is heard or felt by the subject. If no pop is felt or heard, attempt a second mobilization. If no pop is heard, make an attempt to the opposite side. A maximum of two attempts per side will be permitted . Then instruct the subject to perform ten repetitions of the hand-heel rock exercise following the mobilization procedure. Instruct the subject to get on all fours on the bed or the floor and rest some of the weight on her hands and arms. Then ask her to move her hands to just slightly higher than her shoulders. The forward rock is performed by transferring her weight more to her hands, not allowing her arms to bend. Ask her to allow her abdomen to sag towards the surface while she holds her head to look up. Have her pause towards the end of the range and then ask her to return back towards neutral. The backward rock is performed as if she were attempting to sit on her heels. Ask her to allow her back to round out while her hands drag along the surface in order to get the fully backward position. Finally, advise her to remain as active as possible within symptoms.

Manipulation Attempt	**Side Manipulated**	**Cavitation Hurd**	**Comments**
1.	○Right ○Left	○Yes ○No (If yes proceed to exercise)	
2.	○Right ○Left	○Yes ○No (If yes proceed to exercise)	
3.	○Right ○Left	○Yes ○No (If yes proceed to exercise)	
4.	○Right ○Left	○Yes ○No (If yes proceed to exercise)	
Exercise	**Included in Program**	**Repetitions**	**Comments**
Hand-Heel Rock	○Yes ○No (If no, explain in comments)	10 Repetitions	

Telephone Screening Examination Form

Name: _____ Age: _____

Telephone #: _____ Referring Physician:_____

Date: ____/____/____ (mm dd yy) **Insurance: _____**

PT visit/Insurance/Co-payment
Parking/bus fare/$40
2-3 visits depending on your outcomes.

Inclusion Criteria (All answers should be marked "YES"):

1. Do you have a chief complaint of pain in the posterior pelvic region, buttock, and/or lower extremity? ○Yes ○No
2. Did the pain start during pregnancy or postpartum? ○Yes ○No
3. Are you between 6 weeks to one year postpartum? ○Yes ○No
   Date of delivery:_____

Exclusion Criteria: (All should be marked "NO"):

1. Red flags:
   a. Do you have any tumors? ○Yes ○No
   b. Do you have Osteoporosis? ○Yes ○No
   c. Have you had a spinal fracture? ○Yes ○No
3. Did you have this pain before pregnancy? ○Yes ○No
4. Are you currently pregnant? ○Yes ○No
5. Are you going to be available for the next 2 to 3 weeks to complete the study? (Should be marked "Yes") ○Yes ○No
6. On a scale from 0 – 10 with zero being no pain at all, and 10 being the worst pain imaginable. How would you grade your pain? _____/10

*** Set up an appointment. Day: ____ Time:_____ Date: ____/____/____** (mm dd yy)

- **Please bring some shorts to your appointment if you feel uncomfortable in your underwear.**
- **You need a prescription from your PCP. If you would like to have them fax it to Montefiore, the fax number is 412-648-6056.**

Recruitment Script

The results of your examination indicate that you have posterior pelvic pain. This condition is fairly common during pregnancy and postpartum and sometimes causes pain in the lower back, pelvic area, buttock, and legs. Presently there is some amount of uncertainty regarding the best testing procedures for individuals with posterior pelvic pain and thus treatment selection is more difficult and time consuming.

We are presently conducting a study to develop a clinical prediction rule for identifying postpartum subjects with posterior pelvic pain who are likely to improve with a mobilization procedure to the sacroiliac joint. Participants in this study will undergo a series of tests and a mobilization procedure to the sacroiliac joint. If at the end of your three week participation in the study your pain does not improve you will be treated by alternate methods commonly used today.

In order to participate in this study, you will need to consent to attend physical therapy once a week for three weeks. Your physical therapy session will last approximately one hour and will consist of filling out forms, undergoing an examination of your pelvis, and receiving a mobilization to your sacroiliac joint. You or your insurance company will be billed in the usual fashion for physical therapy services.

There will not be any change to your future medical care if you choose not to participate in this study. If you do choose to participate, the results of this study will help us determine the best combination of tests to identify individuals with posterior pelvic pain who will benefit from this specific treatment procedure and thus will cut down assessment and treatment time.

You may also contact the researchers of this study by calling 412-427-6545 to set up an appointment.

HOW DOES THE STUDY WORK?

