NUTRITIONAL SUPPORT DURING LABOUR: A RANDOMIZED CLINICAL TRIAL OF PATIENT CONTROLLED ORAL INTAKE DURING LABOUR

By

Joan Elizabeth Tranmer

A thesis submitted in conformity with the requirements
For the degree of Doctor of Philosophy
Graduate Department of Nursing Science
University of Toronto

The author has granted a non-exclusive licence allowing the National Library of Canada to reproduce, loan, distribute or sell copies of this thesis in microform, paper or electronic formats.

The author retains ownership of the copyright in this thesis. Neither the thesis nor substantial extracts from it may be printed or otherwise reproduced without the author's permission.

L'auteur a accordé une licence non exclusive permettant à la Bibliothèque nationale du Canada de reproduire, prêter, distribuer ou vendre des copies de cette thèse sous la forme de microfiche/film, de reproduction sur papier ou sur format électronique.

L'auteur conserve la propriété du droit d'auteur qui protège cette thèse. Ni la thèse ni des extraits substantiels de celle-ci ne doivent être imprimés ou autrement reproduits sans son autorisation.

Canada

Abstract

Nutritional Support during Labour: A Randomized Clinical Trial of Patient Controlled Oral Intake during Labour

By

Joan Elizabeth Tranmer

Doctor of Philosophy

Graduate Department of Nursing Science

University of Toronto, 1999

Objective

The purpose of this trial was to determine if a policy of unrestricted access to foods and fluids during labor was effective in reducing the incidence of dystocia and in low risk nulliparous women.

Study Design

A randomized clinical trial was conducted at a teaching hospital in southeastern Ontario. Three hundred and thirty low risk nulliparous women were randomized between 30 - 40 weeks gestation to either an intervention or usual care group. Women in the intervention group received, prenatally, an information booklet containing guidelines about food and fluid intake during labor and were encouraged to eat and drink, as they pleased, and as was comfortable for them throughout labor. The oral protocol was discontinued if women received epidural analgesia or complications developed such that they were at risk for a caesarean section birth. Women in the usual care group were restricted to ice chips and water during labor.

Results

Three hundred and twenty eight women were randomized to either the control group (n = 165) or intervention group (n = 163). Of these women 78% (257/328) returned completed postpartum questionnaires. Women in the intervention group reported a significantly different pattern of oral intake, during early labor in the hospital ($\chi2 = 40.7$, p < .001). Most women regulated their intake in response to feelings of

nausea or discomfort. The incidence of dystocia was 36% (n = 58) in the intervention group and 44% (n = 72) in the usual care group and was not significantly different (OR = .71, 95% CI .46, 1.1). There were no significant differences in the other secondary outcomes measured or in the incidence of adverse maternal or neonatal complications.

Conclusion

Patient controlled oral intake during labor did not decrease the incidence of dystocia, was not associated with any adverse maternal or neonatal outcome and was enjoyed by women in labor. In the absence of benefit or harm women should be informed about the results of this trial in order to make their own decisions with regards to oral intake during labour. Further research is warranted to determine if a more prescriptive pattern of oral fluid intake during established labor is beneficial.

Acknowledgements

Table of Contents

Chapter 3: Results

Chapter 4: Discussion

Chapter 5: Summary and Implications for Research and Practice

<u>List of Tables</u>

List of Figures

Chapter 1: Introduction

Background

The high caesarean section rates in North American hospitals continue to be
of concern despite efforts in the last decade to actively decrease them (Canadian
Consensus Conference Report, 1986). Failure to progress in labour or dystocia
remains the most common indicator for caesarean section. Strategies to reduce the
incidence of dystocia and, concomitantly, the caesarean section rate have largely been
unsuccessful. Strategies have focused on identification of dystocia and treatment of
the problem, with little if any attention given to preventing its occurrence in the first
place (Keirse, 1991). Prolonged labours are associated with increased maternal and
neonatal morbidity and are distressful and uncomfortable for the parturient
(Crowther, Enkin, Keirse & Brown, 1991).

Labour is a stressful, energy-consuming event characterized by continuous
physiological and psychological demands that change and intensify during the course
of labour (Simkin, 1986a, 1986b). Little or no information is available on the energy
and nutritional needs of women during labour. Withholding or restricting oral intake
during labour is a routine hospital practice, first initiated in the 1940's and is a form of
care with no proven benefit or harm (Enkin, Keirse, Renfrew & Neilson, 1995). The
purpose of this study was to determine the effectiveness of a policy of unrestricted
oral intake versus a policy of oral restriction during labour on the incidence of labour
dystocia in low risk nulliparous women. Providing free access to a suggested pattern
of food and fluid intake at the beginning of and during labour was hypothesized to
provide the necessary nutrients and fluids to meet the energy needs associated with
labour, prevent an imbalance between energy needs and available resources, and
facilitate the progress of labour.

Review of the Literature

The literature review describes the current research and literature related to
eating and drinking in labour, specifically current practices and the risks and benefits
of restricted and unrestricted oral intake. The review then focuses on progress and
lack of progress in labour (i.e. dystocia). The incidence, causes and current

management practices of dystocia are reviewed. As well, the current literature and research about the relationship between common labour stressors (i.e. pain and anxiety) that may influence labour progress is reviewed. Following this section the rationale for the proposed intervention is presented. The chapter ends with an outline of the conceptual framework of psychophysiological modulation of labour stress, upon which the research was organized. This review was updated during the course of the study.

Eating and Drinking in Labour

Current Practice

In most hospitals oral foods and fluids are restricted during active labour. (Garcia, Garforth & Ayers, 1985; Johnson, Keirse, Enkin & Chalmers, 1991; Michael, Reilly & Caunt, 1991). This policy of food and fluid restriction was introduced in the 1940's by Mendelson when concern was raised about the dangers of maternal mortality and morbidity in association with gastric aspiration of acidic stomach contents. There are two risks associated with this condition: (a) aspiration of food particles of sufficient size to obstruct the main stem or segmental bronchus and (b) aspiration of acidic aspirate causing chemical burning of the airway and disruption of the bronchial and alveolar lining. Mendelson recommended that women should not eat or drink in labour; energy, if required, should be provided intravenously; local anaesthesia should be used in preference to general anaesthesia; attempts should be made to render the stomach contents more alkaline and anaesthesia should only be administered by skilled practitioners (Mendelson, 1946). These criteria have generally been accepted and implemented in most hospital settings and only, recently, are being questioned (Broach & Newton, 1988a; 1988b).

Oral intake is commonly restricted to sips of fluid or ice chips, with no solid food allowed at all in labour. A survey on maternity unit policies of oral intake during labour was conducted in England and Wales in 1989. Three hundred and fifty one units of 383 units responded (91.6%). Ninety six percent of the responding units allowed women some form of oral intake during labour. Of the 268 units allowing oral intake, 67.2% gave drink only and 32.8% allowed both food and drink, with

most just allowing water (Michael, Reilly, & Caunt, 1991). In comparison to a previous survey conducted in 1984, food and fluid polices were more restrictive. Restriction of oral intake is not a common practice in home births or birth centres (Rooks, Weatherby, Ernst, Stapleton, Rosen & Rosenfield, 1989) nor is it consistent across hospital settings (Haire & Elsberry, 1991).

Pengelley and Gyte (1998) reviewed the current practices in the United Kingdom and the Netherlands with respect to eating and drinking during labour. They reported the following: (a) in a 1994 survey of 50 English maternity units 53% permitted food in established labour (how far into established labour was not specified); (b) in a student midwife survey of 11 units only one unit used an evidence-based approach for policy formulation and most reported a "water only policy in established labour"; (c) in a large 1994 National Birthday Trust study of planned home births and hospital births, the amount and pattern of oral intake was similar between the two groups; and (d) in a survey, conducted in the Netherlands of midwives (n= 50) and heads of obstetric departments in teaching hospitals (n=30), just over 50% reported a policy based on the preference of the woman in labour.

It is clear that current practices with respect to oral intake during labour are variable, seemingly based on old or anecdotal evidence, and not reflective of women's preferences. Properly conducted research and reliable information would help professionals and women weigh the risks and benefits in order to make informed decisions about oral intake during labour.

Potential Benefits of Oral Intake Restriction

It is believed that withholding food and fluids during labour (i.e. fasting) decreases the risk of maternal morbidity and mortality from Mendelson's syndrome, if a general anaesthetic is required, because fasting will ensure small gastric volumes. Evidence does not support this. O'Sullivan (1994) reviewed the literature related to gastric mechanisms during labour. There is no evidence to support the concept that withholding food and fluid during labour ensures that the stomach will be empty in the event of a general anaesthetic. Gastric volume on admission to the labour unit does not necessarily reflect gastric volume, if and when a general anaesthetic is

administered. Consequently, women having a general anaesthetic in labour are prepared for anaesthesia with the assumption that the stomach is not empty.

Carp, Jayaram and Stoll (1992) conducted ultrasound examinations to determine the presence of gastric contents on 39 women in active labour at various times post last oral intake. Nearly 2/3 of the sample scanned had food present in the stomach independent of the length of time since last oral intake. Samaan, Swanson, Jackson, Madej & Wheatley (1994) evaluated a selective feeding policy by assessing gastric preparation (i.e. pH >= 3 and volume <= 25 ml) in obstetrical patients having a general anaesthetic (n = 99). Women who were starved and had ranitidine (n = 66) had higher pH and volumes than those women who were allowed drinks and lights snacks during labour (n = 33). Many patients in both groups failed to meet the criteria for low gastric volume (60% in the ranitidine and 45% in the fed group). The audit results supported continuing the policy of feeding in labour for low risk patients with the emphasis on accurate categorization of high risk.

The administration of opioids during labour is associated with delayed gastric emptying (O'Sullivan, 1994; Wright, Allen, Moore, & Donnelly, 1992). Wright et al. (1992) measured gastric emptying, by paracetamol absorption technique, in 30 women in labour, after injection of bupivicaine alone or in combination with fentanyl 100 micrograms. The median times to maximal paracetamol concentration were 60 minutes in the control group and 75 minutes in the fentanyl group, a significant, but small difference. Porter, Benello and Reynolds (1997) reported similar findings. They also suggested that the narcotic effect on gastric emptying is dose dependent as significant delays in gastric emptying only occurred above specific concentration of epidural opioid (i.e. > 100 micrograms of fentanyl). Therefore, it is generally accepted that gastric emptying is slower during labour, and that this delay is enhanced with the administration of opioids. There is no evidence to support the belief that this physiological (and pharmacological enhanced) delay contributes to adverse maternal outcomes, specifically the incidence of gastric aspiration.

There is increasing evidence that unrestricted oral intake during labour is not associated with adverse anaesthetic outcomes. A maternity service in a New York

city hospital, characterized by a 70% high risk and indigent population, showed that in 30,000 births there were no cases of aspiration in women who were allowed to eat and drink during labour (Haire & Elsberry, 1991). Rooks et al (1989) completed a survey of 11,814 women who were admitted to and delivered in 84 free standing birth centres in the United States. All but 8% of these women ate or drank while in labour. There were no incidences of gastric aspiration.

The statistical risk of aspiration—related maternal death is extremely low. McKay and Mahan (1988) reviewed seven state reports on maternal mortality. Of these seven reports, covering varying time periods between 1970 and 1988, 537 women died and 4 deaths (0.74%) were related to gastric aspiration. Kaunitz, Hughes, Grimes, Smith, Rochat & Kafrissen (1985) reviewed 2475 maternal deaths in the United States and reported that approximately 1% of maternal deaths were related to gastric aspiration. International maternal mortality reports cannot be readily compared but do suggest similar conclusions. Gastric aspiration associated with general anaesthesia is rare and less frequent with the advent of regional anesthesia and most frequent with difficult intubation. Canadian maternal mortality rates in 1988 were 0.4 per 100,000 births (AbouZahr & Roytson, 1991). Therefore, if we assume there is a 1% risk of gastric aspiration related maternal mortality the estimated risk in Canada is .004 per 100,000. It is evident that maternal mortality from gastric aspiration is extremely rare. One may argue that this is related to the current policies of food and fluid restriction, but the available evidence suggests that it is related to improved anaesthetic and obstetrical practice.

Potential Risks of Oral Intake Restriction

Potential risks related to food and fluid restriction during labour arise from two sources: (a) the potential risks associated with fasting during labour and (b) the potential risks associated with routine use of intravenous therapy.

Risks associated with fasting

There is little information available on the nutrient needs of women during labour. Glucose metabolism is significantly altered during pregnancy and labour. The continuous metabolic demands of pregnancy are exaggerations of the normal patterns

of anabolism and catabolism when compared to non-pregnant women (Buchanan, 1991; Posner & Silverstone, 1977). Moreover, the energy demands of labour further alter glucose metabolism, such that women are in an accelerated starvation state. As fasting or energy demands increase, there is a progressive rise in ketones; hepatic compensation tends to be incomplete, and plasma glucose declines (Metzger, Ravinikar, Vilesis & Freinkel, 1982).

Some authors believe that for most labours ketosis is a physiological response and has little clinical significance (Cunningham, Macdoanld, Leveno, Grant & Gilstrap, 1993; Schade, Perkins & Drum, 1983; Williamson, 1971). However, for some labours, especially longer labours, ketonuria (presence of ketones in the urine) is associated with poor clinical outcomes (Chang, 1993; Foulkes & Dumolin, 1985). Foulkes and Dumolin (1985) retrospectively examined the effects of ketonuria in labour (n=3511). They found an overall incidence of ketosis in 40% of labours; the degree and duration of ketosis was associated with increased labour length, more obstetrical interventions, and postpartum blood loss. Chang (1993) studied the physiological and psychological distress for women who developed ketonuria during labour. Descriptions of women's labour experiences were obtained in order to examine the prevalence of selected indicators of physiological distress (ketonuria, fluids, length of labour, analgesia utilization) with symptoms of psychological distress and sense of mastery. Prolonged labour, defined as the individualized experience of a difficult, extended labour, challenged the mother's physiological and psychological resources for coping with labour. Sixty - seven per cent of women with prolonged labours had moderate to large amounts of ketonuria and reported a higher degree of physiological and psychological symptom distress. Ketonuria was detected in 21% of nulliparous labours.

Evans, Crawford, Stevens, Durbin and Daya (1986) studied the biochemical consequences of two fluid regimes in induced labours under epidural analgesia: (1) isotonic saline solution (i.e. Hartmanns solution) (n=25) and (2) isotonic saline and dextrose solution (n=25). Women who received Hartmanns' solution had substantially increased concentrations of beta-hydroxybutyrate. Seven out of 25 of

women had values greater than 1000μmol/l at delivery – reflecting a considerable degree of ketosis. The length of time from induction of labour to delivery was longer (8.3±2.76 hours) in women who received Hartmanns' solution in comparison to the women who received dextrose and saline (7.5±4.0 hours). All women had fasted overnight before the induction of labour.

In these studies, it is difficult to determine whether ketosis contributes to the prolongation of labour or whether ketosis is a consequence of prolonged labour. The presence of ketonuria should be considered a signal for metabolic imbalance; the effect of this imbalance is unknown.

Risks associated with intravenous therapy

Intravenous therapy is common in most hospital settings. Intravenous therapy is routinely established during labour for the administration of medication (i.e. oxytocin), administration of fluids in conjunction with epidural analgesia and as a prophylactic measure in case of an emergency. In most cases the solution of choice is Ringer's Lactate (Keppler, 1988). Intravenous prevention and treatment of ketosis is varied (Hazle, 1986; Wasserstrum, 1992).

In the past, intravenous administration of glucose based solutions for the correction and treatment of ketosis was more common. A number of clinical studies evaluated the effect of intravenous administration of glucose based solutions on maternal and fetal outcomes (Grylack, Chu & Scanlon, 1984; Jawalekar & Marx, 1980; Lawrence, Brown, Parsons & Cook, 1982; Morton, Jackson & Gillmer, 1985; Tarnow – Mordi, Shaw, Liu, Gardner & Flynn, 1981). Ketosis is reduced with administration of glucose, but high dose glucose solutions are associated with increase maternal and fetal, serum glucose and, post delivery, with rebound newborn hypoglycaemia. Because of concern about the adverse effect of high dose glucose solutions, guidelines generally recommend low dose glucose solutions (e.g. 5%) in volumes of 100 – 120 cc per hour with hourly glucose doses of about 10 gms per hour. (Cunningham et al, 1993; Morton, Jackson & Gillmer, 1985). For most labouring women, especially for women whose labours are relatively short, a

continuous supply of glucose and fluids is probably not warranted if they started labour in a balanced nutrient and hydrated state.

There are other potential risks associated with intravenous use. These include increased risk of fluid overload and hyponatremia, inflammation and infection, pain, and unnecessary immobilization (Keppler, 1988). Intravenous intake may not be carefully monitored during labour. Cotton, Gonik, Spillman & Dorman (1984) found that the amount of intravenous solution given during labour was often double that which was ordered. Immobilization in itself can adversely affect labour progress (Nikodem, 1994). Women perceive the administration of intravenous fluids and restriction of fluids as stressful; this stress is related to the discomfort of the intravenous line and to the perception that the labour has become complicated and a "sick event" (Simkin, 1986a).

Summary of Risks of Oral Intake Restriction

Relative oral fluid restriction and use of intravenous therapy during labour does not ensure that nutrient and fluid balance is maintained and predisposes women to unnecessary stress and potential complications. It is a practice that has persisted in spite of advances in obstetric and anaesthetic care. Broach and Newton (1988a, 1988b) hypothesize that this restriction represents a well-known phenomenon of culture lag, that is, culturally patterned behaviour and practices continuing long after the need for them is gone.

Evaluation of Eating and Drinking During Labour

Only one trial has systematically evaluated the effects of an oral intake protocol during labour. Yiannouzis (1994) conducted a trial in which women (n=297) were offered, on admission to the labour and delivery unit, a light low fat diet. Women took as much food as they desired for the duration of labour. Observations of women in the experimental group suggested that most did not crave large amounts of food, especially when in active labour. Women in the experimental group were more likely to vomit ($\chi 2 = 6.1$, p=.05) and have longer labours (p = .05). However, the women in the experimental group applauded the availability of choice. It is not clear whether women were unsatisfied or distressed by vomiting or the longer

labour. A more satisfactory approach may be to initiate the oral intake protocol earlier in labour.

Pengelley and Gyte (1998) reviewed and summarized a few small descriptive studies that examined whether women want to eat in labour. They concluded the following:

> A pattern seems to emerge from these studies. Almost all women begin labour wanting to drink, and a majority want to eat. As labour progresses nearly all eat and drink less. The freedom to choose to eat throughout labour sits alongside other freedoms – such as being able to have an "active' labour – which gives control back to the women and thus improve her experience of normal labour. If she is to be advised against doing something she wants to do during her labour, such as eating, this can only be justified if there is good research to show that by doing so she will be putting herself and her baby at risk. The Confidential Inquiry contained one maternal death from acid aspiration over the three years 1991-1993 – for a period when more that two million women gave birth. Women should be informed that this is the level of risk. (p.28).

No clinical trials have examined the effect of eating and drinking during labour on important maternal and newborn outcomes. Eating and drinking during labour may influence the development and incidence of dystocia (i.e. prolonged labour), an important clinical obstetrical problem.

<div align="center">Dystocia</div>

Dystocia, literally defined as difficult labour, is a broad term that describes the conditions of: (a) absolute cephalopelvic disproportion, when the disparity between the fetal head size and maternal pelvic size precludes vaginal delivery; (b) relative cephalopelvic disproportion, when asymmetry or malpresentation of the fetal head precludes passage; or (c) failure to progress, when there is lack of cervical dilatation and or lack of descent of the fetal presenting part, attributable to cephalopelvic disproportion or insufficient uterine contractions (Pritchard, MacDonald & Grant,

1985). The diagnosis of dystocia is problematic in that it is dependent upon two defining criteria: (a) definition of the start of established labour and (b) definition of inadequate progress once labour has started.

Labour is defined as the presence of regular uterine contractions that brings about progressive effacement and dilatation of the cervix. Labour, for most women, begins rather insidiously with intermittent starts and stops frequently termed either "false labour" or "latent phase labour". Labour during this time is characterized by contractions of varying intensity and duration that are at times short-lived. During this phase of labour, the cervix effaces and begins to dilate in preparation for the more active or established phase of labour. This false or preparatory phase of labour may bring women to the hospital. Upon arrival to the hospital, caregivers determine whether the woman is in active or established labour. This designation of established labour is an arbitrary designation of one point in time to a process that is influenced by many factors and is difficult to define as there are not definitive criteria for the diagnosis of established labour (McNiven, Williams, Hodnett, Kauffman & Hannah, 1998).

O' Driscoll, Stronge and Minoque (1984) reported that over 10% of women self-admitted to the labour and delivery unit were assessed by the professional staff as not being in labour, yet within 24 hours of this assessment slightly less than half of this 10% went into labour, reaffirming the difficulty in defining progressive labour. McNiven et al (1998) studied caregivers' use of strict criteria for the diagnosis of active labour in term pregnancy. Two hundred and nine low risk nulliparous women were randomly allocated to an early labour assessment group or direct admission to hospital group. The early labour assessment program was designed to prevent admission to the labour unit, before active labour was established, in order to prevent misdiagnosis of poor progress in labour and interventions (i.e. oxytocin). Women assigned to the early labour assessment group were examined to determine if contractions were regular and painful and if the cervix was dilated at least 3 cm. Women not to in active labour were discharged with instructions to return when contractions were more regular. Sixteen percent and 18.6% of the control and

intervention group, respectively, were discharged home undelivered. Women who had experienced early labour assessment were less likely to receive intrapartum oxytocics (OR = 0.44; 95% C.I. 0.24,0.80), analgesia (OR = .31; 95% C.I. 1.26, 7.13), and reported higher levels of control during labour and birth. Of the caesarean deliveries performed, 2/8 in the assessed group were for dystocia versus 8/11 in the control group.

Because of the difficulty in defining the start of progressive labour, the time of admission to the hospital is often taken as the starting point for labour (Keirse, 1991). Admission to labour and delivery units in the early stages of labour is common and may predispose women (and their caregivers) to wanting to promote labour progress. Stewart, Dulberg, Arnil, Elmslie & Hall (1990) retrospectively reviewed the charts of 3887 primiparous women who gave birth to a singleton fetus during 1984 in a city in Ontario. Thirty percent were diagnosed with dystocia; 75% of all caesarean sections were performed for dystocia, disproportion or failed induction, and of these procedures 41% occurred in the latent phase. The authors concluded that some caesarean sections were performed before adequate trials of labour had occurred.

These studies and others (Lavender, Alfirevic & Walkinshaw, 1998; Peaceman & Socol, 1996) reinforce the need and importance of a clear definition of the start of the active phase of labour, or conversely to define, and accept the prodromal, latent phase of labour as normal and difficult to define. Given one is able to define the start of active labour, the next criterion for the diagnosis of dystocia is a progressive rate of cervical dilatation or descent of the presenting part.

