

Quantitative Research Proposal

Mother's Cordial and the Length of Labor in Nulliparous Women

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Critical Inquiry 2

Fall 2000

Abstract

Herbal preparations are widely used by midwives to promote positive outcomes of pregnancy, labor and childbearing. Additionally, herbal preparations to prepare a woman for childbirth have a long history of use in traditional cultures. The Eclectic Physicians, who practiced at the turn of the century in the U.S., have extensive experience with using certain herbs in a formula they called Mother's Cordial, to tone a woman's uterus and therefore "eliminate false pains of labour" and "ease and speed childbirth"(Felter and Lloyd, 1909). Prolonged latent and active phases of labor are associated with increased obstetrical interventions and adverse outcomes for mother and baby(Kruse, 1993; Chemlow, Kilpatrick, and Laros, 1993). This descriptive correlational study will look at the relationship of the ingestion of Mother's Cordial and the length of labor in nulliparous women in a birth center setting, and compare these women's labor length with women who have not used the Mother's Cordial.

Chapter 1: Introduction to the Study

The factors that may affect the outcome of pregnancy and a woman's labor with her baby are numerous, mysterious, and complex. A midwife, in her craft of assisting the woman in her pregnancy and labor may use many skills and tools to promote a healthy outcome for the mother, baby, family and ultimately the community. Herbal preparations are widely used by Midwives to affect positive outcomes of pregnancy and labor(McFarlin, Gibson, O'Rear, and Harman, 1999; Belew, 1999). There is a deficit of research in the medical and midwifery literature on the effect of herbs in pregnancy and labor. At the same time, there is a clear call for research on complementary and alternative medicine modalities in the current midwifery literature(Murphy, Kronenberg, and Wade, 1999). If midwives are going to prescribe herbs during pregnancy, then they need to provide documented research, case studies, and evidence that the herbs have the effect for which they are prescribed. One of the purposes of this study is to add to the growing body of research on the use of herbs in pregnancy and labor.

The concept of increasing the tone of the uterus by use of oxytocin in labor and postpartum is widely accepted in the practice of midwifery and obstetrics. The use of oxytocin in the U.S. is routine and widespread, and when used to augment labor is associated with a whole host of interventions that do not always improve the outcomes of pregnancy for mother or baby(Goerr, 1995). One study found that prolonged prodrome labor, which can be understood as a lack of uterine muscle tone and organization, is associated with adverse outcomes for mother and baby(Chemlow, Kilpatrick, and Laros, 1993). The medical model focuses on treating symptoms of uterine atony in labor and postpartum, but does not address the concept of preventing uterine contraction problems.

The concept of toning and nourishing the uterus to prepare for labor and to therefore prevent problems in labor is found in western herbal medicine(Belew, 1999; McIntyre, 1994). The Eclectic physicians, who practiced at the turn of the century, used herbs extensively and published an extensive number of studies and textbooks. Their works form the knowledge base of a current movement within herbalism. The Eclectics regularly used an herbal formula they called Mother's Cordial to prepare women for labor(Belew, 1999). A modified version of this formula will be used in this study; it will contain three herbs which each have specific properties for toning uterine muscle.

This will be a quantitative correlational study, and more specifically, a descriptive correlational design. Correlational studies simply examine relationships between variables. This study will seek to describe a relationship that may be present between the use of this herbal formula and length of labor by measuring and comparing the length of labor in women who take the herbs in the last 4 weeks of pregnancy, and in those who do not. The strength of this simple study is that it may be used to develop a hypotheses for future studies

and provoke further study into using herbs prophylactically to prevent prolonged labors and therefore interventions and sometimes adverse outcomes in labor.

The variables in this study can be understood by both their theoretical and operational definitions. The theoretical definition of Mother's Cordial is as follows: An herbal formula in tincture form which has the combined properties of toning the uterus at term in pregnant women to prepare for labor. The formula contains 3 parts Partridgeberry (*Mitchella repens*), 2 parts Black Haw (*Viburnum prunifolium*), and 1 part Black Cohosh (*Cimicifuga racemosa*); all the tinctures will be made from the whole plant parts traditionally used, rather than being standardized extracts of only the active ingredients of the plants. The formula is traditionally prescribed from 36 weeks onwards, as it will be in this study, at a dose of one half a teaspoon three times daily. The operational definition of Mother's Cordial that can be measured in this study is as follows: Each woman in the study will receive 8 oz of the Mother's Cordial with instructions to take the formula at the dose of one half a teaspoon three times daily. She will also be given a form upon enrollment to the study to record her actual use of the formula, including date, time and amount of formula ingested. Actual use of the formula will be measured from the forms completed by the women.