In this research study, we will determine if a group of tests to the pelvis can help identify women who respond to an adjustment of the joints of the pelvis.

You will be asked to fill out a few forms and a questionnaire about your medical history and pain, then a group of physical tests will be performed to help tell us about your pain. Finally, an adjustment to the joints of your pelvis will be performed.

On your next visit you will be asked to fill out the same questionnaire you filled out on your first visit. This will help us determine if there are any changes in your pain.

Depending on the outcome of the questionnaire, the procedure may be repeated a second time.

You will be asked to attend physical therapy a maximum of three times for the study over a 2 week period.

WHAT'S IN IT FOR ME?

Although there are no guarantees you may benefit from this study, it is hoped that you may feel a reduction in low back and pelvic pain by at least half.

WHAT HAPPENS IF MY PAIN IS NOT REDUCED?

If your pain is not reduced by at least half, you will be treated with other physical therapy methods according to your symptoms.

WHAT WILL IT COST ME?

You and your insurer or third payer will not be billed for research-only services which includes the group of specific tests. This will be paid for by the study. You or your insurance company will be billed for regular physical therapy treatment including a standard assessment and the adjustment to your pelvic joints.

Participants will receive $40 for joining the study. Free parking or re-imbursement of bus fare will also be given to participants.

HOW DO I KNOW IF THIS STUDY WOULD BE RIGHT FOR ME?

If you think you are interested in the study, ask your doctor about the study and how to participate.

CALL 412-427-6545

FOR MORE INFORMATION

A RESEARCH STUDY ON LOW BACK AND PELVIC PAIN IN WOMEN AFTER CHILD BIRTH

The department of Physical Therapy is conducting a research study on low back and pelvic pain in women.

WHO IS ELIGIBLE?

Did you deliver 6 weeks to 1 year ago?

Do you have low back, pelvic, buttock, or leg pain?

Are you between 18 and 45 years old?

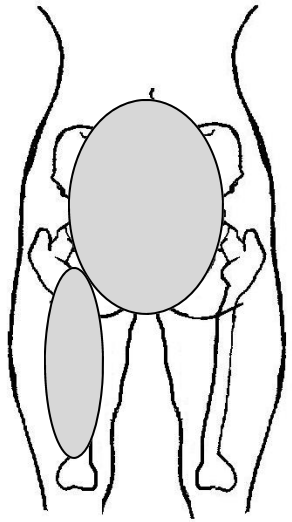
Have you had your pain since pregnancy or after delivery?

University of Pittsburgh

School of Health and Rehabilitation Sciences

Department of Physical Therapy

HAVE YOU HAD LOW BACK OR PELVIC PAIN SINCE PREGNANCY OR AFTER DELIVERY?



University of Pittsburgh

Name:_____ Date: ___/___/___
mm dd yy

VAS (0-10):_____ Type of treatment obtained post study: _____

Number of months after study obtained further treatment: _____ Reason: _____

Pain Intensity

I can tolerate the pain I have without having to use pain medication.
The pain is bad but I can manage without having to take pain medication.
Pain medication provides me complete relief from pain.
Pain medication provides me with moderate relief from pain.
Pain medication provides me with little relief from pain.
Pain medication has no affect on my pain.

Personal Care (Washing, Dressing etc.)

I can take care of myself normally without causing increased pain.
I can take care of myself normally but it increases my pain.
It is painful to take care of myself and I am slow and careful.
I need help but I am able to manage most of my personal care
I need help every day in most aspects of my care.
I do not get dressed, wash with difficulty and stay in bed.

Lifting

I can lift heavy weights without increased pain.
I can lift heavy weights but it causes increased pain.
Pain prevents me from lifting heavy weights off the floor, but I can manage if the weights are conveniently positioned (ex. on a table).
Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
I can lift only very light weights.
I can not lift or carry anything at all.

Walking

Pain does not prevent me from walking any distance.
Pain prevents me from walking more than 1 mile.
Pain prevents me from walking more than ½ mile
Pain prevents me from walking more than ¼ mile.
I can only walk with crutches or a cane.
I am in bed most of the time and have to crawl to the toilet.

Sitting

I can sit in any chair as long as I like.
I can only sit in my favorite chair as long as I like.
Pain prevents me from sitting for more than 1 hour.
Pain prevents me from sitting for more than ½ hour.
Pain prevents me from sitting for more than 10 minutes.
Pain prevents me from sitting at all.