Slow or inadequate progress is dependent upon what is considered to be normal progress, once labour is established. Friedman (1955) described the first statistical analysis of cervical rate of dilatation in 1955. The classic Friedman curve was based on the plotting of the labours of 100 women in spontaneous labour with no exclusions for malpresentation, malposition, analgesia, or use of oxytocin. A large amount of descriptive data exists about normal ranges of length of labour and cervical dilatation rates (Crowther et al., 1991). These data have been used to create labour partograms, graphic representations of essential observations in labour, including

cervical dilatation. On these graphs, actual progress in labour is compared to normative rates, so that when labour progress deviates from the accepted norm, or labour crosses "alert lines" or "action lines," a presumptive or definitive diagnosis of abnormal labour progress is made and further clinical assessment or interventions occur. The partogram is generally accepted as a beneficial tool for the management of labour, as supported by the results of a large World Health Organization (WHO) study in southeastern Asia where the use of the partogram was associated with favorable maternal and neonatal outcomes (Dujardin, DeSchampheleire, Sene & Ndiaye, 1992) and as supported by its widespread acceptance and use in labour and delivery units. However, there are no published clinical trials, to date, that have systematically evaluated the benefits and risks of partogram use on maternal and fetal outcome (Buchmann, Gulmezoglu, & Nikodem, 1999).

Given the complexity of defining dystocia and the paucity of scientific data, the panel of experts at the National Consensus Conference on Aspects of Caesarean Birth (1986) recommended the following guidelines for the diagnosis of dystocia:

1. Before the diagnosis of dystocia is considered, the woman must be in established labour; the latent phase of labour is not considered established labour. Established labour is diagnosed in the presence of painful, regular uterine contractions and cervical effacement with at least 3-cm dilatation.

2. Slow progress in labour is not necessarily a problem in itself, but it is the best available indicator in women in whom dystocia is likely to develop. In the first stage of established labour a diagnosis of dystocia is warranted if there is a lack of progressive cervical dilatation less than 0.5 cm/h over a 4 hour period.

3. The causes of dystocia, the commonest of which is ineffective uterine action, should be sought. Such a diagnostic approach will identify women with dystocia at an early stage and allow management options (e.g. oxytocin, hydration, change of position, ambulating). In some women no intervention is indicated. At this early stage caesarean sections for dystocia are not appropriate. It should be considered much later and then only after satisfactory augmentation of uterine action has failed to secure progress after a reasonable time

4. While there is cause for concern if second stage of labour exceeds the usually accepted duration, no strict time limits should be set as along as there is progressive descent of the fetus. (p. 1350)

The panel also recommended that further studies be conducted to address the: (a) specificity and sensitivity of the proposed working guidelines for the diagnosis for dystocia as predictors of the need for caesarean section; (b) the value of early correction of ineffective uterine action in prevention of dystocia; and (c) the value of alternate methods for the prevention and management of dystocia.

These guidelines were published in 1986. Since then the incidence of caesarean births across Canada (and other countries) has not changed drastically nor has the incidence of caesarean births related to dystocia changed (Bulgar, Hosden-Chapman, & Stone, 1998; Goel, Williams, Anderson, Blackstein-Hirsch, Fooks & Naylor, 1996; Gregory, Curtin, Taffel, & Notzon 1998; How, Foley & Stronge, 1995; Soliman & Burrow, 1993; Werschler, 1998). In Ontario, the rates of caesarean delivery in 1996/97 and 1997/98 increased, and the source of the increase was caesarean for dystocia (Anderson & Axel, 1998).

Incidence of Dystocia

Few if any studies report the incidence of dystocia according to set criteria. In one Canadian study of 925 nulliparous women in spontaneous term labour with a singleton fetus in the cephalic position, the incidence of dystocia was 30.8% when the Canadian Consensus Criteria were applied (i.e. a rate of less than 0.5 cm for a period of 4 hours after a cervical dilatation of greater than 3 cm). Dystocia is often inferred from proxy measures such as the proportion of caesarean section for dystocia or failure to progress or proportion of labours augmented with stimulants (i.e. oxytocin). In nulliparous labour the proportion of women who receive oxytocin infusions during spontaneous labour varies from 5% to 40% (Keirse, 1991). Data from the National Maternity Hospital in Dublin, for the year 1980, reported that 40.6% of nulliparous women received oxytocics. More recent data suggest that rates of oxytocin infusion for the purpose of augmentation continue to be consistently reported around 40% (Boylan, 1989; Fraser, 1992). Failure to progress during labour (whether the woman

is having a trial of labour after a previous caesarean section or not) accounts for 50%
to 75% of caesarean sections in Canada (Canadian Consensus Conference Report,
1986; Stewart et al., 1990).

Causes of Dystocia

Labour progress is dependent upon effective uterine contractions. This process
involves a complex interplay of maternal (and fetal) factors. Muscular contractions:
(a) are produced by the sliding of thick and thin myofilaments (actin and myosin)
relative to one another, (b) are regulated by enzymatic phosphorylation and
dephosphorylation of myosin, (c) occur spontaneously in the absence of neuronal or
hormonal input; and (d) are controlled by myogenic, neurogenic and hormonal control
systems (Challis and Lye, 1994). There is a basic self-regulating cycle to uterine
contractions: (a) the uterus contracts, (b) uterine blood vessels occlude, (c) uterine
oxygen, pH and adenosine triphosphate (ATP) concentration decreases, (d) force
production is limited, and (e) the uterus relaxes allowing for replenishment of
nutrients and removal of waste substances. When physiological mechanisms become
disrupted or unbalanced, the supportive background is altered and uterine force and
frequency may be adversely impacted (Garfield, 1987; Wray, 1993). It is evident that
within the contraction cycle that there are many foci through which the modulating
physiological mechanisms can alter the force and frequency of contractions. Garfield
(1987) and Wray (1993) reviewed the different modulators and their relation to
dystocia (prolonged labour). Table 1 is a summary of the physiological factors related
to dystocia.

Table 1

Physiological factors related to dystocia

Myogenic: Intrinsic Factors

Inadequate depolarization

- ➤ Ionic disturbance (local)
- ➤ Insufficient stimulation or excessive inhibition by hormonal or neural mechanisms
- ➤ Lack of stimulatory receptors or redundant intrinsic inhibitory systems

Deficient propagation of electrical events

- ➤ Lack of development of gap junctions
- ➤ Suppression of channel opening in gap junctions

Incomplete muscle development

Unsatisfactory energy supply for muscle cells and fatigue

Neurogenic: Nerve Factors

Depressed neural output by excitatory neurons

Continued dominance by inhibitory nerves

- ➤ Failure of inhibitory nerves to degenerate

Hormonal: Humoral Factors

Inadequate steroid ratios (estrogen to progesterone)

- ➤ Progesterone dominance
- ➤ Failure of steroid hormones and their receptors to control synthesis of necessary proteins, membrane receptors, gap junctions, etc.

Hormonally regulated closure of gap junction channels

Elevated levels of inhibitory prostaglandins, relaxin, etc.

Failure of stimulatory prostaglandins to increase sufficiently

Metabolic Factors

Reduced uterine blood flow

Hypoxia and intracellular acidification

From: Garfield, R. (1987) Cellular and molecular basis for dystocia. Clinical Obstetrics and Gynecology, 30 (3) and Wray, S. (1993). Uterine contraction and physiological mechanisms of modulation. American Journal of Physiology, 264, C1-C18.

While there is considerable understanding of the physiological mechanisms associated with uterine myometrial activity, it is less clear how these mechanisms modulate (control and regulate) each other, are influenced by psychosocial factors,

and may result in poor progress in labour. Dystocia is more likely to occur when the physiological mechanisms are disrupted and adversely influence the background physiological environment. Physiological factors or psychological factors that elicit a physiological response can influence physiological mechanisms.

Prevention and Management of Dystocia

The most common treatment for dystocia, once identified, is use of one or more interventions associated with active management of labour protocols. Active management of labour is a complex series of interventions including: selective admission to the labour unit, early artificial rupture of membranes (amniotomy), encouragement of ambulation, continuous nurse or midwife support, early administration of oxytocin, conventional means of fetal monitoring (i.e. direct auscultation) and selective use of epidural analgesia (ODriscoll, Foley & MacDonald, 1984). Active management as a form of care was first described and used in the National Maternity Hospital in Dublin. Adaptations of active management protocols have been widely implemented in other settings worldwide.

Selected interventions of the active management protocol have been studied to determine their effectiveness on reducing dystocia and the caesarean section rate. A Cochrane review of routine early amniotomy concluded that early amniotomy was associated with a reduction in labour duration and a possible reduction in abnormal 5-minute Apgar scores, but no reduction in caesarean delivery (Fraser, Krauss, Brisson-Carrol, Thornton & Breart, 1999). A Cochrane Review of 14 trials of continuous support during labour concluded that support during labour reduces the likelihood of medication for pain relief, operative vaginal delivery, caesarean delivery and a 5-minute Apgar score less than 7. Continuous support is also associated with a slight reduction in the length of labour (Hodnett, 1999). The studies of early administration of oxytocin infusion to expedite labour in cases of poor progress are difficult to interpret, since entry criteria, administration doses and titrations of oxytocin and control group characteristics vary. A systematic review of the literature showed that early and liberal use of oxytocin administration, alone, had little if any benefit for women and their newborns (Fraser, 1992).

Only two randomized trials have assessed the effectiveness of both the organizational and medical components of active management of labour on maternal outcomes. In the first trial, Lopez-Zeno, Peaceman, Adashek & Socol (1992) randomly assigned women to an active management group or a traditional care group. Women assigned to the active management group had an amniotomy performed within one hour of diagnosis of established labour and oxytocin infusion when the rate of cervical dilatation was less than 1 cm/hr. The caesarean section rates were 10.5% in the intervention group (n= 351) and 14.1% in the traditional care group (n= 354)(p = .18) The average length of labour, from admission to delivery, was reduced by 1.66 hours in the active management group (p < .0001). The supportive care component of the active management labour protocol was not implemented in this study.

Frigoletto, Lieberman, Lang, Cohen, Barss, Ringer et al (1995) randomized nulliparous women before 30 weeks to an active management group (n=1009) or a usual care group (n=906). The active management group received continuous labour attendance by nurse midwives (who only changed with shift changes) in a separate labour unit. Established labour was diagnosed by the charge nurse midwife as painful contractions accompanied by effacement of at least 80%, bloody show or spontaneous rupture of membranes. Amniotomy was performed within one hour of diagnosis of labour, and oxytocin was initiated if the rate of cervical dilatation in the first stage was less than 1 cm/hr, or during the second stage if the time from full dilatation and the fetus's head reaching the pelvic floor was greater than one hour. Women in the usual care group were managed in the labour delivery unit, staffed with one nurse to every two patients during early labour and one-one nursing during the later stages of labour. There were no strict practice guidelines for amniotomy, oxytocin initiation, or routine cervical examinations. The rates of caesarean delivery were identical (19.5%) in the two groups. More women in the control group (26%) in comparison to women in the intervention group (9%) had labours greater than 12 hours in duration (p < .001). The length of labour was shorter and the incidence of elevated maternal temperature was less in the active management group. Historical retrospective studies report that active management of labour reduces the caesarean

section rate (Boylan, 1989; Turner, Brassil & Gordon, 1988); however, no randomized clinical trials have demonstrated this effectiveness.

Progress in labour must be considered within the context of the mother's well being: "A women whose dilatation rate is 1 cm/hr and is in severe distress is far more worrying than a rate of 0.3 cm/hr in a woman who is comfortable, walking around, drinking cups of tea and chatting with the midwife" (Crowther et al, 1991, p. 843). Dystocia is an important clinical obstetrical problem as it contributes to the high caesarean section rate and for most women, a distressful prolonged labour is unpleasant and is associated with decreased maternal satisfaction, increased pain, difficulty breastfeeding, fatigue, and unpleasant birth memories (Oakley, 1983).

Common Labour Stressors that May Influence Energy Needs and Labour Progress

Pain

Pain during childbirth is common, variable, is more intense in nulliparas (Melzack, Kinch, Dobkin, Lebrun &Tquenzer, 1984), and is a result of the net effect of highly complex interactions of neural systems, mediating influences, and psychological and cultural factors (Bonica, 1994; Melzack, 1993; Wuitchik, Bakal & Lipshitz, 1989). Pain during labour is described as sharp, aching, shooting, hot or heavy and is tiring and exhausting. Women across many countries and cultures consistently report that labour pain is severe and intense. Overall, 10 to 15% report little or no pain; 35% report moderate pain; 30% report severe pain; and 20% report excruciating pain (Bonica & McDonald, 1990).

Pain during labour results in marked stimulation of respiration, circulation, hypothalamic autonomic (predominantly sympathetic) centers of neuroendocrine function, limbic structures and psychodynamic mechanisms of anxiety and apprehension resulting in a "stress response" (Bonica, 1990). With severe labour pain, levels of epinephrine, norepinephrine, beta-endorphin and cortisol increase significantly (Gorland, Wardlaw, Stark & Frantz, 1981). Pain elicits a generalized metabolic response leading to hypermetabolism and acceleration of most biochemical reactions, including substrate mobilization from storage to central organs and

traumatized tissue. The degree and duration of these endocrine and metabolic consequences is related to the degree and duration of pain.

Generally, researchers have not found a relationship between overall pain intensity and duration of labour. For the most part, these researchers have assessed pain during active labour (Melzack et al., 1984) or retrospectively (Davenport-Slack & Boylan, 1974; Reading & Cox, 1985). There is some evidence that the high levels of pain during latent labour may affect labour progress (Wuitchik et al., 1989; Wuitchik, Hesson & Bakal, 1990).

Wuitchik et al (1989, 1990) examined the relationships between pain, cognitive activity, and labour efficiency in 115 nulliparous women. High levels of pain during the latent phase were associated with longer stages of latent labour ($r = 0.58$) and active labour ($r = 0.67$). Distress-related thoughts (versus coping-related thoughts) during latent labour were also predictive of longer stages of latent labour ($r = .31$) and active labour ($r = 0.61$). Self reported pain or coping in the active phases was not associated or predictive of labour length or outcomes. The authors concluded: " that latent labour was a critical phase in the psychobiology of labour and that pain and cognitive activity during this phase were important contributors to labour efficiency and obstetric outcome" (Wuitchik et al, 1989, p.35). Findings from this study need to be interpreted with some caution as complete data on pain and cognitive measures in all phases of labour were available on only 64/115 subjects. Analysis was limited to patients who had not received oxytocin augmentation or epidural analgesia before the second interview, which occurred when the cervix was between 4-7 cm dilated. The findings support the hypothesis that high levels of pain and distress related cognitive activity during the latent phase of labour are potential risk factors but there is no evidence to support that these variables cause dystocia.

While there may be little evidence supporting the relationship between high levels of reported pain during active labour and labour progress, pain management strategies do influence the progress of labour. Women use many prescribed strategies to cope with or manage labour pain. Pain management methods need to be carefully assessed and evaluated on the basis of efficacy, effect on mother and fetus, and effect

on the forces of labour. In many North America hospitals, epidural analgesia is a common form of labour pain management (Douglas, 1994; Howell, 1994; Thorp, Eckert, Ang, Johnston, Peaceman & Parisi, 1991). A Cochrane review of epidural analgesia versus non-analgesia in labour shows that epidural analgesia provides excellent pain relief but is significantly associated with longer first and second stages of labour, increased use of oxytocin, malrotation, instrumental delivery and caesarean sections, particularly for dystocia (Howell, 1999). Ideally, pain relief measures should help women cope with the pain of labour while not adversely affecting its progress or outcome.

Anxiety

Anxiety is an emotional state characterized by feelings of tension, nervousness, worry, apprehension, and heightened autonomic nervous system activity. Spielberger, Gorsuch and Lushene (1970) differentiate between state anxiety as a transitory emotional condition, and trait anxiety as a stable individual difference in anxiety proneness. Anxiety may have a potentiating effect on other stressors by enhancing physical symptoms. Stress-induced anxiety may bring about coping mechanisms to reduce the impact of the stressor or that which caused the stress; but too much stress may interfere with cognitive activity and lead to feelings of helplessness (Lazarus & Folkman, 1984).

Some anxiety may be beneficial in labour, in that it indicates that the woman is confronting and working through the demands associated with labour. In contrast, high maternal anxiety has been associated with prolonged labour (Beck, Siegel, Davidson, Kormeier, Bretenstein & Hall, 1980; Crandon, 1979; Erickson, 1976; Lederman, Lederman, Work, McCann, 1978, 1979;); decreased uterine contractility (Erikson, 1975; Lederman et al, 1978, 1979); increased operative deliveries (Crandon, 1980; Erikson, 1975), low Apgar scores (Crandon, 1980; Erikson, 1975), and maternal complications (Crandon,1980, Erikson, 1979).

Lederman et al (1978,1979) investigated in 32 normal primigravida women, the psychological and physiological correlates of labour to determine if conflicts in pregnancy were predictive of maternal anxiety and intrapartum cortisol and

catecholamine levels in labour, and if these variables were related to labour progression and newborn depression. Self reported anxiety during pregnancy was correlated with intrapartum levels of epinephrine (r =. 60) and cortisol (r = .59). Higher levels of epinephrine were correlated with a longer active labour phase (r=. 60) and lower contractile activity (r = -. 64). These results suggested a relationship between anxiety and the biochemical measures of stress and uterine activity. However, these results should be interpreted with caution as the sample was small, and supposedly consisted of normal, nulliparous women. Most of the sample received medication (stimulant or analgesia), half had operative deliveries, all had intravenous infusions, and all were monitored externally or internally. These factors in themselves may influence labour duration and as well may have been stressful for the women in the sample. The levels of stress hormones increased, but it is not clear whether this increase was related to anxiety about labour or related to anxiety about the medical interventions during labour (Simkin, 1986b).

Other descriptive studies show that high anxiety during pregnancy predisposes women to longer labours. McCool and Susman (1994) investigated the relationship between cortisol levels, anxiety, and maternal intrapartum outcome scores in pregnant adolescents (n = 38). Actual second and third trimester pregnancy levels of cortisol and anxiety, and changes across the two times, were related to increased labour length and negative labour outcomes (as measured by a composite maternal scoring system). In this study intrapartum measures of cortisol and anxiety were not measured; latent phase labour data were incomplete, a composite maternal intrapartum score was used and other potential anxiety producing variables were not described or controlled for, making it difficult to determine the exact relationship between intrapartum anxiety and labour progress.

Smith, Cubis, Brinsmead, Lewin, Singh, Owens et al (1990) prospectively examined the interrelationships, in nulliparous women (n = 97) between pregnancy and intrapartum levels of endorphin, corticotrophin releasing hormone (CRH) and cortisol; psychosocial assessment of mood, sleep, depression, maternal expectations, attitudes, and social supports; and labour outcomes of labour duration, analgesia and

anesthesia, mode of delivery, and need for augmentation. All levels of hormones rose during pregnancy and peaked during labour. There were no significant relationships with labour duration. The mean duration of labour length was 8 hours and 50 minutes, and the emergency caesarean delivery rate was 7%. The levels of circulating CRH correlated with plasma cortisol ($r = 0.54$) and β-endorphin ($r = 0.32$). Women whose mood deteriorated from 38 weeks to 2 days postpartum had larger falls in β-endorphins ($p < 0.01$) than those women whose mood improved or remained constant. The authors stated that the pattern of significant differences suggests two overlapping but relatively independent influences on maternal childbirth experiences. Firstly, some women may have an anxious disposition (i.e. trait anxiety), as evidenced by the relationships between antenatal mood states, mother's ratings of childbirth experiences and levels of pain relief during labour. Secondly, some women may be more reactive to the events of childbirth (i.e. state anxiety) as evidenced in the hormonal influences, changes in β endorphin, postnatal mood disturbances and childbirth experiences.

These descriptive studies suggest that: (a) there is a patterned release of stress hormones during pregnancy and labour; (b) elevated levels of anxiety during pregnancy may affect labour outcomes; and (c) elevated levels of stress hormones during labour correlate to higher levels of anxiety. These findings indicate that each women's unique reaction to stress may influence the birth experience and that the degree of reactivity to stressful events may be indicative of the nature and degree of psychophysiological responses during labour and predictive of obstetric outcome. It is less convincing that elevated levels of stress hormones and high anxiety levels during labour are directly related to labour duration or adverse labour outcomes.

The Intervention: Patient-Controlled Oral Intake

Based on the research cited an intervention of a patient controlled oral (food and fluid) intake protocol initiated at the beginning of labour was hypothesized to facilitate labour progress as it would: (a) provide the necessary nutrients and fluids to meet the normal physical demands (and stressors) associated with labour and (b) be flexible and patient controlled, to accommodate individual variations in preferences

and labour experiences. A policy of oral restriction does not meet these criteria and is a form of care that has no proven benefit and may in some cases be of harm (Enkin, Keirse, Renfrew & Neilson, 1995).

If we assume that labour is an energy-consuming event, then an energy source is needed. The research is limited in this area because of the difficulty in measuring energy intake and output during labour, but the available studies do show that the work of labour follows a similar pattern to the work associated with continuous moderate aerobic exercise (Heston & Simkin, 1991). Oxygen consumption, carbon dioxide production and maternal venous lactate increase; venous pH decreases gradually throughout labour (Eliasson, Phillips, Stajduhar, Carome & Cowsar, 1992; Katz, Kroll, Shapiro, Cristal & Meisner, 1990). Oxygen consumption increases with pain and is reduced when pain is relieved with epidural analgesia (Hagerdal, Morgan, Sumner & Gutsche, 1983; Sangoul, Fox, & Houle, 1975).

As previously discussed, there is little information available on the nutritional needs of mothers during labour. Nutritional needs are individualized and will be influenced by resources (prelabour nutritional state) and the energy demands of each labour experience (e.g. pain intensity, anxiety, and labour duration). Most healthy pregnant women have an abundance of body water in their extravascular space, thus the risk of dehydration and hypovolemia is relatively small (Wasserstrum, 1992). However, if labour is long, and the work of labour becomes intense and prolonged, the energy needs of labour may be similar to those of women participating in moderate, prolonged exercise. Dietary guidelines recommended for use in individuals participating in moderate continuous activity generally recommend that individuals should: (a) consume frequent small servings of plain cool water or other rehydration beverages; (b) become accustomed in advance to drinking at regular intervals (with or without thirst); (c) consume a glucose based beverage with longer duration of exercise (> one hour); and (d) eat and drink foods and fluids that taste good to them and do not cause gastric distress (Canadian Dietetic Association & American Dietetic Association, 1993). The goal of these dietary guidelines is to ensure that there is a readily available source of glucose and water for energy utilization during the athletic

event. In labour, the goal of the guidelines would be to ensure that there is a readily available source of glucose and water for energy utilization, if needed. Ideally, if women could participate in these guidelines and consume a reasonable source of glucose and fluids, enough nutrients and fluids would be readily available to meet the energy consuming demands of labour.

In addition, women would be able to assume some control over one aspect of their labour experience. Providing women with knowledge and support, to cognitively manage as best they can the labour event and the environment, enhances coping and minimizes stress (Humenick & Bugen, 1981). Keirse et al. (1991) stated "There are many features of the contemporary birth environment that increase its stressfulness: the unfamiliarity of the place and most of the people; the variable use of procedures such as routine insertion of intravenous lines; restriction of fluids and foods" (p.806). Hodnett (1989) measured personal control in two groups of women, one group (n=80) who chose home birth and one group (n=80) who chose hospital birth. Women who chose home births had higher levels of perceived control, used less analgesia and had less medical intervention. There was no difference in mean labour length between the two groups, but 81.5% of women in the hospital group received epidural anesthesia, and the use of amniotomy and oxytocics to stimulate labour and the incidence of instrumental deliveries was significantly higher. This suggests that interventions available in the home setting, (one to one support, ambulating, position changes, free access to food) supported and facilitated labour progress and resulted in similar effects as those associated with use of oxytocics and amniotomies.

Allowing women to the freedom to choose what they wish to eat or drink in labour allows women to assume control over one aspect of their labour experience. The physical resource of foods and fluids for labour, the energy consuming event, and the opportunity to assume some control may have a favourable impact on labour progress and the labour experience.