The theoretical definition of the length of labor is as follows: The first stage of labor is defined as beginning with true labor contractions as evidenced by progressive cervical change, and ending with the cervix completely dilated (10 cm). The latent phase of the first stage of labor covers the period of time from the beginning of labor to the point when dilation begins to progress actively. The upper limit of time in nulliparas is 20 hours for this phase. The active phase covers the period of time from the start of active progression of dilation to the completion of dilation, and this occurs at about 1.2cm/hr in nulliparas. The second stage of labor begins with complete dilation of the cervix and ends with the birth of the baby. The average length of time for this stage in nulliparas is 1 hour, with the upper limit of normal being 2 hours, according to Friedman(Varney, 1998). The operational definition of length of labor in this study is as follows: Both the first and second stages of labor will be measured by the attending midwife, and this information, as recorded on the labor summary of the subject's medical chart, will be used in this study.

The weakness of this study is that the information derived from the study will only suggest a relationship between one variable, amongst a vast number of variables that could affect the length of labor, and the study will be inherently limited in that regard. Another weakness of the correlational design is that unless this study includes a large enough number of subjects, it will not be valid to determine the existence of a relationship between the use of Mother's Cordial and the length of labor.

Chapter 2: Literature review of the Variables

The Uterine Toning Herbs of Mother's Cordial

Three herbs, together in a formula, will be used in this study: *Mitchella repens*, *Viburnum prunifolium*, and *Cimicifuga racemosa*. These herbs are chosen out of many possible uterine toning herbs for reasons stated below. This particular herbal formula has never been studied formally for its effects on the outcomes of labor. One Certified Nurse Midwife who used this particular formula with over 500 of her patients, noted that the Cesarean rate in her group practice dropped from 16% to 9% in the first year after initiating use of the formula(Belew, 1998).

None of these three herbs are endangered in the wild, and none are known to have toxic effects at prescribed doses, especially when used together in proportion in a formula. When herbs are used in a formula they are usually considered to be gentle, nourishing, and toning to body systems; and not of a pharmaceutical strength of action(Lee, 1999). When herbs are used in combination they produce their own unique synergistic action; a different action than they would have if each taken separately. The formula used in this study will be an adaptation of the proportions of herbs used by the Eclectic Physicians and modern Midwives: 4 parts *Mitchella* to 2 parts *Viburnum* to 1 part *Cimicifuga*(Thompson, 1841; Belew, 1998). Below is a description of what is known in the literature about the individual herbs that will be used in the formula in this study.

Partridge berry--*Mitchella repens*

Mitchella repens is an herb that has a long history of use to prepare women for childbirth amongst the Native Americans and the Eclectic physicians as well as modern Herbalists. According to herbalist Paul Bergner, *Mitchella* is an herb that has been in continuous use in the U.S. since 1820(1997). *Mitchella* was the one consistent plant ingredient found in all of the different variations found for Eclectics' Mother's Cordial recipe(Thompson, 1841; Felter and Lloyd, 1909; King, 1878). As well, *Mitchella* is the main ingredient found in current herbal formulas designed by modern herbalists to prepare a woman for childbirth.

Mitchella repens, commonly known as Partridgeberry or Squawvine was one of the herbs used by Native American women, who "drank a decoction of this plant for several weeks previous to confinement, for the purpose of rendering parturition safe and easy" (Felter and Lloyd, 1909). An Eclectic Physician named Ellingwood states that *Mitchella* is "par excellence the partus preparator"; he

considered the herb superior to many others used at the time by Native Americans to prepare women for childbirth. He stated that with its use "...labor approaches, devoid of the irritating, aggravating complications; the preparatory stage is simple, the dilation is completed quickly, the expulsive contractions are strong, unirritating, and effectual, and are much less painful than without the remedy; involution is rapid and perfect, there are no subsequent complicating conditions to contend with, the patient's strength is not abated, and the function of lactation is in its best condition"(Felter and Lloyd, 1909). The Eclectics considered *Mitchella* a parturient, diuretic, and astringent, seeming to have a special affinity for the uterus, "...exerting a powerful tonic and alterative influence upon this organ" (Felter and Lloyd, 1909).

Modern Herbalists ascribe properties to *Mitchella* similar to the Eclectics. *Mitchella* is used to tone and strengthen the uterine and pelvic muscles, having a gentle astringent effect on the uterus; as well, the herb helps to maintain the right balance between relaxation and contraction of the uterine muscles and tissue(McIntyre, 1994; Crawford, 1997).