Standing

I can stand as long as I want without increased pain.
I can stand as long as I want but increases my pain.
Pain prevents me from standing more than 1 hour.
Pain prevents me from standing more than ½ hour.
Pain prevents me from standing more than 10 minutes.
Pain prevents me from standing at all.

Sleeping

Pain does not prevent me from sleeping well.
I can sleep well only by using pain medication.
Even when I take pain medication, I sleep less than 6 hours.
Even when I take pain medication, I sleep less than 4 hours.
Evens when I take pain medication, I sleep less than 2 hours.
Pain prevents me from sleeping at all.

Social Life

My social life is normal and does not increase my pain.
My social life is normal, but it increases my level of pain.
Pain prevents me from participating in more energetic activities (ex. sports, dancing etc.)
Pain prevents me from going out very often.
Pain has restricted my social life to my home.
I have hardly any social life because of my pain.

Traveling

I can travel anywhere without increased pain.
I can travel anywhere but it increases my pain.
My pain restricts travel over 2 hours.
My pain restricts my travel over 1 hour.
My pain restricts my travel to short necessary journeys under ½ hour.
My pain prevents all travel except for visits to the doctor/therapist or hospital.

Employment/Homemaking

My normal homemaking/job activities do not cause pain.
My normal homemaking/job activities increase my pain, but I can still perform all that is required of me.
I can perform most of my homemaking/job duties, but pain prevents me from performing more physically stressful activities (ex. lifting, vacuuming)
Pain prevents me from doing anything but light duties.
Pan prevents me from doing even light duties.
Pain prevents me from performing any job or homemaking chores.

Edinburgh Postnatal Depression Scale

Name:_____ **Date: _____/_____/_____**
mm dd yy

As you have recently had a baby, we would like to know how you are feeling. Please UNDERLINE the answer which comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today.

---

1. I have been able to laugh and see the funny side of things.
    - As much as I always could
    - Not quite so much now
    - Definitely not so much now
    - Not at all
2. I have looked forward with enjoyment to things.
    - As much as I ever did
    - Rather less than I used to
    - Definitely less than I used to
    - Hardly at all
3. I have blamed myself unnecessarily when things went wrong.*
    - Yes, most of the time
    - Yes, some of the time
    - Not very often
    - No, never
4. I have been anxious or worried for no good reason.
    - No, not at all
    - Hardly ever
    - Yes, sometimes
    - Yes, very often
5. I have felt scared or panicky for no very good reason.*
    - Yes, quite a lot
    - Yes, sometimes
    - No, not much
    - No, not at all
6. Things have been getting on top of me.*
    - Yes, most of the time I haven't been able to cope at all
    - Yes, sometimes I haven't been coping as well as usual
    - No, most of the time I have coped quite well
    - No, I have been coping as well as ever
7. I have been so unhappy that I have had difficulty sleeping.*

- Yes, most of the time
- Yes, sometimes
- Not very often
- No, not at all

8. I have felt sad or miserable.*
    - Yes, most of the time
    - Yes, quite often
    - Not very often
    - No, not at all
9. I have been so unhappy that I have been crying.*
    - Yes, most of the time
    - Yes, quite often
    - Only occasionally
    - No, never
10. The thought of harming myself has occurred to me.*
    - Yes, quite often
    - Sometimes
    - Hardly ever
    - Never

Name: _____ **Date:** _____/_____/_____
mm dd yy

Age: _____ **Site of Pain:** _____

SIJ Stiffness Test: this test examines the ability of the SIJ to resist vertical and horizontal translation forces applied passively to the non-weight bearing joint. With the subject supine and the knees and hips flexed, the sacral sulcus just medial to the PSIS is palpated with the long and ring fingers while the index finger palpates the lumbosacral junction. The long and ring fingers monitor translation between the innominate and the sacrum while the index finger notes any movement between the pelvic girdle and the L5 vertebra. **Anteroposterior** translation is tested by applying a posterior pressure to the innominate through the iliac crest and the ASIS, and stiffness values are compared between the left and right sides. **Vertical** translation is tested by applying superior/inferior pressure to the innominate through the distal end of the femur, and stiffness is compared between the left and right sides.

If stiffness between the two sides are not equal the test is considered positive regardless of the side.

Plane	**Findings**	
Anteroposterior	○ Asymmetrical	○ Symmetrical
Vertical	○ Asymmetrical	○ Symmetrical