Conceptual framework

This study was conceptually organized on the mechanisms associated with the stress-adaptation model. This model suggests that the relationships and interactions between the event and person-environment factors modulate physical adaptation and psychological coping and influence outcomes (Lazarus & Folkman, 1984). Consistent with the principals of the framework, during labour there are normal occurring labour stressors (i.e. uterine contractions, pain, anxiety) that (a) elicit a psychophysiological adaptation response and cognitive appraisal strategies and (b) utilize physical energy sources (i.e. nutrients and fluid) and cognitive resources (i.e. knowledge). The goal of the interactions and relationships is to support and facilitate favourable outcomes, including satisfactory labour progress and, as well, a sense of personal control during labour and birth. However, if the stressors become too intense or resources are depleted an unfavorable outcome (i.e. poor labour progress) may occur.

Within this framework, two pathways are identified for psychophysiological modulation of labour: 1) cognitive-appraisal and 2) psychophysiological adaptation. Cognitive appraisal involves: (a) primary evaluation of the demands as irrelevant, benign or positive, or stressful and (b) secondary evaluation of the coping options available (Lazarus & Folkman, 1984; Lazarus, 1991). Cognitive appraisal focuses on the problem (pain, hunger) or the emotion (fear, anxiety) the woman is experiencing and will elicit behavioral changes (pain and hunger relief measures, knowledge seeking) to adapt to the demand. The psychophysiological adaptation response produces physiological and biochemical changes directed toward maintaining a homeostatic balance necessary for the stressful event - labour.

The psychophysiological stress response involves activation of the hypothalamic-pituitary adrenal (HPA) axis and sympathetic nervous system. Glucocorticoids and catecholamines (epinephrine (E), norepinephrine (NE) and dopamine) are the critical hormones secreted during the stress response. A number of studies describe the psychophysiological stress response during labour. Labour is associated with increased release of glucocorticoids (Lao & Panesar, 1989),

catecholamines (Burns, 1992; Jones & Greiss, 1982) and endorphins (Chan, Smith, Lewin, Brinsmead, Zhang, Cubis, Thornton & Hurt, 1993; Gorland et al., 1981). Increased levels of stress hormones are associated with pain (De Punzio, Neri, Metelli, Bianchi, Venticinque, Ferdeghini & Fioretti, 1994; Gorland et al., 1981; Lederman et al., 1978; Lederman et al., 1979); anxiety (Lederman et al., 1978; Lederman et al., 1979; McCool & Susmann, 1994), and more difficult deliveries (Jones & Greiss, 1982).

The physiological stress response is logical for it mobilizes energy for immediate use for short-term stress. Acute pain, anxiety and other sources of stress elicit endocrine and metabolic activation and an acceleration of most biochemical reactions, including substrate or glucose utilization. This is accompanied with an alteration in nutritional mechanisms, including decreases in appetite and gastrointestinal function, and increases in feelings of nausea and incidences of vomiting (Bonica, 1994). These responses are further influenced by the magnitude of the stress, the duration of the stress, and the physical and psychological state. Physiological distress or imbalance occurs when the stress response is activated too long, too frequently and the body's systems are unable to mediate the response (Sapolsky, 1992). Psychological distress occurs when the situation or environment is appraised by the woman as taxing or exceeding her resources and endangers her well being (Lazarus & Folkman, 1984).

This psychophysiological framework is appropriate for the study of labour stress, as poor labour outcomes cannot be defined solely as a physiological response. Within this psychophysiological framework, there is a continuous adjustment to labour stresses at the affective, cognitive and behavioural levels together with the associated changes in neuroendocrine and autonomic function. The pattern of neuroendocrine and autonomic response varies according to the demands elicited and as a consequence of the coping behaviours engaged. Individual differences can be acknowledged in the specific patterns of psychophysiological response as stress is mediated by the two major pathways: (1) cognitive appraisal and (2) psychophysiological. The importance of this framework is the underlying assumption

that the relationship between the psychophysiological stress response and coping will not be the same for each women's labour experience and that a range of treatment options may be warranted.

Statement of Problem and Research Questions

Labour is a stressful event. In most cases, psychological and physiological mechanisms interact to modulate the demands. Interventions, such as the proposed patient controlled oral intake protocol, may support this stressful, but normal, process and result in positive outcomes, such as satisfactory progress in labour.

Research Questions

Primary research question:

For low risk nulliparous women, at term, does a policy of unrestricted access to food and fluids during labour increase or decrease the incidence of dystocia, when compared to a policy of oral food and fluid restriction?

Other research questions:

For low risk nulliparous women, at term, does a policy of unrestricted access to food and fluids during labour compared to a policy of oral food and fluid restriction increase or decrease the incidence of other selected psychophysiological labour outcomes? Specifically is there:

1. a higher of lower risk of experiencing moderate to severe pain during labour?

2. higher or lower risk of feeling anxious during labour?

3. a higher or lower level of perceived control during labour?

4. a higher or lower risk of experiencing moderate to severe feelings of thirst, hunger, and fatigue during labour?

5. a higher or lower risk of medical and operative interventions, specifically the use of uterine stimulants, epidural analgesia, opioids and operative deliveries?

6. a higher or lower risk of developing intrapartum complications, including moderate ketosis, elevated temperature > 38 degrees centigrade, and maternal gastric aspiration?

7. a higher or lower risk of neonatal complications, specifically: Apgar < 7 at five minutes, fetal cord pH <7.1, elevated temperature > 38 degrees centigrade within the first 24 hours post delivery, hypoglycaemia <2.2 mmol per litre within the first 24 hours post delivery, and admission to the neonatal intensive care nursery within the first 24 hours post delivery?

Chapter 2. Design and Methods

This study was a randomized controlled clinical trial. Recruitment of low risk nulliparous women between 30 and 40 weeks gestation began in August 1996 and ended in June 1998. Women were randomized to either a usual care or intervention group. Data were collected at randomization and post delivery. This chapter describes the details related to the study methodology: specifically, setting, sample, recruitment, randomization, intervention, and description of the primary and secondary outcome measures. Issues related to study implementation, specifically, compliance, data management and analysis will also be described. The chapter will conclude with a description of the process used to obtain human ethics approval.

Setting

This study was conducted at one tertiary teaching hospital in Southeastern Ontario. This hospital is a designated Level 3 regional perinatal referral centre and is the only hospital within the city that provides labour and delivery services. In 1997 there were 2028 births and in the first six months of 1998 there were 1047 births. In this centre, obstetricians, family physicians and midwives provide intrapartum care and labour-nursing care is provided by registered nurses with designated certification in obstetrical procedures. Labour and delivery nursing policies and procedures are developed regionally in collaboration with the Southeastern Perinatal Education Program of Eastern Ontario (PEPEO). The labour and delivery suite consists of a number of birthing rooms, two operative delivery suites, assessment rooms and a family waiting room. The rates of obstetrical interventions, during 1997 and 1998, were similar to other hospitals in southeastern Ontario. In 1997, 91.2 % of labouring women had electronic fetal monitoring; 53% received epidural anaesthesia; 24.6% of all pregnancies had labour induced and 21.8% of all deliveries were caesarean section. In the first six months of 1998, 91.2% of labouring women had electronic fetal monitoring; 50% of all women received epidural anaesthesia; 29.4% of all pregnancies were induced and 20.1% of all deliveries were caesarean section (Source: PEPEO regional database)

Sample Selection Criteria

Participants were eligible for inclusion if they were nulliparous, at or beyond 30 weeks gestation, with a singleton fetus, and no recorded fetal or maternal complications (i.e. Risk Grade A). Nulliparous women were selected because they were more likely than multiparous women to have longer labours and develop dystocia.

Women were excluded according to the following criteria: (a) planned caesarean section (b) planned delivery at another centre (c) maternal illness such that fluids would be restricted during labour and intravenous therapy required (e.g. diabetes, placenta praevia) and (d) fetal compromise such that there was a high risk of caesarean section (e.g. severe fetal growth restriction, fetal anomalies).

Activities Prior to Implementation

Before the study implementation it was necessary to inform and seek collaboration with medical (family medicine, obstetrics, and anaesthesiology) and nursing departments.

Family physicians, with admitting privileges, who routinely provided obstetrical care, were informed, in writing, about the study. A briefing report, an information notice and accompanying letter was provided. In addition, the principal investigator attended an evening journal session in which the study was explained in detail and recruitment strategies discussed. All family physicians that were contacted agreed to have patients in their care, approached for participation. Initially, the research assistant contacted each physician's office on a monthly basis for the names of those women who met the inclusion criteria and were expected to deliver in the next month. This method proved to be inefficient, and a different method of patient identification was developed. Normally each family physician sends a copy of the antenatal record to the labour and delivery suite at or about 30 weeks gestation. The research assistant reviewed these records and identified women who met the inclusion criteria. All family physicians agreed that the research assistant could approach all eligible patients. An information notice about the study was available in each

physician's office. This method proved to be more efficient and the recruitment rate increased.

Obstetricians received an information letter about the study and the principal investigator attended a departmental meeting, at which the study was explained in more detail. All obstetricians agreed to and supported the protocol. Patients were identified through review of all obstetrical clinic charts located on site at the hospital. An information notice about the study was provided to all potential participants.

Support from the Department of Anaesthesia was more difficult to obtain. This will be discussed in more detail later in this chapter.

Nurses on the labour and delivery unit were invited to two meetings at which time the study protocol was explained in detail. As well, a copy of the protocol was left in the communication book. The Clinical Nursing Director and Vice President supported and approved the conduct of the trial.

To increase community awareness about the study the research assistant attended prenatal classes at the local health unit, community centre and childbirth association. Information packages were made available at these sessions.

Recruitment and Randomization

Patients were enrolled into the study beginning in August 1996. Patients were recruited during the last 3-5 weeks of pregnancy by phone call. The study was explained in detail, by the research assistant and phone consent sought. Once consent was obtained the research assistant randomized participants to the experimental or usual care group. Patients received a copy of the consent form with their prenatal package. See Appendix A for the copy of the consent and information notice.

Three hundred and thirty cards (165 marked control and 165 marked experimental) were paced in sealed, opaque envelopes. All 330 envelopes were shuffled, placed in a sealed container by the principal investigator, and then mixed to ensure that selection by the research assistant was by chance. After obtaining a woman's consent to participate the research assistant selected one envelope from the container, opened the envelope and notified the participant of group assignment. The research assistant was directed specifically to only pick one envelope per consenting

woman. There was no opportunity for self-selection of group assignment. At the end of the study, all 330 envelopes had been opened and all originally marked cards were accounted for.

Following randomization, a notice was placed on the antenatal patient record, informing the attending physician and the labour and delivery nursing staff of each woman's enrolment in the study and group assignment.

Intervention

The intrapartum care of all women was provided according to professional standards and hospital policies and procedures for this site.

Usual Care Group

Participants randomized to the usual care group: (a) received no specific or written instructions on oral intake during labour; (b) were permitted ice chips, popsicles or sips of fluid during active labour; and (c) received intravenous therapy when medically indicated for establishment of epidural or administration of oxytocin.

Intervention Group

Participants randomized to the intervention group: (a) received a booklet containing easy to read guidelines on suggested nutrient and fluid intake during labour (See Appendix B); (b) received a follow-up phone call to determine if they actually received the booklet and if they had any questions about the suggested guidelines; and (c) were allowed unrestricted access to their choice of foods and fluids during labour. The research assistant encouraged the participants to follow the guidelines and to eat easily digestible foods, high in complex carbohydrates and to eat and drink, frequent, small amounts in accordance with following pattern: early labour (4 - 6 servings every 3 - 4 hours); active labour (2 - 4 servings every 2 -3 hours); and very active labour (1 -2 servings every hour). One serving included either one carbohydrate or 1/2 cup of a glucose- containing fluid. This pattern was *not prescribed*. Participants were encouraged to bring to the hospital their own food and drink choices, as the hospital only provided a limited selection of food and drink possibilities. Nurses were informed about the protocol but did not actively encourage or discourage oral intake.

Intravenous therapy was established with the initiation of epidural analgesia, oxytocin administration, or a change in risk status.

The oral intake protocol was discontinued when epidural analgesia was initiated or an intrapartum complication (e.g. non-reassuring fetal heart rate patterns) developed such that the participant was more at risk for a caesarean section.

Compliance

The protocol was designed to be patient controlled. It was assumed that participants' wishes during labour would be respected, encouraged and supported as long as there were no contraindications to continuing the protocol. As oral intake was not consistently recorded in the medical record participants were provided a one-page log record to record their intake during labour if they wished. In addition the follow-up questionnaire included two questions that asked participants to describe what they actually consumed during labour before and during hospitalization. The content of these two questions was analyzed and coded into 4 categories as: (1) no intake; (2) usual intake (water, ice chips, popsicles); (3) fluid energy source (e.g. juices, sport drinks); (4) solid energy source (e.g. toast, bagels, muffin, oranges) and (5) restricted intake (e.g. nothing by os (NPO). The investigator coded responses first. The research assistant who was blind to the principal investigator's codes coded the same responses to these questions. Questionable answers were reviewed by the principal investigator for a second time and a decision was made to delete the response when it was not clear what category the response should be in.

Outcome Measures

Primary Outcome Measure: Dystocia

The primary outcome of the trial was the incidence of *dystocia* defined according to criteria set out by the National Consensus Conference on Aspects of Caesarean Birth (1986). A labour was classified, as definite dystocia if during a period of at least four hours after cervical dilatation had reached 3 cm. the mean rate dilatation was <0.5 cm./hr.

Rates were calculated as a change in cervical dilatation/change in time across all points along the labour curve. After admission to the labour and delivery unit,

each cervical examination and corresponding time were abstracted from the patient record. A rate calculation was determined between all points. When the slope was less than .008 (0.5cm/60 min) and the duration between cervical examinations was greater than 240 minutes at any point in the labour then the labour was classified as dystocia. When dystocia was determined, the reference dilatation and time were designated as Dilatation A and Time A and the endpoint dilatation and time were designated as Dilatation B and Time B.

The following case scenario illustrates how dystocia was calculated. In Appendix C is a copy of the analytical program.

<div align="center">Case Scenario</div>

Exam	Time	Dilat*	Rate**	Rate	Rate	Rate	Rate	Rate	Dystocia
1	06:40	4.5							**Time A** **Dilat. A**
2	07:30	4	- .5/50 .01						
3	10:50	6.5	**2/250** **.008***	2.5/200 .01					**Time B** **Dilat. B**
4	12:30	9.5	5/350 .014	5.5/300 .018	3/100 .030				
5	13:10	10	5.5/390 .02	6/350 .02	3.5/260 .02	.5/40 .01			
6	15:15	10	5.5/515 .01	6/465 .01	3.5/265 .01	.5/165 .003	0/130		
7	16:00	10	5.5/560 .009	6/510 .01	3.5/310 .01	.5/210 .002	0/170	0/45	

* Dilat refers to cervical dilatation

**Rate = change in cervical dilatation (cm) /change in time (min)

Secondary Outcome Measures

Data for the secondary outcome measures was collected by chart abstraction or postpartum recall through the completion of a postpartum questionnaire. A copy of the questionnaire is included in Appendix C. Participants were asked to recall their labour experience and rate their feelings of pain, anxiety, personal control and physical discomfort using the measures listed below. Participants were to asked to rate generally how they felt during labour and not at specific times during the labour. This questionnaire was piloted tested in 20 women on the first or second postpartum day. (The chart abstraction form was also pilot tested for reliability of location and availability of the required chart data.) These women were asked to review the questionnaire for clarity, readability and time to complete. Changes were made in the layout of the questionnaire. The questionnaire took about 20 minutes for women to complete.

Labour and Delivery Outcomes

Labour outcome measures were determined from chart abstraction. The following measures were collected.

1) Induction of labour: Labours were classified as inductions if they were induced for medical, obstetrical or other reasons including labours in which there was prolonged rupture of membranes greater than eighteen hours and no evidence of labour contractions or dilatation of cervix (i.e. cervical dilatation < 3 cm).

2) Augmentation of labour: Labours were classified as augmentation (and not induction) if uterine stimulants were administered during labour, after admission to the labour and delivery suite and when the criteria for induction were not met.

3) Fetal surveillance: Fetal surveillance was either external or internal. External fetal surveillance included those cases in which the external fetal monitor was applied at any point during the labour after the initial admission fetal monitor strip was obtained. Internal fetal surveillance included those cases in which an internal fetal scalp electrode with or without the insertion of an intrauterine pressure device. Some women may have received both external and internal fetal surveillance.

4) Delivery: Deliveries were classified as spontaneous vaginal or vacuum assisted (without forceps), forceps assisted or caesarean section. Some forceps assisted deliveries included those deliveries in which both the vacuum and forceps were applied. Caesarean section births were further classified as failure to progress, fetal distress and other. The indications for caesarean section were determined from the discharge summary. Deliveries were classified as fetal distress if there was clear documentation of fetal distress (i.e. cord artery pH < 7.1 and/or buffer base > 34). If there was documentation of both fetal distress and failure to progress these deliveries were classified as fetal distress. If there was documentation of fetal heart rate abnormalities and failure to progress but no laboratory evidence of fetal distress (i.e. cord artery pH < 7.1 and/or buffer base > 34) these deliveries were classified as failure to progress.

Pain

Information about participants' pain was obtained from two sources: (a) the participant's perception of their pain as measured in the postpartum questionnaire, and (b) pain management strategies used during labour as documented in the medical record. Participants completed the short version of the McGill Pain Questionnaire (Melzack, 1975) and a visual descriptor scale to measure pain intensity. This scale was used to detect differences between groups in reported frequencies of moderate and severe pain descriptors and intensity. The short-form McGill Pain Questionnaire (SF-MPQ) consists of 15 representative words from the sensory (n=11) and affective (n=4) domains of the standard, long form of the MPQ. Using this measure, women in labour commonly describe labour pain as pounding, shooting, stabbing, sharp, cramping, aching that is tiring, exhausting, fearful, rhythmic and intense (Melzack et al., 1984). The SF-MPQ correlates highly with the long form MPQ, is sensitive to clinical therapies and discriminates among different pain syndromes and is more appropriate when time to administer or time to complete is a factor (Melzack, 1987; Melzack & Katz, 1992). This scale has been used to measure labour pain during labour; in this study it was used as a recall measure of pain during labour.

Data were also collected from participants' medical records about the use of and description of pharmacological pain management strategies, specifically, the incidence, timing, and dose of narcotic and epidural analgesia.

Anxiety

Women's level of anxiety was measured with the A - State Scale of the State - Trait Anxiety Scale (Spielberger et al., 1970). The A-State Scale was administered to detect differences in levels of state anxiety. This scale has been tested in psychometric studies, including studies associated with labour and has yielded evidence of reliability and validity. Reliability coefficients have been reported as high 0.9 (Hodnett & Osburn, 1989b) and within the range of 0.7 to 0.9 (Beck et al., 1980; Hodnett & Abel, 1986; Lederman et al., 1979). The mean state anxiety score for a normative sample of working adult females has been reported as 35.2 ± 10.6 (Spielberger et al., 1970)

Personal Control

Women rated their experience of personal control during labour with the Labour Agentry Scale (LAS), Form C, a 29 item summated rating scale. Subjects rated on 7 point Likert-type scales anchored by "rarely" and "almost always" their perceptions of control during childbirth. In over 30 studies of women's experiences of personal control during labour Chronbach's alpha coefficients are consistently reported greater than 0.9 (Hodnett, 1982; Hodnett & Abel, 1986; Hodnett & Osburn, 1989b). Low scores indicate a sense of low control and high scores indicate a sense of high control. Variations in scores have been reported. Hodnett and Osborn (1989) evaluated the effect of continuous intrapartum professional support on selected childbirth outcomes. The mean postpartum LAS scores were 147.6 and 148.7 for the general and Lamaze prepared control group and 151.1 and 166.3 for the general and Lamaze prepared intervention group. In another study, Hodnett and Abel (1986) reported mean LAS scores of 169.5 in women who elected home births.

Physical Feelings of Discomfort

Participants rated their perception of thirst, hunger, nausea and fatigue on 7 point scales anchored at each end with descriptors such as "worst possible nausea" to

"no nausea". These scales were used to determine the difference in moderate to severe feelings of physical discomfort, possibly, associated with nutrition and hydration imbalance during labour.

Fluid and Nutrient Balance

As medical record documentation of oral intake during labour is not consistent or reliable, this was not used as a measure of intake. Medical record documentation of intravenous intake is recorded on a 24-hour intake and output record. The total amount of intravenous intake and the type of solution administered were noted. When urinalysis measures were documented, the presence of ketonuria was noted as mild (< 1+), moderate (1+ to 3+), or severe (>= 3+).

Maternal and Neonatal Complications

Maternal and neonatal complications were determined from chart review. The list of potential maternal complications included incidence of operative delivery, incidence of gastric aspiration, maternal elevated temperature > 38 degrees centigrade or seizures during labour and maternal death. The list of potential neonatal complications included: the incidence of an Apgar score < 7 at 5 minutes, fetal cord pH < 7.10, cord artery buffer base > 34, elevated temperature > 38 degrees centigrade, hypoglycaemia (venous glucose < 2.2 mmol per litre within 24 hours post delivery), a stay in a neonatal intensive care unit > 24 hours, and neonatal death.

Additional Measures: Labour Nursing Support

Provision of physical comfort measures during labour is a component of labour nursing support. It was assumed that women in the intervention group would control their own oral intake. It was unknown whether nurses who cared for women in the intervention group would provide the same or different amounts of supportive care. Given the known benefits of labour support, differing levels of support within the study groups could be a co-intervention. Therefore, participants were asked to recall their labour experiences and rate the labour nursing support provided using the ordinal version of the Labour Support Questionnaire (LSQ)(Hickey, 1992). The LSQ is 20-item questionnaire that measures perceived support during labour, including

emotional support, information, physical comfort measures, and advocacy. A Chronbach's alpha reliability coefficient of 0.9 has been reported (Hickey, 1992).

<div align="center">Sample Size</div>

The rate of dystocia in North American hospitals is consistently reported as 40% of all deliveries (Fraser, 1992; Boylan, 1989). In centres where aspects of active management labour protocols are implemented, 5% to 50% decreases in the incidence of caesarean sections related to failure to progress are reported (Boylan, 1989; Turner et al., 1988a). A 38% reduction in risk from 40% to 25% would be clinically relevant and consistent with the effect of other strategies. Therefore, to adequately test the hypothesis that a policy of unrestricted access to food and fluids decreases the dystocia rate by 38%, with a power of 80% and a two - tailed alpha of 0.05; the calculated sample size was 165 per group for a total sample size of 330 participants (Borenstein & Cohen, 1988).

<div align="center">Summary of Research Design</div>

Four hundred and fifty five women were contacted, via phone, after 30 weeks gestation and were informed about the study, if they had not already been informed by their physician or through prenatal classes. If the woman agreed, the research assistant explained the study in more detail, according to a set script, and sought phone consent. One hundred and twenty five (28%) of those contacted did not wish to participate. Most often, the reason for non-participation was concern and anxiety about their first labour and delivery. Some women were not interested in hearing about the study or being involved in research. Women who wished to speak further with their physician or husband were given this opportunity. A follow-up phone call was made at an agreed to time. Three hundred and thirty women consented, were randomized and enrolled in the study. Of these, one delivered outside the designated centre and a second withdrew her participation after being randomized to the experimental group. She notified the research assistant after her delivery, that after consultation with her husband, she decided that she would not participate in the study. Patient recruitment had ended at this stage and another subject was not

recruited. Therefore, the study sample consisted of 165 women randomized to the control group and 163 women randomized to the intervention group.