The one study found in a literature search of *Mitchella* was done in 1916 in the laboratory which looked at the effect of various herbs on the excized uterus of the guinea pig, showed that *Mitchella* repens neither decreased nor increased tone in the uterine muscle(Pilcher, 1916). *Mitchella*'s known chemical constituents are tannin, saponin, resin, wax, mucilage, and dextrin, and it is "not listed in most of the poisonous plant books"(Willard, 1993; Duke, 1985).

Black haw-Viburnum prunifolium

Viburnum prunifolium, which is considered to be interchangeable with *Viburnum opulus* or Cramp bark, is the second most common ingredient found in the uterine toning formulas of the Eclectics and modern Herbalists and Midwives. *Viburnum* is known for its uterine relaxant and antispasmodic qualities. This plant was used widely by the Eclectics to prepare women for childbirth, as well as to prevent threatened miscarriage(Hoffman, 1989). The Eclectic Physicians said that with *Viburnum*, "false pains of pregnancy are readily controlled, and for after pains it is nearly as valuable as *Cimicifuga* (or Black cohosh). It is very effective in relaxing cramps and spasms of all kinds ..a remedy for the prevention of abortion, and to prepare the way for the process of parturition"(Felter and Lloyd, 1909). Black haw was an official herb in most of the 19th century pharmacopoeias, used for dysmenorrhea, diarrhea, asthma or bronchospasm, and threatened abortion, as well as to generally tone up the whole female reproductive system(Mowrey, 1984-89). The Eclectics considered that this herb will soothe the nervous system and should be used for "nervous irritability"(Felter and Lloyd, 1909).

Modern Herbalists use this herb to alleviate a woman's uterine muscle cramping in cases of dysmenorrhea and threatened miscarriage. It is also used as a uterine and pelvic area toner, and reproductive tract strengthener, having both astringent and diuretic qualities. *Viburnum* is considered to be both relaxing to overly irritated and spasmed smooth muscle while at the same time able to give tone by relieving congestion to over relaxed smooth uterine muscle(McIntyre, 1996).

The most commonly cited study done on this plant demonstrated its specific uterine relaxant properties in the laboratory with the uteri of rats. Extract of the whole plants were used for the tests, and the tests showed that "there is no doubt as to the uterine antispasmodic properties of *Viburnum opulus* and *prunifolium*"(Jarboe, Schmidt, Nicholson, and Zinvi, 1966). This study further isolated the uterine relaxant constituents of the plants which led the authors to postulate the substances are not sympathomimetic in action, but selective uterine relaxants which act directly on the muscle itself.

The uterine relaxant constituents in Black haw are scopoletin, coumarins, and asculetin, and the plant also contains plant acids, tannin, and bitter resin(Leung, 1980; Mowrey, 1984-89). An extract of the bark can have a sedative effect on the CNS, and can cause hypotension in large doses. Large doses of the herb should not be used in conjunction with other CNS depressant or stimulating drugs, although Black haw is nontoxic in therapeutic doses(Mowrey, 84-89).

Black cohosh-Cimicifuga racemosa

Either Black or Blue Cohosh, most commonly Blue cohosh, was always included in the Mother's Cordial recipes of the Eclectics, because of their "partus preparator" qualities. For the purposes of this study Black cohosh, or *Cimicifuga racemosa* will be included as the third herb in the uterine toning formula, as opposed to Blue cohosh. Blue cohosh, or *Caulophyllum thalictroides*, is a powerful herb with the ability to cause strong and sometimes tetanic contractions, and should always be given to a woman with supervision in labor. *Caulophyllum* is shown in studies to cause vasoconstriction and hypertension in laboratory animals(Belew, 1998). A recent case report in the literature involved a pregnant woman who took three times the prescribed dose of *Caulophyllum* in late pregnancy to prepare for labor, and then her neonate suffered a myocardial infarction(Jones and Lawson, 1998). This is only one case report of a possible association of Blue cohosh with a bad neonatal outcome, but because of this and the subsequent current controversy surrounding this herb, *Caulophyllum* will not be used in a Mother's Cordial in this study.

Cimicifuga racemosa has a long history of use by Native Americans, the Eclectic Physicians and modern herbalists, and it is one of the more well studied herbs in the scientific literature. Black cohosh has been studied mainly for its purported estrogen-like activity and its use in treating menopausal symptoms,(Facts and Comparisons, 1998; PDR, 1998) but there are no recent studies in the literature about its use as a partus preparator or its use in labor. What we do know about its use as a partus preparator and its use in labor, therefore is largely from the writings of the Eclectics and modern herbalists.