Figure 1. Summary of Research Design

Women identified as low risk (Grade A), > 30
weeks gestation through antenatal chart
review approached for participation
(n= 455)

Consent and participation in
trial confirmed
(n= 330)

Intervention group
(n= 165)

Usual care group
(n= 165)

1 withdrawal and 1 delivery
outside centre
(n= 163)

Intervention
Information about food and
fluids during labour
Unrestricted access to oral
intake during labour

Control
No prelabour information
Restricted oral intake during
labour

Data collected from labour
record
(n= 328)
Postpartum questionnaires sent

Returned questionnaire
(n= 124)

Returned questionnaire
(n=133)

Data Management and Quality Monitoring

Data were collected from two sources: (1) the patient record and (2) postpartum questionnaire.

The data collection form for the patient record abstraction was developed in Microsoft Access® 97 (1988-1997 Microsoft Corporation). The database variables were identified as numerical, categorical, date, or time. This ensured that the wrong

type or form of variable could not be entered (e.g. delivery date could only be entered as a datetime variable in the format of month-day-year). Questions about coding or inclusion of variables were discussed immediately with the investigator and changes in coding or decision rules were logged and documented. One research assistant entered all medical record data directly into the computerized database. This database was backed up daily onto a second hard drive. The final database was filed and locked in the nursing research office. Once the complete database was obtained the investigator transferred the database file to working spreadsheet files, ensuring the integrity of the original database.

To ensure the accuracy of the data abstraction and reliability of the coding, the investigator reviewed all the medical records (n=328) and entered into a second database all date and time variables related to admission, delivery, cervical examinations, augmentation, and induction. In addition, the logic of the datetime variables associated with interventions (e.g. epidural) were checked to see if they occurred between admission and delivery time. Only cervical examinations conducted during labour, either in the admission unit or in the labour and delivery suite were entered. As this was the primary outcome of the research, 100% accuracy was required. These two databases were compared. Of the approximate 5760 entries for the primary outcome data, 16 coding errors in abstraction were detected for an error rate of 0.28%. These errors were related to either minor typographical errors or in one case, a page of the labour record was missed. These errors were corrected ensuring that the primary outcome data were 100% accurate.

Questionnaire data were entered into a similar database by a second research assistant. To ensure accuracy of coding 10% of the questionnaires were randomly selected and double entered by the first research assistant. In this check there were 4 coding errors found in a possible 363,660 entries, a negligible error rate. Because these scales are summated scores, a decision was made to only calculate scores when at least 75% of the scale statements were answered (i.e. 20 for LAS, 15 for S-Anxiety and 15 for Support). Missing values were replaced with the scale item means, consistent with the sum function in the SAS program

All questionnaires, coding books, logs and computer databases were maintained in a secure and locked office sited in the Nursing Research Unit at the site.

Statistical Analyses

Using the intention to treat approach, results were analyzed on all women who underwent randomization for whom data were available (N= 328/330 randomized). Data were analyzed using the SAS®(6.11) (SAS Institute).

The first step of the analysis described the data elements and ensured the reliability of the data. Frequency counts on categorical variables and univariate analysis on continuous variables were conducted.

To answer the primary research question, the difference in proportions between the two groups in dystocia was determined with the Chi - Square test. An odds ratio and confidence interval of 95 % was estimated around the observed difference in proportions, with the control group as the reference group.

To answer the other research questions, the difference in proportions between the two groups for the rates of categorical variables (e.g. ketonuria, medical interventions, intrapartum complications and neonatal complications) was determined with the Chi - Square test. An odds ratio and confidence interval of 95% were calculated around the observed difference in proportions. For comparison of continuous outcome measures (labour length, anxiety, pain, control, labour support) independent sample means scores were calculated. When continuous outcome data were normally distributed, the Students t − test was used for comparison of sample mean scores. Difference in means and 95% confidence limits were calculated for all continuous outcomes.

The level of statistical significance was $p < .05$ (two-tailed) for all analyses.

Ethical Considerations

The University of Toronto, Human Subject Certification for Physical Sciences and Life Sciences, the Kingston Health Sciences Research Ethics Board, and involved departments approved the research protocol. (See Appendix D).

The Anaesthetic Department raised concerns about the risk and scientific validity of the protocol. The obstetrical anaesthetist was consulted in the early stages

of the research proposal development and appeared to be supportive of the trial. The proposal was fully developed, presented to Anaesthetic Rounds and prepared for submission to the local Research Ethics Board (REB). Concern was raised at this point by the Head, Department of Anaesthesia and anaesthetic departmental support for the study was not obtained. The investigator met further with anaesthetic department designates; reviewed and summarised the anaesthetic risk literature in detail; and consulted with the Chief, Medical Staff and Director, Research of the Faculty of Health Science. The proposal was submitted to the REB with this detailed documentation but not anaesthetic departmental approval. Meanwhile, site approval was sought and obtained at two alternate locations in another city.

The REB approved the conduct of the research pending the addressing of anaesthetic concerns. Anaesthetic departmental approval was eventually obtained with the proviso that the food and fluid protocol would be discontinued if women in the experimental group received epidural analgesia. This amendment was accepted and REB approval was obtained.

The research assistant obtained informed consent was obtained by phone. Participants were free to withdraw at any time and their involvement or non-involvement did not impact care received. Each participant received written information about the study and a copy of the consent. Patient confidentiality was maintained through the coding system that only the investigator had access to. All records were maintained in a locked file in a Nursing Research Unit office.

Chapter 3: Results

This chapter is organized as follows. First the sample is described in two sections: (1) the characteristics of participants at randomization (n= 328) and (2) the characteristics of respondents who returned a postpartum questionnaire (n= 257). Second, the results of the data analysis to determine the effect of the intervention on the primary outcome are described. This is followed by a description of the results concerning the effect of the intervention on other selected psychophysiological outcomes and rates of intrapartum and newborn complications.

Characteristics of Participants

At Randomization

There were no significant differences in baseline characteristics of the women at randomization. Women, on entry to the study were low risk and reported similar rates of smoking during pregnancy, alcohol consumption and pregnancy related risk factors. The incidence of reported family, medical and pregnancy related risk factors, as documented on the Ontario Antenatal Record was similar between the two groups. These risk conditions did not change the physician assignment of a low risk grade A status to the pregnancy. Women classified as risk grade B because of advanced maternal age, greater than 35 years, were included in the study if there no other risk factors were identified. (Table 2)

Table 2
Characteristics of participants at randomization

	Intervention n=163	Control n = 165
Mean age	28.3 yrs ± 5.2	27.9 yrs ± 4.7
Risk Grade A	159 (98%)	161 (98%)
Smoking during pregnancy	38 (23%)	35 (21%)
Alcohol during pregnancy	18 (11%)	15 (9%)
Gravida 1	120 (74%)	112 (68%)
Gravida 2	32 (20%)	44 (27%)

Characteristics of Respondents

Three hundred and twenty eight women were sent the post-partum questionnaire package, containing a cover letter, the questionnaire, copy of the

consent form and a stamped, self-addressed envelope. Some women were given their package during their hospital stay. If the questionnaire was not returned within an appropriate timeframe (approximately 2 weeks) a follow-up phone call either reminded the participant to respond and return the questionnaire or determined if the questionnaire had arrived in the mail. A second reminder phone call was made to non-respondents if there was no response after the first follow-up phone call. Two hundred and sixty participants returned questionnaires, for a return rate of 79%. Three respondents reported that they had mailed the questionnaire, but it failed to show up in the investigator's mail. Therefore, the actual response rate was 78%. The return rate was affected by the following factors: (1) misperception by participants about the usefulness of their feedback and (2) loss of questionnaires. Based on the feedback given to the research assistant when she phoned for questionnaires, many women wrongly perceived that they were no longer part of the study or their feedback would not be useful, because their ability to participate in the protocol or answer the questions was affected by unplanned induction, caesarean section or complications. The covering letter on the questionnaire clearly stated that all feedback was important regardless of labour or delivery complications or experience. Furthermore, when the research assistant called, if questionnaires were not returned, she too reinforced that all feedback was important and that all participants were considered part of the study. Secondly, it was assumed that some questionnaires were lost in the mail through the central mailing service at the university campus site. This service was used as a cost saving strategy because the investigator was only charged postage on returned questionnaires. Unfortunately, the primary mailing return address was not that of the principal investigator and the returned questionnaires were routed first to the university post office, then to the hospital post service and then to the investigator's internal hospital mail box. In this process there were many opportunities to misplace mail. These losses could not be tracked, except when respondents notified the research assistant that they had already returned a questionnaire. These respondents when asked (n=5) were reluctant to complete a questionnaire for a second time.

Nevertheless, 81% (n=133) of women in the control group and 76% (n=124) of women in the intervention group returned questionnaires. There were no significant differences in demographic characteristics of respondents between groups. Most were married, educated, working women, English speaking with a reasonable source of income (Table 3).

Table 3
Demographic characteristics of respondents*

Characteristic	n	Intervention	n	Control
Marital Status	124		133	
Married		88 (71%)		103 (77%)
Common-law		26 (21%)		24 (18%)
Single		8 (7%)		6 (5%)
Highest level of education completed	124		132	
Primary school		3 (2%)		6(5%)
Secondary school		29 (23%)		27 (21%)
Community college		49 (40%)		58 (44%)
Undergraduate university		33 (27%)		34 (26%)
Postgraduate university		9 (7%)		7 (5%)
English speaking	124	115 (94%)	133	124 (93%)
Main activity in past 12 months	124		133	
Working		97 (78%)		100 (75%)
Looking for work		2 (2%)		1 (1%)
School		10 (8%)		14 (11%)
At home		13 (11%)		17 (13%)
Combined total income	117		130	
No income		3 (3%)		2 (2%)
< $14,000		17 (15%)		20 (15%)
$15000 - $29,999		15 (13%)		22 (17%)
$30,000 - $44,000		30 (26%)		18 (14%)
$45,000 - $59,000		19 (16%)		25 (19%)
$60,000 - $74,999		19 (16%)		21 (16%)
> $75,000		14 (12%)		21 (16%)

* This demographic information was collected from the postpartum questionnaire.

An analysis of the baseline characteristics at randomization by group and by respondents showed that the respondents were different than the non-respondents. Non-respondents were more likely to have smoked and consumed some alcohol during pregnancy in comparison to respondents. The distribution of these characteristics was similar between groups. (Table 4)

Table 4
Distribution of baseline characteristics between respondents and non-respondents

	Intervention (n= 163)		Control (n= 165)	
	Respondent (n=124)	Non respondent (n=39)	Respondent (n=133)	Non respondent (n=32)
Mean age	28.8 ± 5.1	26.8 ± 5.4	27.9 ± 5. 4.6	27.6 ± 5.4
Smoking during pregnancy	22 (18%)	16 (41%)	22 (17%)	14 (44%)
Alcohol during pregnancy	11 (9%)	7 (18%)	11 (8%)	4 (13%)

Women in both groups were similar with respect to weight gain, height and prepregnancy weight to height ratio. Many experienced some degree of nausea and vomiting during pregnancy. (Table 5)

Table 5
Pregnancy characteristics of respondents

	n	Intervention	n	Control
Mean pre – pregnancy weight (kg)	122	65.8 ± 16.9	131	65.4 ± 13.7
Mean delivery weight (kg)	122	81.4 ± 16.7	131	81.3 ± 14.0
Mean weight gain (kg)	122	15.8 ± 6.8	131	15.8 ± 6.7
Mean height (cm)	122	162.0 ± 6.5	131	163.4 ± 6.4
Mean weight / height ratio (kg/cm)	122	0.4 ± 0.1	130	0.4 ± 0.1
Nauseated during pregnancy	123	84 (68%)	133	88 (66%)
Vomiting during pregnancy	124	57 (48%)	133	62 (47%)

Compliance

Women described what they ate and drank during labour at home and in hospital on the postpartum questionnaire. One question asked about foods and fluids consumed at home, while in early labour and the second question asked about their intake during labour in the hospital. In 5/257 responses a decision was made to not include the respondents' answer as it was both the research assistant's and the principal investigator's view that the responses were not describing the woman's intake during labour. Four of these five responses concerned the intake question about food and fluids consumed during early labour at home. This question was particularly difficult for women who were admitted to the hospital for induction as they were in the hospital and in early labour. The descriptive responses were categorized to two levels: (1) glucose intake or (2) no glucose intake. Glucose intake was coded if women reported that they ate or drank some source of glucose. No glucose intake was coded if women reported that they were restricted in their oral intake to ice chips, popsicles, or nothing. The descriptive comments and answers to these questions provided descriptive data to determine if women were able to eat and drink during labour. Women were also asked in an open-ended question to provide comments about eating and drinking during labour.

Table 6
Food and fluid intake during early labour at home and in the hospital*

	Intervention (n= 163)	Control (n=165)	p =
Consumed foods and fluids at home	85 (51%)	79 (48%)	0.5
Consumed foods and fluids in hospital	63(38%)	14(8%)	.001**

*Note: It should be noted that information about food and fluid consumption is only available from the postpartum questionnaire. Therefore, if no questionnaire data were available, intake was not known and coded as missing.

** $\chi 2 = 40.7$, p = 0.001

During early labour at home many women in both groups tended to eat and drink what they normally would. Seventy-nine per cent (88/109) of respondents in the intervention group reported that they consumed simple foods and fluids (e.g. fruit cup, cereal, fruits, juices, Gatorade) as outlined in the educational booklet and 65% (79/120) of women in the control group reported eating and drinking some source of glucose. During labour, in the hospital there was a significant difference in what the intervention and control group actually consumed ($\chi2 = 40.7$ p < .001). Women in the control group predominantly consumed ice chips, popsicles and water. Women in the intervention group women consumed a variety of juices and drinks and simple carbohydrate snacks (e.g. toast, fruits, and crackers). Of the respondents in the intervention group 56% (63/119) reported that they ate or drank a glucose based source in comparison to only 13% (15/120) in the control group.

Women in the intervention group commented about aspects of eating and drinking during labour. Some of the comments were: (a) during the more active phases I felt nauseated and only wished fluids; (b) I was starved and glad to be able to eat and drink something; (c) I wished I could have eaten after my epidural as I felt more comfortable; (d) I appreciated the choice and control; and (e) I found eating particular foods and fluids (i.e. warm tea) soothing and comforting

Participants' were not able to continue eating and drinking if they chose to have epidural analgesia. Once epidural analgesia was initiated, oral intake was restricted to ice chips and sips of fluid (i.e. usual care) and an intravenous was started. The incidence of epidural analgesia and intravenous establishment will be reported in the section on secondary psychophysiological outcomes and interventions.

Participant's ability to comply with the protocol was not affected by the support provided by the nurses during labour. The labour support scale scores for the intervention group (n=118) were 39.8 ± 7.8 and for the control group (n=133), 39.3 ± 7.9. Two statements in the labour support scale were analyzed further, specifically questions 5 and 11. Question 5 asked the participants to rate whether the nurse offered ice chips or fluids or drinks. Participants in the intervention group reported:

never (22%, n= 26); occasionally (44%, n= 52); and frequently (34%, n= 40). Participants in the control group reported: never (21%, n= 28); occasionally (35%, n= 48) and frequently (42%, n= 56). These ratings support the descriptive comments of some of the participants that suggested that nurses for the most part did not actively encourage or discourage intake. Question 11 asked the participants to rate how often the nurse supported decisions. Participants in the intervention group reported: never (7%, n= 8); occasionally (35%, n= 42); and frequently (58%, n=70). Participants in the in the control group reported: never (15%, n= 20); occasionally (34%, n= 45) and frequently (51%, n= 67).

Women in the intervention group were able to comply with the protocol in that their oral food and fluid intake was significantly different than that of the control group. Nursing support, specifically, in relation to encouragement of foods and fluids and support of decisions was not different between groups.

Primary Outcome

The primary research question was: What is the effect of a policy of unrestricted versus restricted access to food and fluids during labour on the incidence of dystocia in uncomplicated nulliparous labours?

There were no significant differences between women in the intervention group in comparison to women in the control group in the incidence of dystocia as measured by the criteria proposed by the Canadian Consensus Conference on Aspects of Caesarean Birth (36% vs. 44%, OR = 0.7, 95% C.I. = 0.5, 1.1). Nor were there any significant differences in the incidence of dystocia when a rate criteria of 1.0 cm/hr was substituted for the 0.5 cm/hr. There was a non-significant trend towards fewer women in the intervention group developing dystocia in comparison to women in the usual care group (Table 7).

Table 7
Comparison of the likelihood of developing dystocia using the Canadian consensus
rate criteria of 0.5 cm/hr or a rate criteria of 1.0 cm/hr

	Intervention n=163	Control n = 165	OR	95% C.I
Incidence of labours classified as dystocia with the 0.5 cm/hr rate criteria	58 (36%)	72 (44%)	0.7	0.5,1.1
Incidence of labours classified as dystocia with the 1.0 cm/hr rate criteria	82 (50%)	100 (61%)	0.7	0.4, 1.0

As described in the methods section, rates of cervical dilatation were determined between each documented cervical dilatation. For each classification of dystocia a reference time and dilatation were designated as the time and dilatation used as an initial reference point for the purpose of calculating the rate (i.e. Time A and Dilatation A). A terminal time and dilatation was designated as the time and dilatation used as an end point (i.e. Time B and Dilatation B). Univariate analysis of the reference dilatations (n= 130) showed a mean reference dilatation of 5.1 ± 2.2 cm, a median of 4 cm and a mode of 3 cm. Univariate analysis of the terminal dilatations (n= 130) showed a mean of 6.8 ± 2.5 cm, a median of 6 cm and a mode of 10 cm. Three terminal dilatations were less than 3 cm. In these three cases the vaginal examinations indicated a cervical dilatation greater than 3 cm at some point in the labour with subsequent examinations documenting cervical dilatation less than 3 cm. Plotting of the terminal dilatation by group showed that the terminal dilatations followed a bimodal pattern (Figure 3).

Figure 2: Distribution of terminal dilatations used in the calculation of definite dystocia
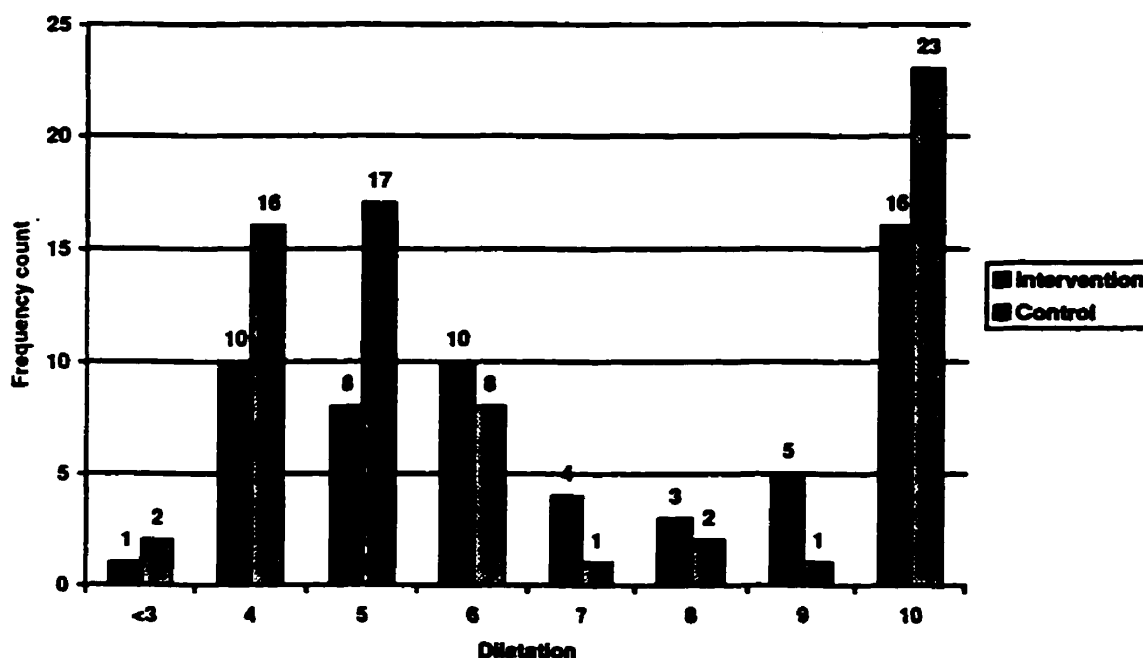
Secondary Outcomes

Labour Duration

Three different calculations for labour length were determined: (1) the length of labour as assessed by the caregiver and documented in the medical record; (2) the length of labour as assessed by the participant and documented in the postpartum questionnaire; and (3) the length of labour from admission to the labour and delivery suite to delivery (Table 8).

The lengths of labour as documented by caregivers and perceived by respondents were similar between groups. Participants reported longer labour durations when compared to the caregivers' assessment of labour duration. There was also a wide degree of variation in patient-reported labour length (min-max = 1.5 hours-18 hours). Caregiver assessment of labour length showed similar degrees of variation. The length of labour, from admission to the labour and delivery suite to delivery was also similar between groups and slightly shorter than the caregiver report

of labour duration. More women (54%, n=89) in the intervention group when compared to women (45%, n=75) in the control group were admitted to the labour and delivery unit before 3 cm dilatation, but the difference was not statistically significant ($\chi 2 = 2.4$, p = .12).

Table 8
Comparison of labour length and admission dilatation

	Intervention	Control	Statistic	p =
Documented length of labour (hrs)*	11.7± 6.3 (n= 153)	11.7± 5.9 (n= 159)	t = -0.03	0.98
Perceived length of labour (hrs)**	19.9 ±12.2 (n=117)	20.6 ± 16.6 (n=127)	t =0.36	0.1
Length of time from admission to delivery (hrs)	10.3 ± 6.6 (n=163)	9.5± 5.6 (n=165)	t = - 1.42	0.15
Number of women with cervical dilatation less than 3 cm on admission	89(54%)	75 (45%)	$\chi 2 = 2.4$	0.12

*Excludes those labours for which there was no start time documented (i.e. planned C/S for breech or emergency C/S with no labour).
**Perceived length of labour was only calculated for participants who returned the postpartum questionnaire and answered that specific question

Interventions during Labour

The frequency of obstetrical interventions was similar for both groups (Table 9). Fifty–two (32%) women in the intervention group and 43 (26%) women in the control group had labour induced. Reasons for induction included postdates > 41 weeks, 24 (47%) in the intervention group and 23 (55%) in the usual care group; increased blood pressure, 9 (18%) in the intervention group and 7 (17%) in the usual care group; prolonged rupture of membranes greater than 18 hours with no contractions, 11 (22%) in the intervention group and 9 (22%) in the usual care group and other, 7 (14%) in the intervention group and 3 (7%) in the usual care group. The rates for spontaneous vaginal delivery, forceps delivery, vacuum delivery and caesarean section for both groups are also listed in Table 9. There were no significant differences between groups in mode of delivery or rationale for operative deliveries. The overall caesarean section rate was 22% (n=73).

Table 9
Comparison of labour and delivery outcomes

	Intervention (n=163)	Control (n=165)	Comparison statistic	p =
Induction of labour	51 (32%)	42 (26%)	$\chi2 = 1.7$	0.18
Any augmentation during labour	92 (57%)	91 (55%)	$\chi2 = 0.09$	0.76
Augmentation started at cervical dilatation < 3cm	40 (25%)	34 (21%)	$\chi2 = 0.62$	0.43
Mean dilatation of cervix at oxytocin administration	4.0 cm ± 2.7 (n=92)	4.5 cm ± 3.0 (n=89)	t = 0.70	0.49
Types of uterine stimulants administered:			$\chi2 = 1.3$	0.73
Prostin only**	6 (4%)	7 (4%)		
Oxytocin only	63 (39%)	69 (42%)		
Both prostin and oxytocin	29 (18%)	22 (13%)		
Artificial rupture of membranes	97 (60%)	95 (58%)	$\chi2 = 0.10$	0.76
Episiotomy	67 (42%)	61 (37%)	$\chi2 = 0.66$	0.42
External fetal monitoring	160 (98%)	163 (99%)	$\chi2 = 0.00$	0.99
Internal fetal monitoring	100 (61%)	98 (59%)	$\chi2 = 0.19$	0.66
Delivery method			$\chi2 = 2.02$	0.55
Spontaneous vaginal	68 (42%)	80 (49%)		
Vacuum only	32 (20%)	31 (19%)		
Forceps*	21 (13%)	22 (13%)		
Caesarean section	41 (25%)	32 (19%)		
Caesarean section indication			$\chi2 = 3.12$	0.54
Failure to progress	29 (18%)	22 (14%)		
Fetal distress	8 (5%)	4 (3%)		
Other (e.g. breech)	4 (3%)	6 (4%)		

*Includes deliveries in which both the vacuum and forceps were used. **Inductions only

Pain

Participants were asked to recall their labour experiences and rate various aspects of pain associated with labour. Two hundred and forty nine respondents rated the intensity of their pain on a five point visual descriptor scale anchored with 0 = no pain to 5 = excruciating pain. Twenty seven percent (n = 32) of intervention group respondents and 32% (n = 42) of control group respondents rated labour pain as distressing; 25% (n = 30) of intervention group respondents and 19% (n = 24) of control group respondents rated labour pain as horrible; and, 18 % (n = 21) of

intervention group respondents and 19% (n = 25) of control group respondents rated labour pain as excruciating. Overall, approximately 70% of all respondents reported labour pain intensity as distressing, horrible or excruciating.

Using the SF-MPQ respondents described the affective and sensory components of their labour pain on a 4 point Likert scale according to the categories of none, mild, moderate or severe. The most common descriptors were "sharp", "cramping" and "tiring-exhausting". Respondents reported moderate or severe levels of pain as throbbing (38%); shooting (47%); stabbing (51%); sharp (69%); cramping (82%); gnawing (31%); hot and burning (29%); aching (65%); heavy (49%); tender (32%); splitting (38%); tiring and exhausting (75%); sickening (35%); fearful (31%); and punishing and cruel (28%). There were no differences between groups in how they described or rated their pain. The mean sensory, affective and total MPQ scores were not significantly different between groups (Table 10).

Epidural analgesia was the most common pain management strategy used. Seventy six percent (n = 249) of the sample received epidural analgesia, 79% (n = 129) in the intervention and 73% (n = 120) in the control group. Epidural analgesia was initiated at a mean cervical dilatation of 3.8 ± 1.8 cm in the intervention group and 4.2 ± 2.0 cm in the control group. There were no differences in the use and type of intramuscular opioids administered.

Table 10

Comparison of aspects of labour pain

	n	Intervention	n	Control	Statistic	p =
Mean pain intensity score*		3.2 ± 1.2 (n= 121)	130	3.2 ± 1.2 (n=133)	$t = -0.37$	0.71
Moderate/ severe pain	119	83 (70%)	130	91 (70%)	$\chi2 = 1.8$	0.18
Mean sensory pain score	121	15.3 ± 6.1	132	14.7 ± 6.3	$t = -0.7$	0.46
Mean affective pain score	121	5.1 ± 2.9	132	4.7 ± 2.9	$t = -1.2$	0.23
Mean total pain score	121	20.5 ± 7.7	133	19.3 ± 8.2	$t = -1.2$	0.25
Epidural analgesia	163	129 (79%)	165	120 (73%)	$\chi2 = 2.1$	0.14
Mean cervical dilatation at epidural initiation (cm)	124	3.9 ± 1.8	112	4.2 ± 2.1	$t = 1.4$	0.15
Epidural started < 3cm cervical dilatation	163	31 (19%)	165	21 (13%)	$\chi2 = 2.3$	0.13
Opioid administered	163	98(61%)	165	99 (60%)	$\chi2 = .01$	0.92
Morphine		25 (16%)		37 (22%)	$\chi2 = 3.3$	0.19
Demerol		73 (45%)		62 (38%)		

Anxiety, Personal Control and Labour Support

Participants were asked to recall their labour experience and rate statements about feelings of control (LAS), anxiety (S-Anxiety scale) and support provided by nurses. Cronbach's coefficient alpha was determined for the three scales. For the LAS scale the item-total correlations ranged between 0.28 to 0.78, and the Cronbach's alpha reliability coefficient was 0.94; for the Spielberger State Anxiety Scale the item-total correlations ranged between 0.29 and 0.74, and the Cronbach's alpha reliability coefficient was 0.93. For the Labour Support Scale the item-total

correlations ranged between 0.35 and 0.65 and the Cronbach's alpha reliability coefficient was 0.89.

There were no significant differences in anxiety, control or support scores between groups (Table 11).

Table 11
Comparison of anxiety, control and support scores

	n	Intervention	n	Control	Statistic	p=
S- Anxiety Score	121	44.1± 12.4	133	41.8±11.3	t = -1.5	0.12
Labour Agentry Score	121	155.2± 29.2	131	158.4± 25.4	t = .98	0.33
Labour Support Score	123	38.9± 9.8	133	39.3 ± 7.9	t = .32	0.75

Perceptions of Thirst, Hunger, Nausea and Fatigue

Women rated their feelings of thirst, hunger, nausea and fatigue during labour on a 7 point Likert type scale, linked at one end with the worst possible thirst or hunger to the other end with no thirst or no hunger. There were no significant differences in ratings between groups (Table 12).

Table 13
Comparison of perceptions of moderate or severe feelings of thirst, hunger, nausea and fatigue

	Intervention (n = 133)	Control (n = 122)	χ^2	p =
Moderate or severe thirst	79 (65%)	95 (71%)	1.31	0.25
Moderate or severe hunger	17 (14%)	18 (13%)	0.01	0.92
Moderate or severe nausea	39 (32%)	34 (26%)	1.28	0.26
Moderate or severe fatigue	74 (61%)	76 (57%)	0.05	0.83

Thirst, hunger, nausea and fatigue were measured on a 7-point scale with the anchors "no thirst/hunger/fatigue" to "worst possible thirst/hunger/fatigue". Moderate or severe ratings were defined as scale readings greater than or equal to 5 and were only available from respondents who answered that question.

The perception of thirst was more severe than that of hunger. Greater than 60% of women respondents in both groups reported moderate to severe thirst and approximately 13% reported moderate to severe hunger. These scale ratings were consistent with the written descriptive comments, in that feelings of severe thirst were reported and commented on more frequently than feelings of severe hunger. Moderate or severe thirst was reported by respondents in the intervention group (65%, n=79) and by respondents in the usual care group (71%, n = 95). Moderate or severe nausea was reported by respondents in the intervention group (32%, n = 39) and respondents in the control group (26%, n = 34). For most respondents, labour elicited moderate to severe feelings of thirst and fatigue and to a lesser extent, feelings of nausea and hunger.

Fluid and Nutrient Balance

Ketones > 0.5 were detected in 22% (n = 36) and 22% (n = 36) of labours in both the intervention and control groups, at a mean dilatation of 4.7 ± 3.1 cm and 4.6 ± 2.8, respectively. There was no difference between groups with respect to the number of ketone readings noted or the severity (Table 12). Moderate ketone levels were detected in 17% (n = 27) and 17% (n = 28) of labours in the intervention and control groups, respectively. Severe ketone levels were detected in 6% (n = 9) and 5% (n = 8) of labours in the intervention and control groups, respectively. In 6% (n = 12) of women in the intervention group and 5% (n = 7) of women in the control group, ketones were detected in second subsequent readings. In 2 cases in the intervention group and 1 case in the control group, ketones were detected three times during the course of labour.

Intravenous therapy was initiated in 85% (n = 278) of all labours in this study group, generally between 3 and 4 cm dilatation, usually for the initiation of oxytocin or epidural analgesia. The mean intravenous intake during the course of labour (and immediate postpartum period while in the labour and delivery suite) was 3234 ± 1473 ml in the intervention group and 3279 ± 1671 ml in the control group. Solutions administered were either normal saline or Ringers Lactate. In two cases (one in each group) the initial solution was 2/3 glucose and 1/3 saline followed by Ringers Lactate,

as one woman in the intervention group was vomiting on admission and one woman in the usual care group had mild ketonuria on admission.

Table: 12
Comparison of incidence of ketonuria and intravenous use and intake

	Intervention (n = 163)	Control (n = 165)	Comparison statistic	p =
Ketonuria				
Any Ketones > =1	36 (22%)	36 (22%)	$\chi 2 = 0.00$	1.0
Moderate (> =1 and < 3)	27 (17%)	28 (17%)	$\chi 2 = 0.08$	0.78
Severe (>= 3)	9 (6%)	8 (5%)		
Mean dilatation of cervix at first ketone reading (cm)	4.7 ± 3.1 (n= 36)	4.6 ± 2.8 (n=36)	t = 0.00	0.99
Intravenous therapy				
IV established during labour*	138 (85%)	140 (85%)	$\chi 2 = 0.01$	0.93
IV established with cervical dilatation < 3cm	53 (39%) (n= 136)	50 (36%) (n= 139)	$\chi 2 = 0.26$	0.61
Mean intravenous intake (ml)	3234 ±1473	3279 ± 1671	t = .21	0.84
Mean dilatation of cervix at intravenous onset (cm)	3.2 ± 1.8 (n=136)	3.5 ± 2.1 (n=139)	t = 1.1	0.28

*Includes only women who had an intravenous started on the labour and delivery unit. In 3 cases dilatation at intravenous initiation was not documented, as they were emergency caesarean sections for breech presentation.

Complications

There were no occurrences of maternal gastric aspiration or death in either group. As previously reported the overall incidence of caesarean section deliveries was 22% (n = 73) with the most common reason for caesarean section being failure to progress. Rates of other intrapartum complications (elevated temperature > 38 degrees centigrade, bleeding, meconium) are reported in Table 14. There were no significant between-group differences.

There were no newborn deaths in either group and there was no statistically significant difference between groups in the incidence of newborn complications (Table 14). Twenty-nine newborns (9%) developed a temperature > 38 degrees centigrade in the first 24 hours. Of these newborns, six in the intervention group and four in the control group received antibiotics. Of those newborns with low blood glucose within the first 24 hours, one in each group received an intravenous infusion.

Table 14

Comparison of intrapartum and newborn complications

	Intervention (n = 163)	Control (n = 165)	χ^2	p =
Maternal				
Elevated temperature	16 (10%)	14 (9%)	0.19	0.66
Abnormal Bleeding	1 (1%)	4 (2%)	1.77	0.18
Meconium	36 (22%)	45 (27%)	1.11	0.29
Newborn				
5 minute Apgar <7	8 (5%)	5 (3%)	1.7	0.19
Cord artery pH <7.1*	17 (10%)	11 (7%)	2.3	0.13
Cord artery buffer base > 34	25 (15%)	17 (10%)	2.6	0.11
Elevated temperature	16 (10%)	13 (8%)	0.38	0.54
Blood glucose <2 mmol in first 24 hours	3 (2%)	7 (4%)	1.6	0.21
Admission to the NICU in first 24 hours	37 (23%)	31 (19%)	.76	0.38

* Arterial cord gases were available in 93% (152/163) of the newborns in the intervention group and 96% (158/165) of newborns in the control group.

Summary

Three hundred and thirty nulliparous women, greater than 30 weeks gestation were randomized to either an intervention or usual care group. This chapter presented the descriptive characteristics of 328 women at randomization, 257 women who responded to the postpartum questionnaire, the between-group comparisons in the primary outcome measure (dystocia), the secondary psychophysiological outcomes and maternal and newborn complications. Women randomized to the intervention group were similar in baseline characteristics to women in the control group, were more likely to eat and drink a self-selection of foods and fluids during labour. There were no significant group differences in all outcomes measured or in the incidence of adverse maternal or neonatal complications.

Chapter 4: Discussion

This chapter begins with a description of the methodological strengths and limitations of the study. Next there is a discussion of the research results in relation to the effect of the intervention on the incidence of dystocia and on the secondary psychophysiological outcomes of pain, anxiety and physical feelings of discomfort. The chapter will conclude with a discussion of the conceptual framework of psychophysiological modulation of labour.

Strengths and Limitations

The purpose of this study was to determine the effectiveness of a policy of unrestricted access to food and fluids during labour on the incidence of dystocia. This study was a randomized clinical trial, the optimal study design to determine causality and the first North American trial to systematically evaluate the effectiveness of the current policy of restriction of oral intake versus a new policy of unrestriction of oral intake on selected maternal and newborn outcomes. Elements of the psychophysiological labour stress-adaptation-response provided the framework for the outcome measures and design of the intervention. The research questions were clinically important and relevant. The intervention, patient controlled intake, if effective could be easily implemented in the practice setting. Moreover, the intervention is congruent with the belief that for most women labour is a relatively normal but stressful event. Interventions during labour should support and help women during this experience. However, there were methodological limitations with respect to the randomization process, estimation of sample and effect size and missing data for secondary outcome measures.

Patients were randomized to one of two groups by selecting, by chance, from a sealed container, sealed opaque envelopes that contained cards designated as control or experimental. The preferred method of randomization is to use a computer generated list of random numbers, ideally allocated through a centralized service. Because the process is concealed from patients and the researcher and caregivers this

method ensures unbiased and blinded assignment of participants to groups. Randomization ensures that each subject has an equal chance of being assigned to one of two groups. Participants in each group, at the time of randomization, should be similar with respect to baseline and demographic characteristics. In this study, this was the case. Women in both groups were similar with respect to baseline, demographic and pregnancy characteristics.

Loss to follow-up was not a problem for the primary outcome as data were available for the primary outcome measure in all but two participants. However, the secondary psychophysiological outcome measures were determined by responses to the postpartum questionnaire. The postpartum questionnaire response rate of 78% was less than expected and less than desired for clinical trials where the goal of the trial is to measure the effectiveness of an intervention on outcomes. The response rate, however, was similar between groups and those who responded were similar with respect to baseline characteristics. Therefore, although greater than 20% of the sample was lost for the secondary outcomes, there is no evidence that this introduced any bias. The respondents and non-respondents, while equally distributed between groups were different. Non responders reported higher rates of smoking and alcohol consumption but were similar with respect to physical characteristics and risk grade status. Thus the results of this study may not be generalizable to all low risk pregnant women. Dillman (1978) stated that "the process of sending a questionnaire to prospective respondents, getting them to complete the questionnaire in an honest manner and return it can be viewed as a special case of social exchange" (p.12). People who respond are motivated to return because they feel their responses are valued and may bring about certain actions. One could hypothesize that non-respondent participants in the intervention group may not have participated as much in the protocol, because they needed to review, understand and "buy into" the nutritional guidelines and participate in the intervention, including returning the questionnaire.

Compliance to the protocol was determined through the review and analysis of questionnaire responses about food and fluid intake during labour. To minimize

the effect of non-respondent bias and to obtain a better measure of compliance, oral intake should be collected more systematically during labour and not based on patient recall. Nurses in this centre do not systematically document oral intake in labour unless there are deviations from the norm. Participants were provided a log to record their intake and they were guided to use this tool to help them complete the questionnaire. Therefore, concurrent measurement of oral intake during labour, by either the nurse or patient, may have provided a more accurate assessment and measurement of compliance.

The selection of the primary outcome, dystocia, was a problem in this study. Dystocia was selected because it is a common obstetrical complication and is the most common indicator for primary caesarean section deliveries. However, dystocia may not have been the best primary outcome because it is difficult to diagnose, define and measure. While the literature suggests a relational link to the physiological stress response, there is not a causal pathway between dystocia and stress.

The sample size was calculated using the incidence of dystocia and the effectiveness of current treatments. It was hypothesized that patient controlled oral intake would have a moderate effect, that is, reduce the incidence of dystocia by 38%. This was based on the assumption that the preventive effect of patient controlled oral intake would have a similar effect as other treatment strategies on the incidence of dystocia. This estimated effect size may have been too large and, thus, the sample size too small to confidently determine the effect of patient controlled intake on dystocia.

The findings from this study are only generalizable to similar labour and delivery units. The site hospital was a tertiary teaching hospital in southeastern Ontario. The types and frequencies of obstetrical interventions and care are similar to other teaching hospitals in Ontario, but may not be reflective of community hospitals or hospitals in other provinces or countries. Furthermore, the overall nature and culture of childbirth in this hospital setting may have influenced the effect of the intervention. For the intervention to have maximum effect, it was assumed that women would be able to regulate and control their oral intake and that these actions

would be supported by the labour and delivery caregivers. Labour support scores were not different between groups. The overall mean Labour Support Score (LSQ) score was 39.6±7.8. This score is slightly higher (i.e. women perceived that the nurses provided more supportive care actions), than the mean score of 37.0 ± 6.3 reported by Hickey (1992) in her study of 201 women in an Ontario teaching hospital. Labour support was measured to determine if nurses would provide different types or amounts of support to women in the intervention group. It is evident from the labour support scores and from the comments of some of the respondents that nurses provided varying amounts of supportive advice and encouragement. This finding is reassuring, in that the effectiveness or lack of effectiveness of the intervention was probably not influenced by the care provided by the nurses.

Some of these limitations were anticipated when the project was proposed. Their influence was addressed through the study methodology (i.e. measurement of labour nurse support) and will be addressed in the following sections regarding interpretation of results.

Primary Research Question: The Effect of Patient Controlled Oral Intake on the Incidence of Dystocia

There were no significant differences in the incidence of dystocia in women who were allowed free access to food and fluids during labour in comparison to women who were restricted in their access to food and fluids. The incidence of dystocia was 36% (n= 58) in the intervention group and 44% (n= 72) in the control group when dystocia was defined according to the Canadian Consensus Criteria, and 50% (n= 82) in the intervention group and 61% (n= 100) in the control group when dystocia was defined as a rate of 1.0 cm/hr over a 4 hours period.

This incidence of dystocia was similar to rates reported in the literature (Canadian Consensus Conference, 1986; Fraser et al., 1993; Stewart et al., 1990). In Fraser's study, the incidence of dystocia, using the Canadian Consensus Criteria, in 925 nulliparous women randomly assigned to early rupture of membranes or conservative management of labour, was 34% in the amniotomy group and 45% in the conservative group with a relative risk of 0.8 (95% C.I., 0.6,0.9).

In the current trial the rates of medical stimulation of labour with oxytocin were 39% in the intervention group and 42% in the control group and are similar to reported rates (Fraser, 1993; Keirse, 1991). Similarly, of those women having caesarean sections, the proportion of caesarean sections performed for failure to progress in labour was 70 % in the intervention group and 69 % in the usual care group. These results are consistent with rates reported in North America (Canadian Consensus Conference, 1986; Stewart et al., 1990). In this study, there were no differences between groups with respect to medical stimulation of labour with oxytocin and caesarean section for failure to progress in labour.

Providing access to food and fluids during labour was hypothesized to decrease the likelihood of dystocia in that it would facilitate labour progress. Dystocia was diagnosed during the first and second stages of labour. The lack of significant effect of patient controlled intake on the incidence of dystocia can be explained or attributed to the following: (a) the provision of oral glucose as an energy source for labour was inadequate; (b) the provision of glucose as an energy source had limited, if any effect on contraction force; (c) dystocia as an outcome, was difficult to diagnose and was often managed before the effect of preventive strategies could be determined; and /or (d) the potential strength of the intervention was influenced by the practices of a highly technological, interventionist birth setting. Each of these possibilities will be discussed in turn below.

Inadequate Energy Source

Patient controlled oral intake was hypothesized to provide an adequate and available glucose source for the work of labour. Women in the intervention group received a teaching booklet outlining: (a) the importance of food and fluids during labour as an energy source; (b) types of easily digestible foods and fluids that may provide this energy source and be easily digestible; (c) suggested guidelines about quantities and the frequency of eating and drinking during labour; and (d) general instruction to eat and drink frequent, small amounts. Participants reviewed the guidelines with the research assistant and had questions answered. Compliance to the oral protocol was determined through review of the questionnaire responses that

addressed food and fluid intake during early and active labour. During the early stages of labour at home, most women ate and drank according to their normal pregnancy pattern. Women naturally reduced their solid intake as labour progressed or if they became nauseated or uncomfortable. Women in the intervention group reported that they ate and drank more carbohydrate-based foods and fluids in comparison to women in the usual care group in the hospital ($\chi 2 = 40.7$, p<. 001) and so in this study, the lack of effect, was not because women did not receive and participate in the intervention. However, the lack of effect may be attributed to early cessation of the oral protocol

The oral protocol was stopped if women in the intervention group received epidural analgesia. Seventy six percent (n=249) of the sample received epidural analgesia at a mean cervical dilatation of 4 cm. Thirty-one women (19%) in the intervention group and 24 (15%) women in the control group received epidural analgesia before the cervix reached 3-cm dilatation. Therefore, for many women, including those in the intervention group, epidural analgesia was started fairly early in labour. Trials of epidural analgesia versus non-epidural analgesia have demonstrated that epidural analgesia increases the use of oxytocin, is associated with longer first and second stages of labour, increases the incidence of fetal malposition, increases the use of instrumental deliveries and increases the incidence of caesarean delivery (Howell, 1999). Howell (1999) in a systematic review of epidural versus non-epidural analgesia concluded that women receiving epidural analgesia should no longer be considered to be in "normal labour" because of the impact of the epidural analgesia on labour dynamics. In this trial, the effect of the intervention was influenced by the direct effect of epidural analgesia on labour progress and by the indirect effect of the epidural analgesia on discontinuation of the protocol, thus limiting the available energy source. The use of epidural analgesia was frequent and similar for both groups. Because epidural analgesia was used frequently, there were inadequate numbers to determine, through a secondary analysis, if patient controlled intake affected labour progress when epidural analgesia was not administered.

Intravenous therapy is always initiated with epidural analgesia and for the purpose of medication administration (i.e. oxytocin). The incidence of intravenous therapy was similar for both groups. Eighty five per cent of the women had an intravenous infusion established at or about 3.5-cm cervical dilatation. All, except one woman in each group received either Ringers Lactate or normal saline solutions (i.e. physiologically isotonic solutions without a glucose source). Women received an average of 3200 ml with ranges from 1500 to 4800 mL during labour. In this study the duration of labour from the time of admission was approximately 10 hours; thus, the average infusion rate was 300 - 400 cc of fluid per hour. Intravenous fluids were a source of fluids but not glucose for women in labour.

The presence of ketonuria was used as metabolic marker of inadequate energy source. There was no difference in the incidence of ketonuria between groups. Ketonuria was detected in 22% of the participants, which is consistent with rates reported in Chang's (1992) study. Ketones develop with (a) the delivery of free fatty acids from adipose tissue; (b) hepatic oxidation of the free fatty acids; and (c) reduction in ketone uptake by the peripheral tissues. Ketones are more likely to develop in prolonged labours (Chang, 1992; Foulkes & Dumolin, 1985) and with fasting (Metzger et al., 1982). Ketones are not consistently measured on admission to the labour and delivery unit or during labour. Therefore, the incidence of ketonuria may be underreported. In this trial, ketonuria, when it was detected, occurred at or about 4 to 5-cm cervical dilatation. Women in the intervention group were encouraged, and were able to eat and drink early in labour. Although, urinary ketones were not measured in all patients in a consistent way, the lack of effect may mean that the food and fluids consumed were not adequate enough to meet the continued energy requirements of labour, especially for longer labours when the duration of time between last glucose intake is longer and the demands of labour are extended.