The Eclectics used Black cohosh as a preparator for labor par excellence, "if given for several weeks before confinement". Black cohosh will help to produce natural intermittent contractions, and eliminate false, ineffective early labor pains: it "coordinates muscular contractions, at the same time increasing their power. It stimulates normal contraction instead of inducing spasmodic uterine action"(Felter and Lloyd, 1909). The Eclectic physicians used this herb during labor as well. An interesting study published in the New York Medical Journal in 1885, observed the labors of 160 women with whom *Cimicifuga* was used during labor. The herb seemed to mildly sedate women, reduced discomfort in the first stage, increased the rhythm of the second stage, relaxed the soft tissue, and reduced lacerations(Brinker, 1996).

Black cohosh seems to have the quality of giving tone to the uterine muscle because it is an effective emmenagogue and promoter of uterine contractions in labor, but at the same time this herb will help relax ineffective spasming of the uterine muscle. Herbalists call this herb an antispasmodic and normalizer of the female reproductive tract(Hoffman, 1989; McIntyre, 1994).

The uses and actions of Black cohosh in historical and modern use are widely varied. In addition to its antispasmodic qualities, Black cohosh contains salicylates which studies have shown to have an anti-inflammatory effect(Brinker, 1996; McIntyre, 1994). Black cohosh also has compounds which will lower the Luteinizing Hormone level by binding to estrogen receptors temporarily, therefore being an effective treatment for menopausal hot flashes(PDR 1998; Snow, 1996). Black cohosh is well known and well studied for its use in depression that is especially associated with premenstrual syndromes and menopause(Bradley, 1992).

Some herbal and scientific references list Black cohosh as contraindicated in pregnancy, while others do not(Bradley, 1992). Black cohosh has a long history of use in the last few weeks of pregnancy. A recent case report published in the New Zealand Medical Journal suggested that Black and Blue cohosh, which were used to induce labor in a postdates pregnant woman, had an association with her depressed infant at birth, who has ongoing neurological damage due to anoxia(Gunn and Wright, 1996). The authors of the case report suggest that the action of peripheral vasodilation in Black cohosh may have caused a decrease blood flow to the placenta during labor. A response to this case report challenged this association for many reasons. The one and only study which demonstrated the peripheral vasodilation and therefore the hypotensive effect of Black cohosh was seen in rats and only when an extract of the herb was given by intravenous injection(Bailie and Rasmussen, 1997). No other references or contraindications to the use of Black cohosh either as a partus preparator or during labor were found in the literature.

Prolonged Latent Phase of Labor

Conservative management of prolonged latent phase of labor includes therapeutic rest, and occasional oxytocin augmentation. If these guidelines are followed, Dr. Friedman's experience is that "prolonged latent phase of labor offers no increased risk to either mother or baby"(Friedman, 1981). In contrast to this statement are the findings of one large retrospective study done at the New England Medical Center in Boston, published in 1993, which looked at the labors of 10,979 women. Of these women, 713 (6.5%) had a prolonged latent phase of labor. This study found that prolonged latent phase of labor is independently associated with an increased incidence of subsequent labor abnormalities (42.9 vs16.3%), need for cesarean delivery (24.4 vs 6.9%), depressed Apgar scores, and need for newborn resuscitation(Chemlow, et al., 1993).

Prolonged Active Phase of Labor

Two most common causes of prolonged active phase of labor are fetopelvic disproportion and uterine inertia(Kruse, 1993). Almost all prolonged labor is treated with interventions that optimize effective uterine contractions, with intravenous infusion of oxytocin being the most widely used treatment for prolonged labor. The rates of oxytocin use in nulliparous women to augment spontaneous labor varies from 5% to more than 50%(Kruse, 1993). Potential complications associated with oxytocin, although difficult to quantify, include the excessive use of analgesics, intravenous infusions and electronic fetal monitoring, which all limit the mobility of the laboring woman and thus potentially and paradoxically slow the progress of labor(Kruse, 1993).

What we do and do not know from the literature about the effects of prolonged labor

The literature shows that there is definitely an association with increased obstetrical intervention with both prolonged latent and active phases of labor. Although, there may be a greater risk for problems in the women's labor and with her baby when there is a prolonged latent phase, as opposed to a prolonged active phase of labor. What we do not know from these quantitative studies on prolonged labor are the effects of the obstetrical interventions on the mother's and baby's well being, as well as the impact of prolonged labor on the

resources of the health care system.