The energy requirements of labour are unknown and will be influenced by the labour experience. The work or energy requirements of labour are more likely related to the work required to cope with events, such as painful contractions during labour. (Eliasson et al., 1992; Hagerdal et al., 1983) and were hypothesized to be similar to

the energy requirements of moderate prolonged exercise. Both events elicit a stress response that impacts carbohydrate metabolism and needs. Similar to exercise, the longer the event or the longer the labour, the greater the need to provide an ongoing source of glucose. A depletion of carbohydrate stores during moderate prolonged (> 1 hour) exercise leads to feelings of fatigue, lethargy, and overall poor performance but not necessarily muscle fatigue (Coggan & Coyle, 1991). Feelings of fatigue are associated with prolonged labour and increase incidence of ketosis (Chang, 1992). The majority (58 %, n=150/257) of women in this study reported moderate to severe feelings of fatigue. The oral intake protocol did not provide the carbohydrate source to minimize feelings of fatigue or performance, when performance was measured in terms of labour progress and uterine effeciency.

Limited Effect on Uterine Contraction Force

As previously discussed, the clinical significance of glucose availability or unavailability (i.e. ketosis) on uterine contraction force and labour progress has not been determined. Wray (1993) reviewed metabolic modulation and the effects of alteration in oxygen supply and pH on uterine force production. Animal studies showed that intracellular metabolic changes can depress uterine contraction force (Wray, Duggins, Iles, Nyman & Osman, 1992). This effect is not possible to extrapolate to humans. It may be that the uterine muscle needs a limited amount of glucose fuel and relies principally on the stores in the body and thus is unaffected by eating or drinking during labour. More research on the physiology of labour would be useful to determine the influence of glucose levels on uterine contractility.

Problematic Primary Outcome: Dystocia

Dystocia, poor progress in labour, was a problematic outcome in this study as: (a) the definition was based on arbitrarily defined criteria for established labour and rates of cervical dilatation that have not been adequately validated; (b) dystocia evolved throughout the course of the labour; therefore, its management was influenced by the caregiver's clinical judgement; and (c) progress in labour was one measure of "performance" and may not be a desired or the best outcome to measure from a patient's perspective.

Dystocia was diagnosed if the rate of cervical dilatation was less than 0.5 cm/hr for a period of 4 hours after an initial cervical dilatation of 3 cm, in accordance with criteria established by the Canadian Consensus Conference (1986). Rates of cervical dilatation during labour used to develop rate criteria are based on descriptive retrospective data of women supposedly in normal established labour. In this study, 249 (76%) women received epidural analgesia, 183 (56%) women received oxytocin or prostin stimulation for either induction or augmentation, and 93 (29%) had labour induced. At present, there are no evidence-based criteria for determining what constitutes abnormal and normal rates of dilatation during epidural analgesia, augmentation, and induction of labour. The panel of experts at the Canadian Consensus Conference guidelines did acknowledge the lack of research evidence available to define the diagnostic criteria for dystocia and recommended further research. In this study, many women were assessed and treated for probable dystocia before the criteria were met. Moreover, approximately half of this sample of healthy nulliparous women developed, according to the criteria, difficult prolonged labours.

Therefore, dystocia, as an outcome, was problematic as slower rates of cervical dilatation, as defined in this study and in this sample, may be common. As Crowther (1991) stated, a woman who is comfortable and progressing in labour, at no defined rate, should not be a concern (Crowther et al., 1991). It may be more appropriate to select outcomes that evaluate aspects of physical comfort and psychological coping. It would seem that in this setting, and in other North American hospitals, the diagnosis of dystocia, based on varying definitions, occurs frequently in normal nulliparous labours and is an overdiagnosed condition that seems to predispose women to strategies to actively manage and ensure labour progresses at a set, but ill-defined rate.

Inadequate Strength of the Intervention in a Medicalized Birth Setting

The intervention was designed to provide both a physical and psychological resource. The intervention may have been a weak physical and psychological resource, especially within a medicalized environment. Women in the intervention group, in comparison to women in the control group, were provided with the

opportunity to control one aspect of their labour, the ability to consume food and fluids, for a limited amount of time. This hospital, as are other North American hospitals, was characterized by a high degree of medicalization (i.e. high rates of electronic fetal surveillance, epidural analgesia, and oxytocin augmentation). This medicalized environment influenced the options available (i.e. fluid restriction in conjunction with epidural analgesia) for women which may have influenced feelings of personal control.

The mean personal control score, as measured with the Labour Agentry Scale, was 156.9 ± 27.3, higher than the mean LAS score (133.7 ± 28.3) in a study of women who developed ketonuria during labour (Chang, 1993), and lower than the mean LAS score (166.3±26.9) of a sample of Lamaze prepared women who received continuous intrapartum support during labour (Hodnett, 1989a). Participants in the intervention group commented favorably on being able to choose foods or fluids that they liked, being able to stop if they wished, and having their thirst quenched. These comments are consistent with those reported by women, in the intervention group, in Yiannouzis's (1994) study as they also commented positively on the availability of choice.

Women in the intervention group were encouraged to control their pattern of eating and drinking during all stages of labour, with an emphasis on adjusting their pattern in response to phases of labour. During early labour, women in the intervention group were encouraged to eat and drink small snacks in order to "bolster" their energy for the anticipated upcoming demands. This encouragement during the early phase of labour was an important aspect of the protocol because during early labour women were able to, and should be encouraged to, implement and use strategies to help themselves. However, some women in the intervention group who came to the hospital early in labour or not in labour (i.e. for induction), did not have the opportunity to "bolster" if epidural analgesia was established or caregivers restricted their intake. This latent phase of labour is often not recognized as clinically important.

As previously discussed, Wuitchik et al (1989) assessed 115 women in the latent, active and transition phases of labour for levels of pain and content of women's cognitive activity on a continuum of coping-related thoughts to distress-related thoughts. Wuitchik proposed that cognitive behavioural strategies may be more effective in the latent phases of labour. In this study, women in both groups reported earlier start times for labour than those recorded by caregivers. If women were allowed an even greater opportunity to participate actively during early labour (i.e. regulate and control their oral intake), the beneficial effect of this intervention may be more apparent.

Summary of Effect on Primary Outcomes

Patient controlled oral intake during labour had no impact on the incidence of dystocia, as measured in this trial, for possibly, one or more of the reasons stated above. Further research is required to determine if there is a more effective pattern of patient controlled oral intake during labour either alone or in combination with other strategies. Dystocia is an important clinical obstetrical problem but was a problematic outcome to measure. Psychophysiological outcomes that are congruent with patients' expectations of how they wish to "perform" and progress in labour and are congruent with the proposed effect of the intervention may be more appropriate. The next section will discuss the secondary psychophysiological outcomes measured in this study.

Secondary Research Question: The Effect of the Intervention on: Pain, Anxiety, and Physical Feelings of discomfort

Anxiety, pain and physical feelings of discomfort were measured retrospectively via postpartum recall. There were no significant differences between women in both groups with respect to their ratings of each of these outcomes. Simkin (1991; 1992) reported that women's recall of their labour experience is accurate and reflective of their overall perception of the event. However, prospective measurement of these factors during labour would have provided contemporaneous findings, which may or may not have reflected differences.

Pain

Women rated the intensity, affective and motivational aspects of pain using the short form of the McGill pain questionnaire. There was no significant difference in sensory, affective or total pain scores between groups. The sample mean sensory, affective and total scores for all women were, respectively, 13.4 ± 7.8; 3.9 ± 3.9 and 17.2 ± 11 and were slightly higher than those reported by Melzack (1987) in 20 labouring women prior to epidural analgesia. The mean pain intensity scores were exactly the same in both groups (3.2 ± 1.2) and higher than the mean pain intensity score of 2.5 ± 1.1 reported by Melzack. The differences between the scores on the pain scale in this study in comparison to those in Melzack's study are probably attributable to when pain was assessed. Women in this study were asked to recall their pain, whereas, in Melzack's study pain was measured prospectively, during earlier phases of labour, before pain management strategies were implemented. Consistent with other studies of labour pain, the most frequently reported descriptors were cramping, aching, and tiring and exhausting (Bonica et al., 1990; Lederman, 1984). Also, as consistently reported, women found labour pain to be distressing and excruciating.

Women's perception of pain is influenced by physical, psychological and contextual factors (e.g. culture, meaning, previous experience). Pain intensity and the spatial distribution of pain is variable throughout labour and unique to each women's childbirth experience (Melzack, 1984). At this hospital, the research site, epidural analgesia was administered to relieve pain in over 75% of the women. However, women's recall of their pain indicated that they perceived pain as distressing, exhausting and intense in spite of the intervention. Melzack (1984) determined the effectiveness of epidural analgesia on intensity and spatial distribution of pain in 12/240 women studied and found that pain scores decreased in 89% and that anaesthesia was ineffective in 33% (n=4). He contributed the high failure rate to the small sample size (i.e. longitudinal data only available on 12 subjects) and inexperience of beginning anaesthetic residents. If epidural analgesia is purportedly the most effective pharmacological analgesia to use during labour, women should be

informed not only about its effect on labour dynamics but the risk of inadequate pain relief. The results of this study suggest epidural analgesia has little effect on women's recall of the intensity and affect of pain.

Epidural analgesia decreases the intensity of physiological stress responses (De Punzio et al, 1994) which in turns effects carbohydrate metabolism and glucose needs. Epidural analgesia is associated with longer labours and, in this study, oral intake (glucose) restriction. These two factors (i.e. longer labour and fasting), suggest that there may be a need for a continued source of nutrients whether or not a woman has epidural analgesia. Oral intake was restricted at this research site because of the Department of Anaesthesia's concern about the influence of epidural analgesia (with or without opioid) on gastric emptying and gastric contents. Recent studies show that gastric emptying is not influenced by epidural administration of an anaesthetic agent alone (Wright, 1992) but is decreased with epidural administration of opioids. Porter, Bonello & Reynolds (1997) demonstrated that gastric emptying was delayed when women received a cumulative dose of greater than 100 micrograms of fentanyl. These women also had been in labour longer, so it was difficult to differentiate the labour versus the medication effects. Gastric emptying is influenced by many factors, including but not limited to, gastric contents, opioids, pain, labour etc. All or some of these factors will influence the rate of gastric emptying but do not influence the skill with which general anaesthesia is initiated and administered, if and when it is needed, and as a consequence have limited influence on the risk of adverse outcome related to gastric aspiration in labour. Therefore, at present, there is no empirical evidence for prohibiting oral fluid intake during labour in low risk women, with or without epidural analgesia.

Providing women the access to food and fluids during labour did not affect pain intensity or influence the use of other pharmacological interventions to manage pain. Further research is warranted to measure the effectiveness of pain management strategies and comfort measures (i.e. oral intake) on women's perception of pain.

Anxiety

The mean state anxiety scores were similar to mean state anxiety scores reported by Lederman et al (1989b; 1988) and higher than those reported in normative sample of working females (Spielberger et al., 1970). This level of anxiety is more than likely normal for women in labour and should be perceived positively. Heightened anxiety suggests that women are attuned, aware, and responsive to their physical feelings and surroundings during labour. There is no evidence that moderate levels of anxiety are influenced by this patient controlled intervention (eating and drinking in labour), and may in most cases, be an expected phenomenon associated with labour.

Physical Feelings of Discomfort

There were no significant between-group differences in the reported feelings of moderate to severe thirst, hunger, nausea, and fatigue. Moderate or severe thirst was reported by 68% (n=174) of the respondents, moderate or severe fatigue by 40% (n= 103) of the respondents and moderate or severe nausea by 28% (n=73) of the respondents.

Feelings of nausea in association with oral intake during labour were reported in Yiannouzis's (1994) study and are also consistent with historical rationale for not allowing women to eat and drink during labour. Descriptive comments on the questionnaire suggested that women, in this study, responded to nausea by voluntarily reducing their intake, and they were able to identify foods that contributed to their nausea. Therefore, they were able to manage the symptom. The questionnaire did not measure how distressed women were with the presence of an uncomfortable symptom; it only rated the intensity and occurrence of the symptom. Assessing the impact and the ability to control a symptom is important when assessing the full impact of a discomforting symptom experience. Moreover, discomforting symptoms rarely occur in isolation. For example, a woman who is fatigued, thirsty and in pain may feel more nauseated than one who is not. Findings in this study and others suggest that discomforting symptoms are associated with prolonged labour (Crowther et al., 1991). Whether symptoms develop as an outcome of the prolonged labour or

as a contributor to its development is unclear. Discomforting symptoms during labour should serve as indicators for further assessment and intervention to prevent the development of worsening symptoms and potential adverse outcomes.

Summary of the Effect of the Intervention on Secondary Outcomes

The intervention had no impact on the secondary outcomes measured. The explanations for this lack of effect are similar to those presented for the primary outcome or in other studies. Patient controlled intake, as a singular intervention used for a limited time during labour did not influence feelings of pain, anxiety and discomfort. Secondly, the measures used may not have been sensitive enough to measure the effect especially when measures were determined via postpartum recall and only 78% of the sample responded. Conceptually there is an association with pain, anxiety and discomfort and the psychophysiological stress response. The discussion will now address the usefulness of this framework for this study.

Psychophysiological Modulation of Labour

The conceptual framework for this study was based on the mechanisms associated with stress-adaptation (Lazarus & Folkman, 1984). The following hypothesis were generated: (a) labour was a normal but stressful process; (b) each woman had her own unique resources and stressors; (c) labour stressors were continuously assessed and adapted to throughout labour; and (d) a successful outcome (i.e. labour progress) would more likely occur if there was a balance between energy consuming stressors and energy conserving resources. Dystocia, poor progress in labour, would occur if there was an imbalance between available resources and stressors. The use of a psychophysiological framework for labour stress was appropriate for this study as women did perceive aspects of their labour to be stressful (i.e. painful, anxiety producing, fatiguing) and each woman's response was unique. Within this framework, the influence of the birth environment on the psychophysiological adaptation response could have been better addressed.

Researchers suggest that the birth environment influences the labour experience (Hodnett, 1987; Hodnett, 1989a). The psychophysiological framework assumed individual beliefs and values were incorporated into how each woman

assessed and responded to stressors during labour. Within the adaptational encounter, each woman's intrapersonal goals, beliefs and state would be influenced by interactions with caregivers and the practices and culture of each respective birth environment. In this hospital setting, there was a high degree of medicalization of the birth process. If each woman's reaction is dependent on subjective evaluation of her goals within the context of the environment, then caregivers have an opportunity to shape goals and response. Each caregiver's goal for each woman's childbirth experience could be assumed to be similar to that each woman's goal - a safe, comfortable, progressive labour. The difficulty arises in defining the boundaries of safety, comfort and progression in labour from both a provider and patient perspective. Within a medicalized birth environment, in comparison to a home environment, there will be different options offered to women when their labour is perceived as not progressing. The challenge becomes to define evidence-based strategies for use in any setting.

Each woman's labour will have a unique set of psychological and physiological stressors. The challenge is threefold: (a) to identify when the relationship between stressors and response to stressors is distressful within the context of labour and the environment; (b) to implement appropriate strategies to continually assess and monitor the encounter, not necessarily remove it; and (c) to identify the appropriate outcomes that are sensitive and specific to monitoring the degree of distress and the effectiveness of strategies. Labor can be considered within a conceptual framework of a psychophysiological stress-response encounter that continuously unfolds throughout the labour process. There is a need to provide a supportive physiological and psychological environment for the process to unfold.

In this study, patient controlled oral intake did not decrease the likelihood of dystocia, did not decrease the stress associated with labour and did not decrease the incidence of adverse maternal or neonatal outcomes. Conversely, patient controlled oral intake did not increase the incidence of dystocia, did not increase the stress associated with labour, and did not increase the incidence of adverse maternal or neonatal outcomes. Women in the intervention group regulated their own oral intake

during labour until they were limited by environmental factors (i.e. practices related to induction of labour and epidural analgesia).

Chapter 5. Summary and Implications for Research and Practice

This final chapter summarizes the study and proposes recommendations for further research and implications for practice.

<u>Summary</u>

In 1986, a panel of experts of the National Consensus Conference on Aspects of Caesarean Birth submitted a final report containing recommended clinical policies for aspects of caesarean birth. These policies were developed through a consensus approach, in consultation with clinical experts and others and reflected the best available evidence at the time. These practice guidelines were endorsed by the Society of Obstetricians and Gynaecologist and were widely disseminated to physicians in an effort to change practice and, ultimately, decrease the rising trend of caesarean births. The Canadian rate in the mid -1980's was approximately 20%, almost twice as high as rates reported in European countries. Ten years later, the Canadian rate has not decreased and there is still disparity between the Canadian rate and rates in other countries. Within Canada, variations in rates among institutions, cities and provinces exist (Werschler, 1998). The consensus report outlined guidelines to appropriately diagnose dystocia, as dystocia was, and currently is, the primary indicator for caesarean section. The hope was that if dystocia was correctly diagnosed, appropriate assessment and intervention would follow and the caesarean section rate would decline.

The purpose of this study was to determine if a supportive care strategy (i.e. allowing women to eat and drink as they please in labour) was more effective than the usual practice of relative oral food and fluid restriction in preventing dystocia in low risk nulliparous women.

Labour was hypothesized to be a normally stressful energy consuming event. A contingent source of energy was needed to meet the expected and unexpected demands of labour. Patient controlled oral intake would provide a physiological source of energy (e.g. glucose) and would also allow each woman to control her own

intake in accordance with her needs. The intervention was conceptually based on mechanisms of stress – adaptation (Lazarus, 1988).

The research design was a randomized clinical trial. Three hundred and thirty women were recruited between 30 and 40 weeks gestation and were randomly assigned, after consent was obtained, to either a usual care or an intervention group. Before labour, women in the intervention group received easy to read guidelines about food and fluids during labour. These guidelines were based on fluid and nutrient recommendations prepared by the Canadian Dietetic Association for athletes participating in prolonged moderate aerobic activity. During labour, women were encouraged to eat and drink in small frequent amounts that were comfortable for them. Women in the intervention group were restricted in their intake if complications developed or an epidural was established.

Primary and secondary outcome data were collected via chart abstraction or postpartum questionnaire. Three hundred and twenty eight women were sent a postpartum questionnaire, within one week of delivery. The postpartum questionnaire was a compilation of the Labour Agentry Scale (LAS), the A-State Anxiety Scale, the short form McGill Pain Questionnaire (MPQ), the Labour Support Questionnaire (LSQ), a series of physical discomfort visual descriptor scales; a series of food and fluid intake questions and demographic information questions. Two hundred and fifty seven (78%) women returned questionnaires, 124 (76%) in the intervention group and 133 (81%) in the usual care group.

Data to determine the incidence of the primary outcome in the two groups were collected via chart abstraction. Dystocia was considered present if the rate of cervical dilatation was less than 0.5 cm for a period of 4 hours after a cervical dilatation of 3 cm. had been reached. There was no significant difference in the rate of dystocia between groups. Dystocia occurred in 36 % (n= 58) of women in the intervention group and 44% (n=72) of women in the usual care group. There were no significant differences between groups with respect to the other secondary outcome measures. Women in the intervention group reported a significantly different pattern of oral intake during labour. The majority of women in the intervention group did eat

and drink glucose based foods or fluids, while most women in the usual care group only had sips of fluids or ice chips. The descriptive comments from women in the intervention group suggested that they: (a) enjoyed the choice of eating and drinking; (b) felt they needed the energy source, especially if labour was longer; (c) decreased their oral intake voluntarily, if they felt nauseated; (d) would have preferred to be able to continue the protocol, once epidural analgesia was established and they were comfortable; and (e) were neither encouraged or discouraged in their preferences for food and fluids during labour by the nurses.

In summary, the findings from this trial show the intervention of patient controlled oral intake during labour did not significantly decrease the incidence of dystocia. Further study is warranted to determine the effectiveness of this policy, or an adapted version of this policy, on important childbirth outcomes (i.e. satisfaction and caesarean delivery).

Implications for Further Research

Two general areas for further research are identified. First, the research study could be repeated with the methodological limitations addressed and a better primary outcome selected. Secondly, further research could determine if changing the intervention would increase its strength and effect.

As previously identified there were methodological limitations in the study. The methodological problems of randomization are easily corrected with the use of a list of computer generated random numbers in consecutively numbered sealed, opaque envelopes or with allocation through a centralized randomization service. Administering patient questionnaires during the hospital stay could increase response rates. Ideally, data to evaluate the outcome measures should be available on the majority of participants in the study. The most significant limitation was the selection of dystocia as the primary outcome.

The primary (and secondary) outcome measures should evaluate the effect of strategies that help to maintain physiological and psychological balance during labour and the impact of this balance on important clinical outcomes (e.g. the incidence of maternal complications and caesarean deliveries) and important patient outcomes (e.g.

satisfaction with labour experience, levels of symptom distress). To determine the effectiveness of interventions on clinical outcomes large sample sizes and strong effective interventions are required. Therefore, this study, as designed with the primary outcome of dystocia, should not be repeated unless the intervention is strengthened and sample size increased. Moreover, because there was no evidence of clinical benefit or risk in this study, important patient outcomes (not clinical complications) may be more appropriate. These outcomes could include measures to determine the degree of symptom distress throughout labour, where symptoms would include feelings of thirst, fatigue, hunger and pain and the degree of satisfaction with selected aspects of the childbirth experience.

Global measures of symptom distress, used in medical surgical populations, rate the frequency of the symptom, the intensity of the symptom and degree of distress caused by the symptom (Portenoy, Thaler, Kornblith, Lepore, Frielander-Klar, Kiyasu et al., 1994). These measures could be developed and tested for use in women in labour. Global measures of patient satisfaction with hospital care generally evaluate the patients' perception of how care was provided in relation to their expectations for care (Gerteis, Edgman-Levitan, Daley & Delbanco, 1993). A measure of overall patient satisfaction with the childbirth experience and satisfaction with specific aspects of care (i.e. pain management, food and fluid management), in addition to measures of personal control would evaluate the effectiveness of interventions on how women felt about their experience and would be a measure of personal performance.

Further research is warranted to determine if changing the intervention could enhance its effectiveness. The intervention could be changed in two ways: (1) changing the pattern and content of the carbohydrate resource and (2) combining the single supportive care intervention (i.e. patient controlled oral intake) with other supportive care or active management strategies that are proven to be effective.

To strengthen the physical resource, a carbohydrate source should be available for low risk women throughout labour regardless of whether women have epidural analgesia, induction of labour or augmentation of labour. Women would be

encouraged to eat or drink a carbohydrate source early in labour as they did in this study. In more established labour, with or without epidural analgesia, women would be encouraged to consume a regular pattern of carbohydrate based fluids only. Labour was compared to a prolonged moderate aerobic athletic event. The energy requirements during exercise are different than those required during labour, but similarities do exist as both events elicit a psychophysiological stress-response that was energy consuming. Maintaining a plasma glucose concentration was hypothesized to be beneficial in supporting the work of labour and oral intake (not intravenous intake) was the preferred mode of administration. Therefore, fluid replacements that contain a carbohydrate source (glucose, fructose, sucrose, maltodextrins), small amounts of electrolytes and other elements, such as buffering agents, may be more appropriate for consumption during active labour in that these drinks provide a readily available carbohydrate source that is easily absorbed. Based on the findings of this study and the conceptual link with exercise, an oral intake protocol that was patient controlled but restricted to glucose-based fluids (i.e. sport drink supplements) during established labour may be more effective than the protocol studied.

Secondly, the intervention could be enhanced if it was part of a "package" of supportive care or active management strategies in labour that have evidence of effectiveness. The rest of the "package" could include strategies appropriate for the early phases and more active phases of labour. For example, this hospital, as do many other North American hospitals, utilize components of the active management polices for labour. Use of diagnostic admission criteria for established labour could be supplemented with instructions and support, inclusive of food and fluid intake, about how to self-manage the latent phase of labour either in hospital or at home. Women would be encouraged to eat and drink during this time in order to bolster energy resources for the active phases of labour. Once the woman established a more active labour pattern, the supportive care strategies, including physical (i.e. oral intake) and emotional support would be contingent to each woman's needs during more active labour. Ideally these resources would help each woman cope with the

demands of labour and facilitate progress, where progress would not be solely defined as rate of cervical dilatation, but would also take into account each women's psychophysiological response to the experience.

In summary, further research is warranted to determine: (a) how to strengthen the effect of the intervention (i.e. fluid replacement drinks during active labour; regular food and fluids during early labour); (b) how to minimize the influence of current practices and policies (i.e. epidural analgesia, early interventions); and (c) the effectiveness of these interventions on important childbirth outcomes (satisfaction, symptom distress, and caesarean deliveries).

Implications for Practice

The findings from this trial do not provide convincing evidence to change practice. However, they do provide information about how women, who were encouraged to eat and drink, as they desired, were able to participate in this aspect of labour and enjoyed the participation. The intervention did not increase the incidence of prolonged labour nor did it decrease the incidence of prolonged labour. In the absence of evidence of benefit or harm, women should be provided with information about the trial results, and encouraged to make their own decisions about oral intake during labour.

References

AbouZahr, C., & Royston, E. Maternal Mortality: A Global Factbook. (1991). Geneva: World Health Organization.

Anderson, G. & Axel, T. (1998, December) Cesarean Section Rates in Ontario: An ICES Practice Atlas Update. Technical Report. Institute of Clinical Evaluative Sciences, Toronto, Ontario.

Beck, N. C., Siegel, L. J., Davidson, N. P., Kormeier, S., Breitenstein, A., & Hall, D. G. (1980). The prediction of pregnancy outcome: Maternal preparation, anxiety and attitudinal sets. Journal of Psychosomatic Research, 24, 343-351.

Bonica, J., & McDonald, J. (1990). The pain of childbirth. In J. Bonica (Ed.), The Management of Pain. (pp. 1313-1343). Malvern, Pennsylvania: Lea & Febiger.

Bonica, J. (1994). Labour pain. In P. Wall & R. Melzack (Eds.), Textbook of Pain. (pp. 615-641). London, UK: Churchill Livingstone.

Borenstein, M., & Cohen, J. (1988). Statistical Power Analysis: A Computer Program. New Jersey: Lawrence Eribaum Associates, Inc.

Boylan, P. (1989). Active management of labour: Results in Dublin, Houston, London, New Brunswick, Singapore and Valparaiso. Birth, 16(3), 114-118.

Broach, J. & Newton, N. (1988a). Food and beverages in labor. Part 1: Cross-cultural and historical practices. Birth 15(2), 81-85.

Broach, J. & Newton, N. (1988b). Food and beverages in labor: Part 1: The effects of cessation of oral intake during labor. Birth 15(2), 88-92.

Brown, J. & Kahn, E. (1997). Maternal nutrition and the outcome of pregnancy: A renaissance in research. Clinics in Perinatology, 24(2), 433- 449.

Buchanan, T. A. (1991). Glucose metabolism during pregnancy: Normal physiology and implications for diabetes mellitus. Israel Journal of Medical Sciences, 27, 432-439.

Buchmann, E. J., Gulmezoglu, A., & Nikodem, V. C. (1999). Partogram for assessing the progress of labour (Protocol for a Cochrane Review).In The Cochrane Library, Issue 2. Update Software Inc.

Bulgar, T., Hosden-Chapman, P., & Stone, P. (1998). A cut above: the rising caesarean section rate in New Zealand. The New Zealand Medical Journal, 111(1059), 30-33.

Burns, J. K. (1992). Parameters of catecholamine metabolism in pregnancy presage the duration of labor. Journal of Psychosomatic Obstetrics and Gynaecology, 13, 37-49.

Canadian Consensus Conference Report (1986). Indications for caesarean section: Final statement of the panel on the National Consensus Conference on Aspects of Caesarean Birth. (1986). Canadian Medical Association Journal, Volume 134.

Canadian Dietetic Association, & American Dietetic Association. Physical Fitness and Athletic Performance: Joint Position Paper. (1993).

Carp, H., Jayaram, A., & Stoll, M. (1992). Ultrasound examination of the stomach contents of parturients. Anesthesia & Analgesia, 74(5), 683-687.

Challis, J. R. G., & Lye, S. J. (1994). Parturition. In E. Knobil, J. Neill, G. Greenwald, C. Markert, & D. Pfaff (Eds.), The physiology of reproduction. (pp. 985-1032). New York: Raven Press.

Chan, E., Smith, R., Lewin, T., Brinsmead, M., Zhang, H., Cubis, J., Thornton, K., & Hurt, D. (1993). Plasma corticotropin-releasing hormone, beta-endorphin and cortisol inter-relationships during human pregnancy. Acta Endocrinologica, 128(4), 339-344.

Chang, S. (1993). The psychological and physiological effects of ketonuria during labour. Unpublished dissertation University of Michigan.

Coggan, A. & Coyle, E. (1991), Carbohydrate ingestion during prolonged exercixe: effects on metabolism and performance. Exercise and Sport Sciences Reviews, 19, 1-40.

Cotton, D. B., Gonik, B., Spillman, T., & Dorman, K. F. (1984). Intrapartum to postpartum changes in colloid pressure. American Journal of Obstetrics and Gynecology, 149(2), 174-177.

Crandon, A. J. (1979). Maternal anxiety and obstetric complications. Journal of Psychosomatic Research, 23, 109-111.

Crowther, C., Enkin, M., Keirse, M., & Brown, I. (1991). Monitoring the progress of labour. In Iain Chalmers (Ed.), Effective Care in Pregnancy and Childbirth. (pp. 833-845). Oxford: Oxford University Press.

Cunningham, F. G., MacDonald, P. C., Leveno, K. J., Gant, N. F., Gilstrap, L. C. & Clark, S. I. (1993). Williams Obstetrics. (19th ed.). Norwalk, Connecticut: Appleton & Lange.

Davenport-Slack, B., & Boylan, C. (1974). Psychological correlates of childbirth pain. Psychosomatic Medicine, 36(3), 215-223.

De Punzio, C., Neri, E., Metelli, P., Bianchi, M. S., Venticinque, M., Ferdeghini, M., & Fioretti, P. (1994). The relationship between maternal relaxation and plasma B-endorphin levels during parturition. Journal of Psychosomatic Obstetrics and Gynecology, 15, 205-210.

Dillman, D. (1978). Mail and Telephone Surveys: The Total Design Method. New York Chichester Brisbane Toronto Singapore: John Wiley & Sons.

Douglas, M. J. (1994). Current research in obstetric anesthesia. Annales CRMCC, 27(6), 350-352.

Dujardin, B., DeSchampheleire, I., Sene, H., & Ndiaye, F. (1992). Value of the alert and action lines on the partogram [Abstract]. Lancet, 339, 1336-1338.

Eliasson, A. H., Phillips, Y. Y., Stajduhar, K. C., Carome, M. A., & Cowsar, J. D. (1992). Oxygen consumption and ventilation during normal labor. Chest, 102(2), 467-471.

Enkin, M., Keirse, M., Renfrew, M., & Neilson, J. (1995). Effective care in pregnancy and childbirth: A synopsis. Birth, 22(2), 101-110.

Erickson, M. T. (1976). The relationship between psychological variables and specific complications of pregnancy, labor and delivery. Journal of Psychosomatic Research, 20, 207-210.

Evans, S. E., Crawford, J. S., Stevens, I. D., Durbin, G. M., & Daya, H. (1986). Fluid therapy for induced labour under epidural analgesia: biochemical consequences for mother and infant. British Journal of Obstetrics and Gynaecolgy, 93, 329-333.

Foulkes, J., & Dumoulin, J. G. (1985). The effects of ketonuria in labour. British Journal of Clinical Practice, 91, 59-62.

Fraser, W. D. (1992). Early oxytocin to shorten spontaneous labour. In The Cochrane Collaboration Update Software Ltd.

Fraser, W. D., Marcoux, S., Moutquin, J., Christen, A., and the Canadian Early Amniotomy Study Group (1993). Effect of early amniotomy on the risk of dystocia in nulliparous women. The New England Journal of Medicine, 328 (16), 1145-1149.

Fraser, W. D., Krauss, I., Brisson-Carrol, G., Thornton, J., & Breart, G. (1999). Amniotomy for shortening spontaneous labour (Cochrane Review). In: The Cochrane Library, Issue 1. Oxford: Update Software.

Friedman, E. A. (1955). Primigravida labour - a graphicostatistical analysis. American Journal of Obstetrics and Gynaecology, 6, 567-589.

Frigoletto, F. D., Lieberman, E., Lang, J. M., Cohen, A., Barss, V., Ringer, S., & Datta, S. (1995). A clinical trial of active management of labour. New England Journal of Medicine, 333 (12) 745-750.

Garcia, J., Garforth, S., & Ayers, S. (1985). Midwifes Confined? Labour ward policies and routines. Research and the Midwife Conference Proceedings., 2-30.

Garfield, R. E. (1987). Cellular and molecular bases for dystocia. Clinical Obstetrics and Gynaecology, 30 (1), 3-18.

Gerteis, M., Edgman-Levitan, S., Daley, J. Eds. (1993). Through the Patients' Eyes: Understanding and Promoting Patient Centred Care. Jossey-Bass Publishers. San Francisco.

Goer, H. (1993). Active management of labor: Not the answer to dystocia. Birth, 20(2), 99-100.

Goel, V., Williams, J., Anderson, G., Blackstien-Hirsch, P., Fooks, c., Naylor, C (eds). (1996) Patterns of Health Care in Ontario. The ICES Practice Atlas. 2nd edition. Ottawa: Canadian Medical Association.

Gorland, R., Wardlaw, S., Stark, R., & Frantz, A. (1981). Human plasma beta-endorphin during pregnancy, labor and delivery. Journal of Clinical Endocrinology and Metabolism, 52, 74-78.

Gregory, K., Curtin, S., Taffel, S. M., & Notzon, F. C. (1998). Changes in indications for caesarean delivery: United States, 1985 and 1994. American Journal of Public Health, 88(9), 1384-1387.

Grylack, L. J., Chu, S. S., & Scanlon, J. W. (1984). Use of intravenous fluids before caesarean section: Effects on perinatal glucose, insulin and sodium homeostasis. Obstet Gynecol, 91, 97-98.

Hagerdal, M., Morgan, C. W., Summer, A. E., & Gutsche, B. B. (1983). Minute ventilation and oxygen consumption during labour with epidural analgesia. Anesthesiology, 59(5), 425-427.

Haire, D. B., & Elsberry, C. C. (1991). Maternity care and outcomes in a high risk service: The North Central Bronx Hospital experience. Birth, 18(1), 33-37.

Hazle, N. R. (1986). Hydration in labor: Is routine intravenous hydration necessary? Journal of Nurse Midwifery, 31(4), 171-176.

Heston, T. F., & Simkin, P. P. (1991). Carbohydrate loading in preparation for childbirth. Medical Hypotheses, 34(2), 97-98.

Hickey, R. (1992). The relationships among intrapartum environmental resources, personal variables, and women's recall of support during labour. Unpublished mater's thesis, University of Toronto; Toronto, Ontario, Canada.

Hodnett, E. (1982). Patient control during labour: Effects of two types of fetal monitors. Journal of Obstetric, Gynaecologic and Neonatal Nursing, 11 (2), 94-99.

Hodnett, E. D., & Abel, S. M. (1986). Person - environment interaction as a determinant of labour length variables. Health Care for Women International, 7, 341-356.

Hodnett, E. D. (1987). The environmental load of childbirth settings: Development and testing of a measurement tool. Nursing Papers, 19(2), 3-16.

Hodnett, E. D. & Simmons-Tropes, D. A. (1987). The labour agentry scale: Psychometric properties of an instrument to measure control during childbirth. Research in Nursing & Health, 10, 301-310.

Hodnett, E. D. (1989). Personal control and the birth environment: Comparisons between home and hospital settings. Journal of Environmental Psychology, 9, 207-216.

Hodnett, E. D. & Osborn, R. W. (1989a). Effects of continuous intrapartum professional support on childbirth outcomes. Research in Nursing & Health, 12, 289-297.

Hodnett, E. D., & Osborn, R. W. (1989b). A randomized trial of the effects of monitrice support during labor: Mothers views two to four weeks postpartum. Birth, 16(4), 177-183.

Hodnett, E. D. (1999). Caregiver support for women during childbirth (Cochrane Review). In: The Cochrane Library, Issue 1. Oxford: Update Software.

Hodnett, E. d. (1999). Home-like versus conventional institutional settings for birth (Cochrane Review). In: The Cochrane Library, Issue 1. Oxford: Update Software.

How, K., Foley, M., & Stronge, J. (1995). Nulliparous caesarean section in the home of active management of labour. Australian & New Zealand Journal of Obstetrics and Gynaecology, 35(1), 12-15.

Howell, C. (1994). Epidural versus non-epidural analgesia in labour. In M. Enkin, M. Keirse, M. Renfrew, & J. Neilson (Eds.), In: Pregnancy and Childbirth Module. 'Cochrane Updates on Disk', Oxford: Update Software.

Howell, C. J. (1999). Epidural versus non-epidural analgesia in labour (Cochrane Review). In Update Software (Ed.), In: The Cochrane Library, Issue 2. Oxford: Update Software.

Humenick, S., & Bugen, L. (1981). Mastery: The key to childbirth satisfaction? A study. Birth and the Family Journal, 8, 84-89.

Jawalekar, S., & Marx, G. F. (1980). Effect of IV fluids on maternal and fetal blood glucose. Anesthesiology, 53(3), S311

Johnson, C., Keirse, M., Enkin, M., & Chalmers, I. (1991). Nutrition and hydration in labour. In I.Chalmers (Ed.), Effective care in pregnancy and childbirth. (pp. 827-832). Oxford: Oxford University Press.

Johnson, E. O., Kamilaris, T. C., Chrousos, G. P., & Gold, P. W. (1992). Mechanisms of stress: A dynamic overview of hormonal and behavioral homeostasis. Neuroscience and Biobehavioral Reviews, 16(2), 115-130.

Jones, C. M., & Greiss, F. C. (1982). The effect of labor on maternal and fetal circulating catecholamines. American Journal of Obstetrics and Gynecology, 144(2), 149-153.

Katz, M., Kroll, D., Shapiro, Y., Cristal, N., & Meizner, I. (1990). Energy expenditure in normal labour. Israel Journal of Medical Sciences, 26(5), 254-257.

Kaunitz, A. M., Hughes, J. M., Grimes, D. A., Smith, J. C., Rochat, R. W., & Kafrissen, M. E. (1985). Causes of maternal mortality in the United States. Obstetrics Gynaecology, 65(5), 605-612.

Keirse, M. J. N. C. (1991). Augmentation of labour. In Iain Chalmers (Ed.), Effective Care in Pregnancy and Childbirth. (pp. 951-966). Oxford: Oxford University Press.

Keppler, A. B. (1988). The use of intravenous fluids during labour. Birth, 15(2), 75-79.

Klein, M. (1993). The active management of labour: Whose Agenda? Birth, 20(2), 97-99.

Lao, T., & Panesar, N. (1989). The effect of labour on prolactin and cortisol concentrations in the mother and the fetus. European Journal of Obstetrics, Gynecology & Reproductive Biology, 30(3), 233-238.

Lavender, T., Alfirevic, Z., & Walkinshaw, S. (1998). Partogram action line study: a randomized trial. British Journal of Obstetrics and Gynaecology, 105(9), 76-980.

Lawrence, G. F., Brown, V. A., Parsons, R. J., & Cooke, I. D. (1982). Feto - maternal consequences of high dose glucose infusion during labour. British Journal of Obstetrics and Gynaecology, 89, 27-32.

Lazarus, R., & Folkman, S. (1984). Stress, Appraisal and Coping. New York: Springer Publishing Co.

Lazarus, R. (1991). Emotion and Adaptation. New York: Oxford University Press.
Lederman, R. P., Lederman, E., Work, B. A., & McCann, D. S. (1978). The relationship of maternal anxiety, plasma catecholamines, and plasma cortisol to progress in labour. American Journal of Obstetrics and Gynecology, 132(5), 495-500.

Lederman, E., Lederman, R. P., Work, B. A., & McCann, D. S. (1981). Maternal psychological and physiologic correlates of fetal-newborn health status. American Journal of Obstetrics and Gynecology, 139(8), 956-958.

Lederman, R. P., Lederman, E., Work, B. A., & McCann, D. S. (1979). Relationship of psychological factors in pregnancy to progress in labour. Nursing Research, 28(2), 94-97.

Lind, T. (1983). Fluid balance during labour: a review. Journal of the Royal Society of Medicine, 76, 870-875.

Lopez - Zeno, J., Peaceman, A., Adashek, J., & Socol, M. (1992). A controlled trial for the active management of labour. The New England Journal of Medicine, 326, 450-454.

Ludka, L. & Roberts, C. (1993) Eating and drinking in labor. Journal of Nurse-Midwifery. 38(4), 199 207.

McCool, W. F., & Susman, E. J. (1994). Cortisol reactivity and self-report anxiety in the antepartum: predictors of maternal intrapartal outcomes in gravid adolescents. Journal of Psychosomatic Obstetrics and Gynecology, 15, 9-18.

McKay,S. & Mahan, C. (1988). How can aspiration of vomitus in obstetrics best be prevented? Birth 15(4), 222-229.

McNiven, P. S., William, J. I., Hodnett, E., Kaufman, K., & Hannah, M. E. (1998). An early labor assessment program: a randomized, controlled trial. Birth, 25(1), 5-10.

Melzack, R., & Katz, J. (1992). The McGill Pain Questionnaire: Appraisal and current status. In D. Turk & R. Melzack (Eds.), Handbook of pain assessment. (pp. 152-168). New York, NY: The Guildford Press.

Melzack, R. (1975). The McGill pain questionnaire: major properties and scoring methods. Pain, 1, 277-299.

Melzack, R., Kinch, R., Dobkin, P., Lebrun, M., & Tquenzer, P. (1984). Severity of labour pain: Influence of physical as well as psychologic variables. Canadian Medical Association Journal, 130, 579-584.

Melzack, R. (1987). The short-form McGill Pain Questionnaire. Pain, 30, 191-197.

Melzack, R. (1993). Labour pain as a model of acute pain. Pain, 53, 117-120.

Mendelson, C. (1946). The aspiration of stomach contents into the lungs during obstetric anaesthesia. American Journal of Obstetrics and Gynaecology, 52, 191-195.

Metzger, B., Ravnikar, V., Vileisis, R., & Freinkel, N. (1982). "Accelerated starvation" and the skipped breakfast in late normal pregnancy. The Lancet, 588-592.

Michael, S., Reilly, C., & Caunt, J. (1991). Policies for oral intake during labour: A survey of maternity units in England and Wales. Anaesthesia, 46, 1071-1073.

Morton, K. E., Jackson, M. C., & Gillmer, M. D. (1985). A comparison of the effects of four intravenous solutions for the treatment of ketonuria during labour. British Journal of Obstetrics and Gynaecology, 92, 473-479.

Murray, R. (1987) The effects of consuming carbohydrate-electrolyte beverages on gastric emptying and fluid absorption during and following exercise. Sports Medicine, 4, 322-351.

Newton, N., Newton, M., & Broach, J. (1988) Psychologic, physical, nutritional and technological aspects of intravenous infusion during labor. Birth 15(2), 67-72.

Nikodem, V . (1994). Upright vs recumbent position during first stage of labour. In Pregnancy and Childbirth Module (eds. Enkin, M. Keirse, M., Renfrew, M., Neilson, J. Cochrane Database of Systematic Reviews. . Oxford: Update Software.

Neumark, J., Hammerle, A., & Biegelmayer, C. (1985). Effects of epidural analgesia on plasma catecholamines and cortisol in parturition. Acta Aneasthesiology Scand. 29, 555-559

Oakley, A. (1983). Social consequences of obstetric technology: The importance of measuring 'soft outcomes'. Birth, 10(2), 99-108.

Odent, M. Laboring women are not marathon runners. (1994) Midwifery Today, 31, 23-25.

O'Driscoll, K., Foley, M., & MacDonald, D. (1984). Active management of labor as an alternative to caesarean section for dystocia. Obstetrics and Gynecology, 63(4), 485-490.

Onur, E., Ercal, T., & Karsioglu, I. (1989). Prolactin and cortisol levels during spontaneous and oxytocin induced labour and the effect of meperidine. Archives of Gynecology and Obstetrics, 244, 227-232.

O'Sullivan, G. (1994). The stomach: Fact and fantasy: Eating and drinking during labour. International Anaesthesiolgy Clinics, 32, 31-44.

Peaceman, A. M., & Socol, M. L. (1996). Active management of labor. American Journal of Obstetrics and Gynaecology, 175(2), 363-368.

Pengelley, L. & Gyte, G. Eating and drinking in labour (Part 1 – V) (1998). The Practising Midwife, Volume 1, Number 7-12.

Pollack, L. D. (1988). Commentary: Reconsidering the risks and benefits of intravenous infusion in labour. Birth, 15 (2), 80

Porter, J. S., Bonello, E., & Reynolds, F. (1997). The influence of epidural administration of fentanyl infusion on gastric emptying in labour. Anaesthesia, 52(12), 1151-1156.

Portenoy, R. K., Thaler, H. T., Kornblith, A. B., McCarthy, J., Friedlander-Klar, H., Kiyasu, E., Sobel,. K., Coyle, N., Kemeny, N., Norton, L. & Scher, H. The memorial symptoms assessment scale: an instrument for the evaluation of symptom

prevalence, characteristics and distress. (1994). European Journal of Cancer. 30A(9), 1326-1336.

Posner, N. A., & Silverstone, F. A. (1977). Carbohydrate metabolism in pregnancy. Obstet Gynecl Ann. 6, 67-125.

Reading, A. E., & Cox, D. N. (1985). Psychosocial predictors of labor pain. Pain. 22, 309-315.

Rooks, J., Weatherby, N., Ernst, E., Stapleton, S., Rosen, D., & Rosenfield, A. (1989). Outcomes of care in birth centres: The National Birth Centre Study. The New England Journal of Medicine, 321, 1804-1811.

Samann, A., Swanson, L., Jackson, M., Madej, T., & Wheatley, R. (1994). Criterion based audit of gastric preparation in obstetric patients having general anaesthesia, in a unit with selective feeding policy. International Journal of Obstetirc Anaesthesia., 63-64.

Sangoul, F., Fox, G. S., & Houle, G. L. (1975). Effect of regional analgesia on maternal oxygen consumption during the first stage of labour. American Journal of Obstetrics and Gynaecology. 121(8), 1080-1083.