Conceptual Framework

A conceptual framework for this study will provide structure and meaning which will guide the development of the study and the theory about uterine toning herbs which will hopefully develop as a result of this study. As was stated previously, the factors that contribute to the onset of labor, let alone the phenomenon of prolonged labor are numerous, complex and mysterious. On a purely physiological level, it is proposed that when there are painful but ineffective uterine contractions at term there might be underlying primary incoordination of uterine contractions, or this might be a sequela of an imbalance in the endocrine milieu controlling the uterine activity(Tay, 1991). One physiological study showed an "insufficient remodeling of the connective tissue", or deposition of collagen in the cervix and isthmus of the uterus in women who had cesarean section for slow progress of labor(Granstrom, Ekman, and Malmstrom, 1991). The true physiological mechanisms of prolonged labor are not well established. We do know that the uterus of a woman in labor does seem to respond to the intravenous infusion of the synthetic hormone oxytocin by contracting more powerfully. On the other hand, Dr. Friedman uses substantial doses of narcotics to rest the woman and her uterus by stopping the contractions of false labor, therefore differentiating between false and prodromal labor. This study is based upon the concept that uterine atony or dysfunction may be contributing to the prolonged length of labor.

There are no conceptual studies in the literature looking at using an intervention, such as the ingestion of herbs to prevent uterine contraction problems. Furthermore, the exact mechanisms of action of the herbs used in this Mother's Cordial have not been established through scientific study. Our knowledge of the herbs is mostly from historical and anecdotal use, save for a few laboratory studies of the actions of the herbs on uterine muscle tissue, described above. A proposed theory or conceptual framework for this study is that the herbs in Mother's Cordial tone and nourish the pelvic region and uterine muscle of a pregnant woman by providing micronutrients which promote the effective and efficient functioning of the uterine muscle. Furthermore, the use of Mother's Cordial over time in late pregnancy and in doses that do not overwhelm natural body mechanisms, but rather support them, may prevent uterine contraction problems in labor. One outcome of labor, namely its length, which will be measured in this study was chosen from an understanding of the indications for which the Eclectics physicians used the partus preparator herbs: "to ease and speed childbirth" (Felter and Lloyd, 1909). The conceptual relationships in this line of inquiry are diagrammed in the conceptual map below.

MC(-)->LL

MC=Mother's Cordial

LL=Length of labor

Chapter Three: Research Design

Using a descriptive correlational research design, this study will look at the relationship of the length of labor in nulliparous women who have used Mother's Cordial. The results of the study will be compared to length of labor in nulliparous women who have not used the Mother's Cordial. The study will take place at a freestanding birth center. This researcher is choosing this particular simple study design as a place to start to look at the relationship of an herbal uterine toning formula on labor. A descriptive correlational design examines the relationships that exist in a natural setting without many controls of the setting(Burns and Grove, 1997). This study will not be able to establish causality between uterine toning herbs and length of labor. Although, if this study can establish a strong enough relationship between the uterine toning herbs and length of labor, it could serve as the theoretical basis upon which to design stronger studies looking at the effects of uterine toning herbs on labor.

When seeking to understand the effect of one variable on the length of a woman's labor, there will be numerous confounding variables to take into account, or at least acknowledge. There are variables before one even gets into labor that can effect length of labor such as nipple stimulation, use of other herbs in pregnancy, frequency of sex before labor that may have ripened the cervix, the preparation gained from childbirth education classes or exercises such as yoga, the birth stories and ideas formed about labor during the prenatal period or one's life, the quality of support of one's partner, whether one was ever sexually abused or raped, age, race, cultural heritage, genetic heritage, state of nutrition and hydration and restedness, to name a few variables. During labor, one thinks of the "many P's" as variables which influence labor: the power of contractions, the woman's pelvis, the size of the "passenger", the position of the passenger, the psyche of the woman in labor, the philosophy of the provider and how they manage the labor and the use of pitocin to induce or augment labor. This study will not be able to control for all of the above variables, except for the use of other herbs in pregnancy, parity, and the use of pitocin.

Selection bias is a real internal threat in this study; women will self select into the group choosing to use the herbal formula and participate in the study. The instrument used to measure length of labor will be recorded by various midwives, and will include their own bias and definition of when true labor began. Furthermore, the women in the study group themselves will be asked to record the

amount of herbal formula ingested and this self-recorded data collection tool is potentially fraught with inaccuracies as well.

There will be certain threats to external validity with the results of this study; the population is not only nulliparous, but a self selected group of women birthing at a birth center, and furthermore at a birth center which has its own unique population and practice which might be difficult to generalize to other birth center populations. On the other hand, there are some generalizations which can be made about nulliparous women, and women choosing to birth in a birth center. Furthermore, this birth center is nationally accredited by and therefore accountable to the National Association of Childbearing Centers, and has licensed Certified Nurse Midwives on staff who are accountable to the American Council of Nurse Midwives. Therefore, with these guidelines, some of the integrity of external validity for the results of this study is preserved.

Sampling methods

The study will be conducted at Holy Family Services, a freestanding birth center in Weslaco, Texas. This is a well established birth center that has a moderate volume of clients, drawing from the border region of Texas and Mexico. There are an average of 30 women on the caseload per month, with a total (antepartum and intrapartum) transfer rate of 30%. An average of 100 primiparous women successfully deliver their babies at Holy Family Services every year. The majority of women are Mexican or Mexican-American; 90% are Spanish speaking only, and 85% of the clients are low income, or financially indigent. This study would look at the length of labor in 100 nulliparous women who have taken the Mother's Cordial formula. The results of the study will then be compared to the length of labor in an additional 100 nulliparous women who did not receive the herbal formula, who birthed at the same birth center. This comparison population will be selected from a retrospective chart review from the past two years. The subjects will meet all of the inclusion and exclusion criteria listed below, except that they will not have used the herbal formula.

This birth center has a history of using uterine toning herbs and homeopathics to prepare women for labor, and so the notion of conducting a study using uterine toning herbs is a comfortable, familiar idea for the staff midwives of Holy Family Services. This researcher is a former staff of Holy Family Services, and has an ongoing relationship with the center's director. The director has indicated that she is willing to pursue implementing such a study at the birth center.

Because this is a descriptive correlational study, the intention of sampling criteria is tending towards insuring a broad heterogeneous population from which to develop hypotheses (Burns and Grove, p. 294). Nulliparous pregnant women will be the population of interest in this study with the following inclusion criteria:

- 1) All nulliparous eligible to birth at the birth center will be potential subjects, regardless of age and race.
- 2) All women willing to participate in the study by taking an herbal tincture 3 times daily from 36 weeks onwards in pregnancy, and willing and able to record amounts of herb taken daily, (ie. literate in either english or spanish).
- 3) Women who may deliver precipitously at home or en route to the birth center will be included in the study, in spite of not actually completing their delivery at the birth center. In fact the inclusion of these subjects may offer important information for the study.

Exclusion criteria will include the following:

- 1) Women taking any other herbal, homeopathic or vitamin supplements in pregnancy, other than prenatal vitamins, calcium and folic acid, as the ingestion of substances other than the traditional supplements may confound the relationship of the Mother's Cordial and length of labor.
- 2) Women who transfer to the hospital in labor for any reason during labor, as the interventions in labor that occur in the hospital will not be able to be controlled for in the scope of this study, although this information will be recorded as part of the study.

One obvious weakness of the comparison group is that it might not be possible to obtain information about other herbal or homeopathic substances they might have ingested during the last part of their pregnancy. Yet, the historical records of this particular birth center, because it is a training center as well, are of a high standard, and the record of any supplement and medications used in pregnancy have been traditionally and intentionally recorded in the charts.

Ethical considerations that come to mind with this type of study in this particular site and population are the following: Herbal medicine preparations are not substances that can be exactly measured in their strength and actions as compared with the exact measurements of amount and type of constituents of pharmaceuticals. Untoward side effect of the herbs are possible, although they will be prescribed in doses traditionally used and found to be safe in the last part of pregnancy. The women who participate in this

study will do so with full informed consent about the nature of herbal medicines. Other ethical considerations that come to mind involve the language barrier that may be present between researcher and subject. If the informed consent is given by a researcher who is not literate in Spanish, the information may not be fully communicated, nor understood by the subject. It will be important to have a fluent researcher, or trained staff available full time to both enroll women into the study and be available to clarify any questions that may arise during the study period. As a safeguard to human subject's rights, this research proposal will be submitted to the Philadelphia University Institutional Review Board and reviewed by the administration of the Holy Family Birth Center.

Data collection procedures

Once the approval of the study being conducted at the Holy Family Services is given, the permanent staff will be trained in implementing the different data collection tools and dispensing the herbal formula to women. It is expected that at this site, the time frame to collect enough data on 100 nulliparous women who will use Mother's Cordial will be about one full year. Since the clients at HFS rotate their prenatal visits with different staff midwives, the identified nulliparous women will be scheduled for their 36 week visit with either of two identified, trained, spanish speaking midwives involved in this study. At that visit the client will be introduced to the study and the herbal formula and asked if she would like to participate in the study.

If the woman gives consent, she will be enrolled into the study. She will receive full informed consent in English or Spanish about the nature of the study, the herbal formula and be instructed in its use. She will sign this informed consent, and receive a copy for her records at home. She will receive 8 ounces of the Mother's Cordial in a bottle, along with a form on which she will record her actual use of the formula. She will be instructed to use one half teaspoon of the tincture three times daily; the tincture may be taken in warm or just boiled water to allow some of the alcohol content to evaporate off, or she may take it in water or juice. She will be instructed to record the day time and amount of herb ingested. This record will be kept by the woman up until she goes into labor. She will bring the record sheet to her subsequent prenatal visits if she has any questions about the study or the procedure. If the enrolled woman has any questions about the study or the record sheet, the identified staff trained in implementing the study will be a resource for her. The record form will be collected when the woman arrives at the birth center in labor.

The record form used by the women enrolled in the study will be an instrument used to measure the actual ingestion of the herbal formula. The reliability, and therefore the validity, of this instrument will depend upon how well the women understand how to use it and how diligent they are themselves in recording their ingestion of the herb. The population of this birth center is also asked and actually required to understand and record fetal movement counts on a chart at home from 30 weeks onwards. It is this researcher's observation that the majority of women are quite capable and willing to use a self recorded instrument when they have a good initial understanding of their task. It is the women who are not literate that have a hard time with this task, and these women will be excluded from the study with the above exclusionary criteria.

Once the woman has completed her labor, the Midwife in attendance of her labor will record the length of labor on the labor summary in the subject's medical chart. The three different stages of labor are broken down and recorded as well. The researcher will obtain the lengths of the different stages of labor, and total length of labor from the medical charts. As it was stated above, although the parameters of the different stages of labor are clearly defined in the literature, how the Midwife attending the labor defines the start of each stage of labor will be somewhat subjective. The definitions of labor as delineated in this paper will be reviewed during the staff orientation to the study to minimize provider subjectivity in this variable.

The comparison group will be created from a retrospective chart review. The researcher will do a chart review of 100 previous nulliparous clients who delivered at the birth center in the past 2 years who meet the inclusion and exclusion criteria listed above, and obtain information about the length of labor from these charts.

Data analysis plan

The research question this study is asking is: What is the relationship of the ingestion of Mother's Cordial, used to tone the uterus in nulliparous women at term, and the length of their labors? The relationship of the above may be further understood when compared to length of labor in women who have not used the Mother's Cordial.

It will be necessary to analyze both variables in this study. First of all, from the self-reported forms, ingestion of the Mother's Cordial, the independent variable or treatment in this study, will be determined. If all the subjects report ingestion of the herbs exactly according to how they are prescribed (1/2 tsp three times daily from 36 weeks onwards to labor), then this variable will not be as important to measure--it will be a nominal variable. If the self-reported forms reveal a variable use of the herb, such as high use, or low use of the herbs, then this will need to be accounted for when analyzing data. One possibility is that the researcher will have to divide the subjects up into high and low ingestion of the herbs and describe the relationship to length of labor from these vantage points. The

dependent variable, the length of labor, will be analyzed in terms of hours; it is an ordinal variable and will be measured in progressive numerical terms.

Once the data is collected, it will be organized into a contingency table, with two rows for the independent variables: the group who took Mother's Cordial, and the one which did not. The columns will show hours of total labor: <2, 2-3, 4-6, 7-10, 11-15, >15. This study would fit the criteria to then use the Chi-Square Test of Independence, (Burns and Grove, p.454) to analyze the numerical data in the different cells. The Chi-Square Test would tell us if there is any statistically significant differences between the group which used the herb, compared to the group which did not, in the length of the women's labors.

Since there are few demographic variables to account for in this study, the covariable of age will be interesting to consider. If there seems to be some sort of trend or grouping in a certain age group within the data, this data will be analyzed to see if there is any statistical significance between the age groups as well.

Plan for disseminating research findings

It will be especially important to disseminate the findings of this descriptive correlational study, since it will be used for developing hypotheses about the action of herbs and their impact on the function of the uterus and therefore the length of labor. A study such as this one could be submitted for publication in journals such as Birth and the Journal of Midwifery and Women's Health. This researcher knows that interest in the study of this particular herbal formula, and its impact on labor outcomes is of interest to midwife researchers at the University of California at San Francisco, primarily motivated by staff midwife and herbalist, Cindy Belew at San Francisco General Hospital. Sharing the study results with these researchers for possible further collaboration is certainly in mind. A small descriptive study such as this one would not be significant for developing clinical protocols, but it may, if it showed to have positive impact on labor by shortening it and making it more efficient, be the basis upon which to get more extensive experimental studies approved for larger populations.

Other ideas for disseminating research findings would be to submit proposals to speak at different conferences which may find this information valuable. In particular, the annual meeting of Midwifery Alliance of Northern America (MANA), and the annual Women's Herbal Conference in New England would be good opportunities to share the findings of this study.

APPENDICES

BUDGET FOR MOTHER'S CORDIAL STUDY

Developing a budget for this study will not be that complex, as the main cost of the study will be the herbal formula itself. Providing 100 subjects with 8 ounces of herbal formula will be an expense. The other costs involved in this study will be the informed consent form and the self record provided to the women. The time and money spent traveling to the site by the researcher to provide initial training for the study and then visits to the site once during the year for a review of the process, and then at the end of the study to gather data will be another expense. The cost of analyzing the data with computer software will be considered into the budget as well.

Mother's cordial and bottles for 100 subjects \$1500

Consent and self record forms \$ 50

Researcher travel expenses (2-3 visits) \$1000

Data analysis software \$ 300

Research assistants, follow up phone and internet communication \$1000

Total budget \$4000

TIMELINE FOR MOTHER'S CORDIAL STUDY

Submit to the Institutional Review Board @ Philadelphia U. Summer 2001

Approval obtained from IRB! pronto

Site visit to train two Midwives and introduce study to staff Fall 2001

Site visit to review progress of study and to obtain

comparison group data from charts Winter and Summer 2002

Final site visit to wrap up study and obtain final data Fall 2002

Data entry, cleaning, analysis and writing time Winter 2002-3

Dissemination of findings Spring and Summer 2003

Demographic Information for subjects of the Mother's Cordial study

Age 15-19y Ethnicity Hispanic

20-29y Caucasian

30-35y Other

36-40y

40y+

Data Collection Form for the Use of Mother's Cordial

(will also be translated into Spanish)

Thank you for joining this study which uses the herbal formula called Mother's Cordial. Mother's Cordial contains three different herbs which can act to tone your uterus for labor. You have been given 8 ounces of Mother's Cordial at your 36 weeks prenatal appointment, which should be enough tincture to last until your 40 week appointment. Start taking 1/2 teaspoon of this herbal tincture 3 times a day. You can take the tincture in warm water or tea, or juice, or water to dilute the taste. Please record below every time you take the herb! This is very important. You can keep this paper next to the tincture bottle to make recording your intake of the herb easier. If you forget to take the herb, just leave that entry blank. You will still be in the study still *no matter* how much you take the Mother's Cordial. Just keep on recording how much of the herb you are actually using. Please bring this form with you to all of your prenatal appointments, and when you come in for your labor. Again, thank you for participating in this study!

Gestational Age/ Date Time of Day Amount of herb taken

examples: 36wks/May 1st 2:00pm 1/2 tsp in juice

8:00pm 1/2 tsp in juice

36wks+1day/May 2nd 7:00am 1/2 tsp in juice

Consent form for the Mother's Cordial Study

(will also be translated into Spanish)

Study Title: Mother's Cordial and Length of Labor in Nulliparous Women

Investigator: Chris Perkowska, CNM

Ms. Perkowska is a Midwife studying the relationship of herbs which are claimed to tone the uterus and prepare a woman for birth, and she would like to see in this study if there is any difference in the length of labors in women who use these herbs and women who do not. When you participate in this study, you will agree to take this herbal formula, called Mother's Cordial, three times a day from 36 weeks of pregnancy onwards to your labor. You will be asked to record how much of the herb you actually take, and when. You may benefit from this study directly by having a shorter labor, but you may also not have any difference in the quality of your labor. By participating in this study, you are contributing to our information about the actions of herbal medicines.

These herbs are known to be safe in this part of pregnancy. They have a long history of safe use in pregnant women. However, you may have some side effects from taking the herbs. You must call your Midwife if you feel you are experiencing any side effects of the Mother's Cordial. Because this is a study in which we are seeking to understand more about these herbs, we cannot predict all of the effects they may have on you. It is important that you understand that you are making an informed choice about taking these herbs.

Your participation in this study will be kept confidential, just as your medical chart and information are kept confidential. The staff of Holy Family Birth Center, and the researcher will know that you are in the study, but otherwise your participation will be kept confidential from other people, clients, and family members. Your name will not be published nor used in any sort of document about the results of this study.

You may have information about the study and its elements at any time. You may withdraw from this study at any time. It is important that you understand that you are making an informed and free choice to participate in this study. By signing below, you consent to participate in this study according to the above terms. Thank you for your participation in this study!

Subject's Signature Date

I have explained this study to the above subject and have sought her understanding for informed consent.

Investigator's Signature Date

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