Sapolsky, R. (1992). Neuroendocrinology of the Stress-Response. In J. Becker, M. Breedlove, & D. Crews (Eds.), Behavioral Endocrinology. (pp. 287-324). Cambridge, Massachusetts: A Bradford Book. Massachusetts Institute of Technology.

Schade, D. S., Perkins, R. P., & Drumm, D. A. (1983). Interpreting ketosis warnings in pregnancy. Contemp Obstet Gynecol. 21(6), 91-109.

Scott, D. (1978). The history of Mendelsons's syndrome. Journal of Internal Medicine Research, 6, Suppl 1 47-51.

Simkin, P. (1986a). Stress, pain, and catecholamines in labor: Part 1. A Review. Birth. 13(4), 227-233.

Simkin, P. (1986b). Stress, pain, and catecholamines in labour: Part 2. Stress associated with childbirth events: A pilot survey of new mothers. Birth. 13(4), 234-240.

Simkin, P. (1991) Just another day in a woman's life? Women's long-term perceptions of their first birth experience. Part 1. Birth 18(4), 203-210.

Simkin, P. (1992) Just another day in a woman's life? Part 2: Nature and consistency of women's long-term memories of their first birth experience. Birth 19 (2), 64-81.

Smith, R., Cubis, J., Brinsmead, M., Lewin, T., Singh, B., Owens, P. et al. (1990). Mood changes, obstetric experience and alterations in plasma cortisol, beta-endorphin and corticotrophin releasing hormone during pregnancy and the puerperium. Journal of Psychosomatic Research. 34(1), 53-69

Soliman, S. & Burrow, R., (1993). Caesarean section: analysis of the experience before and after the National Consensus Conference on aspects of caesarean birth. CMJA, 148 (8), 1315 - 1320.

Spielberger, C., Gorsuch, R., & Lushene, R. (1970). Manual for the State - Trait Anxiety Inventory. Palto Alto, California: Consulting Psychologists Press.

Stewart, P., Dulberg, C., Arnill, A. C., Elmslie, T., & Hall, P. F. (1990). Diagnosis of dystocia and management with caesarean section among primiparous women in Ottawa-Carleton. Canadian Medical Association Journal, 142(5), 459-463.

Tarnow - Mordi, W. O., Shaw, J. C., Liu, D., Gardner, D. A., & Flynn, F. V. (1981). Iatrogenic hyponatremia of the newborn due to maternal fluid overload: a prospective study. British Medical Journal, 283, 639-642.

Thorp, J., Eckert, L., Ang, M., Johnston, D., Peaseman, A., & Parisi, V. (1991). Epidural analgesia and caesarean section for dystocia: risk factors in nulliparas. American Journal of Perinatology, 8(6), 402-410.

Thorp, J., & Breedlove, G. (1996). Epidural analgesia in labor: An evaluation of risks and benefits. Birth, 23(2), 63-83.

Thornton, J. & Lilford, R. (1994). Active management of labour: current knowledge and research issues. British Medical Journal 309(6951), 366-9.

Turner, M., Brassil, M., & Gordon, H. (1988a). Active management of labor associated with a decrease in the caesarean section rate in nulliparas. Obstetrics and Gynecology, 71(2), 150-154.

Wasserstrum, N. (1992). Issues in fluid management during labor: General considerations. Clinical Obstetrics & Gynecology, 35(4), 505-513.

Werschler, T. (1998). Pregnancy –related hospital use. Health Reports. 10 (1), 21-27.

Williamson, D. H. (1971). Physiological ketosis, or why ketone bodies? Postgrad Med J. 47(supplement), 371-375.

Wray, S. (1993). Uterine contraction and physiological mechanisms of modulation. American Journal of Physiology. Cell Physiology 33, C1-C18.

Wray, S., Duggins, R., Iles, R., Nyman, L, and Osman, V. (1992). The effects of metabolic inhibition and intracellular pH on uterine force production. Experimental Physiology. 77, 307-319.

Wright, P. M., Allen, R. W., Moore, J., & Donnelly, J. P. (1992). Gastric emptying during lumbar extradural analgesia in labour: effect of fentanyl supplementation. British Journal of Anaesthesia. 68(3), 248-251.

Wuitchik, M., Bakal, D., & Lipshitz, J. (1989). The clinical significance of pain and cognitive activity in latent labour. Obstetrics and Gynecology. 73(1), 35-42.

Wuitchik, M., Hesson, K., & Bakal, D. (1990). Perinatal predictors of pain and distress during labour. Birth. 17(4), 186-191.

Yiannouzis, K. (1994). Randomized controlled trial measuring the effects on labour of offering a light, low fat diet. In C. Simms, H. McHaffie, M. Renfrew, & H. Ashurst (Eds.), The Midwifery Research Database (MIRIAD): A sourcebook of information about research in midwifery. (pp. 196-197). Cheshire, England: Books for Midwives Press.

APPENDICES

Appendix A: Ethics Approval and Consent Form

University of Toronto

OFFICE OF RESEARCH SERVICES

<u>Approval by Review Committee on the Use of Human Subjects</u>

Protocol Reference #160/95

Principal Investigator	:	Dr. E. Hodnett, Nursing (J. Tranmer)
Title	:	Fluid and Nutritional Support During Labour: A Randomized Controlled Clinical Trial of a Patient Controlled, Oral Intake Protocol
Review Committee	:	Professor D. Craig, Nursing Dr. D. Wells, Nursing Prof. B. Schlesinger, Social Work
Documents Submitted to Review Committee	:	A protocol, an ORS7 Form, a consent form and questionnaires, a letter from J. Tranmer, a revised consent form, a subject statement form, a statement of the investigator form and an attachment: Obtaining Consent.
Subjects	:	Healthy, pregnant women
Procedures	:	As described in the attached, revised consent documents
Method for Obtaining Consent	:	Information and consent forms, revised as attached. Patients are to be given a copy of the forms to keep.
Remarks	:	
Date of Approval	:	May 31, 1995

*During the course of the research, any significant deviations from the approved protocol and/or any unanticipated developments within the research should be brought to the attention of the Office of Research Services.

*A copy of this approval form is available to Review Committee members upon request.

SP/hg

cc: Dean D. Pringle

Susan Pilon, Executive Officer
Human Subjects Review Committee
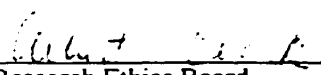
QUEEN'S UNIVERSITY HEALTH SCIENCES AND AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD ANNUAL RENEWAL

Queen's University. in accordance with the "Guidelines on Research Involving Human Subjects. 1987." prepared by the Medical Research Council. requires that research projects involving human subjects be reviewed annually to determine their acceptability on ethical grounds.

A Research Ethics Board composed of:

Dr. A.F. Clark	**Associate Dean, Medical Research Services** **Faculty of Medicine, Queen's University** **Director of Research, Kingston General Hospital (Chair)**
Dr. B. Appleby	**Community Member**
Dr. N.J. Delva	**Associate Professor, Department of Psychiatry, Queen's University**
Dr. S. Irving	**Psychologist, St. Mary's of the Lake Hospital**
Dr. K. James	**Associate Director, National Cancer Institute of Canada Clinical Trials,** **Queen's University** **Associate Professor, Community Health & Epidemiology**
Professor E. Kauffman	**Assistant Professor, School of Nursing, Queen's University**
Dr. J. Low	**Professor, Department of Obstetrics and Gynaecology,** **Queen's University and Kingston General Hospital**
Dr. J. Parlow	**Assistant Professor, Department of Anaesthesia** **Assistant Professor, Department of Pharmacology & Toxicology, Queen's University**
Professor P. Peppin	**Associate Professor, Faculty of Law, Queen's University** **Associate Professor, Department of Family Medicine, Queen's University**
Dr. J. Rapin	**Assistant Professor, Department of Emergency Medicine, Queen's University**
Dr. W. Racz	**Professor, Department of Pharmacology & Toxicology, Queen's University**
Dr. M. Schumaker	**Professor, Department of Religious Studies, Queen's University**
Dr. S. Taylor	**Bioethicist, Faculty of Medicine, Queen's University and Kingston** **General Hospital; Assistant Professor, Department of Family** **Medicine, Queen's University**
Dr. G. Torrible	**Community Member**

has reviewed the request for renewal of Research Ethics Board approval for the project entitled **"Fluid and Nutritional Support During Labour: A Randomized Controlled Trial of a Patient Controlled Oral Intake Protocol vs. Relative Oral Food and Fluid Restriction"** as proposed by Joan E. Tranmer of the Department of Nursing at the Kingston General Hospital. The approval is renewed for one year, effective September 17, 1997. If there are any further amendments or changes to the protocol affecting the subjects in this study it is the responsibility of the principal investigator to notify the Research Ethics Board. Any adverse events must be reported to the Chair within 48 hours.

_____   _____
Chair. Research Ethics Board   Date

KC+I KINGSTON
GENERAL
HOSPITAL

76 STUART STREET
KINGSTON. ONTARIO
K7L 2V7
TEL. 613-548-3232

CONSENT FORM

FLUID AND NUTRITIONAL SUPPORT DURING LABOUR

You are being asked to participate in a research project about nutritional and fluid support during labour conducted by J. E. Tranmer, PhD student under the supervision of Dr. E. Hodnett, Faculty of Nursing, University of Toronto and in conjunction with Kingston General Hospital.

Purpose of Study

The purpose of this study is to determine if encouraging women to drink and eat during labour has an effect on progress and other selected outcomes of labour. Standard practice in most North American Hospitals, and Kingston General Hospital is to restrict oral food and fluids once you are admitted to the hospital in labour. It has been suggested that this may be a routine hospital practice that is unlikely to be beneficial and may contribute to poor progress in labour.

Inclusion and Exclusion Criteria

You will be considered for inclusion in the study if you are having your first baby and are at least 37 weeks pregnant. You will not be considered for the study if you have complications in your pregnancy or anticipate complications in your labour such that you may have a cesarean section.

Details of the Study

If you agree to participate, there is an equal chance of you being assigned to the eating/drinking group or the usual care group. If you are in the usual care group, when you are admitted to the hospital in labour, your oral fluids will be restricted and solid foods will not be allowed. If you are in the eating/drinking group, you will be given an information sheet outlining suggested food and drink

choices, and how much and how often you should try to eat or drink during labour.

If you agree to participate you will be asked to keep a record of what you eat and drink during labour. A log sheet will be provided for this purpose. As well, after you give birth, you will be asked to complete a questionnaire. This will take about fifteen minutes of your time. Information about your labour will be taken from your medical record.

Benefits

While you may not benefit directly from this study, results from this study may provide useful information about nutritional and fluid support during labour.

Risks

There is little evidence of risk directly related to drinking and eating during labour. In the past, in a very small number (<1 per 10,000) there were deaths related to regurgitation and aspiration of stomach contents in women who received general anaesthetic. Anaesthetic techniques and treatments have improved and it is felt that the incidence and risk of death in low risk women related to gastric aspiration is even less now.

The oral protocol will stop and usual care will proceed if your labour becomes complicated and there is a potential of a general anaesthetic or if you decide to have an epidural. You will still be considered part of the study and will be asked to complete the questionnaire after you give birth.

Voluntary Participation

Regardless of which group you are in, you will receive care in accordance with accepted medical and nursing practice. Your best interests will take precedence over the objectives of the study. You are free to withdraw from the study at any time or refuse to answer any of the questions without it affecting your care at this hospital.

Confidentiality

All information from this study will be confidential and all records will be maintained in a locked file in the research office. Your name or other identifying

information will not be disclosed in any coding of data or reporting of the results. Only members of the investigative team will have access to the data collected.

FLUID AND NUTRITIONAL SUPPORT DURING LABOUR
SUBJECT STATEMENT

I have read and understand the consent form for this study.

I have had the purpose and procedures of this study explained to me. I understand the following: a) that this is a study looking at the effect of eating and drinking during labour; b) I will be assigned to either an usual care group or an eating/drinking group; c) I will asked to keep a log of what I eat and drink during labour; d) I will be asked to complete a questionnaire after delivery and e) information will be collected from my medical record. I understand that there is little evidence of risk to eating and drinking during labour, but in the past an extremely small number of women developed complications related to aspiration of stomach contents. If I am in the eating/drinking groups and my labour becomes complicated or I request an epidural the oral protocol will stop.

I have been given sufficient time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form.

I will receive a copy of this consent form for my information.

If at any time I have any questions or concerns about this study I may contact Dr. E. Hodnett, Director, Perinatal Nursing Research Unit, Mount Sinai Hospital, Toronto, Ontario (416- 586 - 8416), J.E. Tranmer, Principal Investigator, Kingston General Hospital (613 - 548 - 3232: Ext. 4952); L. S. Davis, Vice President, Kingston General Hospital (613 - 548 3232: Ext. 6004) or Dr. M. McGrath, Associate Professor and Chair, Division of Maternal and Fetal Medicine (613 - 548 3232: Ext. 4082)

By signing this form, I am indicating that I agree to participate in this study.

_____   _____
Signature of Patient   Date

_____   _____
Signature of Witness   Date

FLUID AND NUTRITIONAL SUPPORT DURING LABOUR
STATEMENT OF INVESTIGATOR

I, or one of my colleagues have carefully explained to the subject the nature of the above research study. I certify that, to the best of my knowledge, the subject understands clearly the nature of the study and demands, benefits and risks involved to participants in this study.

_____   _____

Signature of Principal Investigator   Date

Appendix B: Patient Teaching Pamphlet

FOOD AND FLUIDS DURING LABOUR

A SUGGESTION FOR A HOME MADE LABOUR DRINK
- LITRE OF WATER
- 100 ML OF HONEY
- 100 ML OF LEMON/ORANGE CONCENTRATE
- 5 ML TSP SALT
- 5 ML BAKING SODA
- 500 MG CALCIUM

IMPORTANT THINGS TO REMEMBER!

- Taste is important. If you like the taste, you may drink (or eat) more and the more fluids you drink, the better.
- Eat and drink frequently. Smaller amounts are easier to digest.
- As labour progresses you need to maintain your energy source. Keep at it!
- Bring your own supplies and special foods and drinks to the hospital. Sometimes they do not have the drinks or foods you like.

Most importantly, remember your labour and delivery is special for you but by maintaining a well balanced diet before and during labour you are better prepared for the physical demands of labour and postpartum recovery - to enjoy your time as a family.
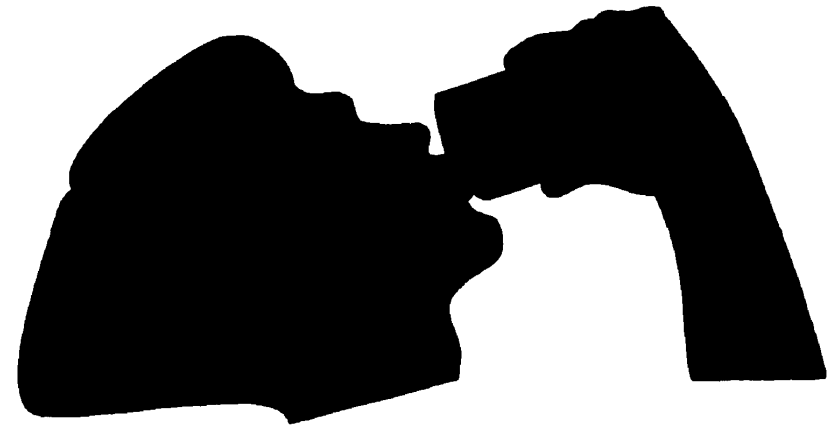
WHY DO I NEED TO EAT AND DRING DURING LABOUR?

Pregnancy and labour can be demanding on you and your body. A well balanced diet goes a long way to meeting this demand.

To meet the special demands of labour you need to pay special attention to the food and fluids you eat and drink during labour, especially at the beginning.

The food and fluids you drink during labour need to do two things:
1. Replace the fluids you lose due to the work of labour
1. Replenish your energy (carbohydrate) stores that are used during labour

WHAT DO I EAT AND DRINK ?

As the start of labour is unpredictable, you need to keep the following points in mind:
- Fluids are generally tolerated better than solids
- Cool fluids are better absorbed into the blood
- Choose foods and drinks that you enjoy and feel comfortable eating and drinking. This is not the time to try something new!

You have your own food and fluids likes and dislikes, but some suggested ideas for what you may want to eat or drink include...

Fluids: Fluids such as fruit juices, sport drinks (e.g. Gatorade, Energade), fruit popsicles, and home made labour drinks can provide both an energy and fluid source.

Water: You can drink as much water as you wish, but remember it will not be a source of energy for your labour.

Solid snacks: Foods such as breads, bagels, muffins, crackers, fresh fruits, dry cereals, cookies (fig bars, digestives) and yogurt can provide a quick energy source are usually tolerated well.

HOW OFTEN SHOULD I EAT AND DRINK?

You need to drink and eat before you feel thirsty and hungry.

As labour starts...Try and eat or drink frequent small meals, 4-6 servings, every 3-4 hours.

As labour becomes more active and the contractions more regular you may want to eat less, but more frequently, 2-4 servings spread out during the hour, so that you are drinking or eating almost every 15-20 minutes. Do what feels comfortable for you. You can keep on this pattern until you deliver!

As labour becomes more intense you may not feel like eating or drinking. Try and take small frequent sips of your energy fluids. This is when you will need it! It may be a good idea to use a "water bottle or straw".

PICTURE YOUR FOOD AND DRINK PATTERN DURING LABOUR
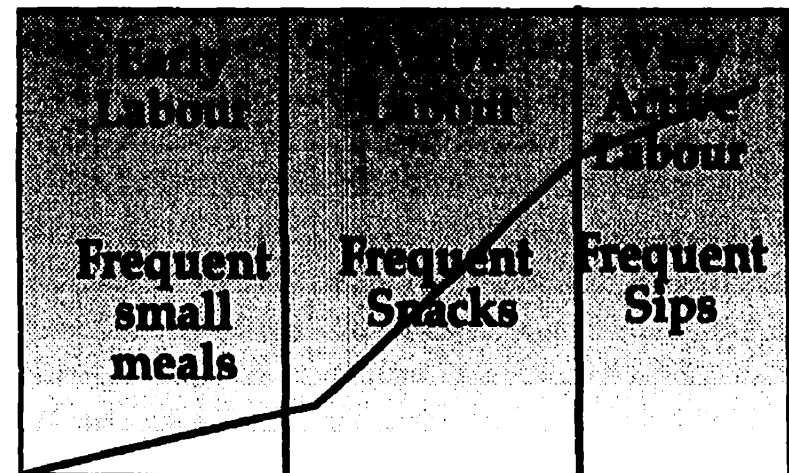
Note: Consider one serving to be either 125 ml (½ cup) of fluids or one portion of a snack

Appendix C: Postpartum Questionnaire

NUTRITIONAL SUPPORT DURING LABOUR

POSTPARTUM PATIENT QUESTIONNAIRE BOOKLET

Please complete the entire booklet

Return to:
Joan Tranmer
Director, Nursing Research
Kingston General Hospital
76 Stuart St.
Kingston, Ontario
K7L 2V7

NUTRITIONAL SUPPORT DURING LABOUR
POSTPARTUM PATIENT QUESTIONNAIRE

Thank you for your participation in the study of **NUTRITIONAL SUPPORT DURING LABOUR.**
An important part of the study is how participants felt about certain aspects of their labour.

I realize that you were in one of two groups. Feedback from both groups, regardless of the
circumstances surrounding each labour experience, is important in order to have enough
information in both groups to make comparisons.

The feedback will come from the completion of the questionnaires and any additional
comments you wish to make. All your answers will be strictly confidential.

**Please return the questionnaire, in hospital, to the nursing desk, or at home, in the
stamped envelope provided.**

GENERAL INSTRUCTIONS FOR ALL PARTS OF THE QUESTIONNAIRE

This package contains five short questionnaires. Each questionnaire will ask a series of
questions about your labour experience. Just as no two women are exactly alike, no two
women experience the same feelings and sensations during labour. Think about your
labour and try to remember what you *generally* felt and experienced during this time. Of
course, you had many different feelings during the course of labour, but when you
answer the questions try and recall how you *generally felt* or what you *generally*
experienced.

There are no right or wrong answers. Do not spend too much time on any one statement
but give the answer which seems to describe what you generally felt.

Please feel free to add comments at any point in the questionnaire.

PART 1

Instructions

Please mark an "X" in the circle that best describes how you generally felt during labour. For example:
The first statement is "I felt confident". If you felt confident all or almost all of the time, place your "X" in the space closest to "Almost Always".

1.   I felt Confident
Almost Always   O   O   O   O   O   O   O   Rarely
                7   6   5   4   3   2   1

If you felt confident a lot of the time, but not almost always, place your "X" in the second space near "Almost Always".
1.   I felt Confident
Almost Always   O   O   O   O   O   O   O   Rarely
                7   6   5   4   3   2   1

If you felt confident a little more than half the time, place your "X" in the third space near "Almost Always".
1.   I felt Confident
Almost Always   O   O   O   O   O   O   O   Rarely
                7   6   5   4   3   2   1

If you felt confident about half the time, place your "X" in the middle space.
1.   I felt Confident
Almost Always   O   O   O   O   O   O   O   Rarely
                7   6   5   4   3   2   1

If you felt confident slightly less than half the time, place your "X" in the third space near "Rarely".
1.   I felt Confident
Almost Always   O   O   O   O   O   O   O   Rarely
                7   6   5   4   3   2   1

If you sometimes felt confident, place your "X" in the second space near "Rarely".
1.   I felt Confident
Almost Always   O   O   O   O   O   O   O   Rarely
                7   6   5   4   3   2   1

If you never or almost never felt confident, place your "X" in the space closest to "Rarely".
1.   I felt Confident
Almost Always   O   O   O   O   O   O   O   Rarely
                7   6   5   4   3   2   1

Start Here:

Part 1: This is the first questionnaire. Please try and rate each statement independently of how you rate other statements.

1.   I felt confident

Almost Always	O 7	O 6	O 5	O 4	O 3	O 2	O 1	Rarely

2.   I felt defeated

Almost Always	O 1	O 2	O 3	O 4	O 5	O 6	O 7	Rarely

3.   I felt important

Almost Always	O 7	O 6	O 5	O 4	O 3	O 2	O 1	Rarely

4.   I felt tense

Almost Always	O 1	O 2	O 3	O 4	O 5	O 6	O 7	Rarely

5.   I had a sense of understanding what was happening

Almost Always	O 7	O 6	O 5	O 4	O 3	O 2	O 1	Rarely

6.   I felt insecure

Almost Always	O 1	O 2	O 3	O 4	O 5	O 6	O 7	Rarely

7.   I felt relaxed

Almost Always	O 7	O 6	O 5	O 4	O 3	O 2	O 1	Rarely

8.   I felt competent

Almost Always	O 7	O 6	O 5	O 4	O 3	O 2	O 1	Rarely

9.   Someone or something else was in charge of my labour

Almost Always	O 1	O 2	O 3	O 4	O 5	O 6	O 7	Rarely

10.   I felt inadequate

Almost Always	O 1	O 2	O 3	O 4	O 5	O 6	O 7	Rarely

11.   I experienced a sense of distress

Almost Always	O 1	O 2	O 3	O 4	O 5	O 6	O 7	Rarely

12.   Everything seemed unclear and unreal

Almost Always	O 1	O 2	O 3	O 4	O 5	O 6	O 7	Rarely

13.   I was completely aware of everything that was happening

Almost Always	O 7	O 6	O 5	O 4	O 3	O 2	O 1	Rarely

14.   I felt panicked

Almost Always	O 1	O 2	O 3	O 4	O 5	O 6	O 7	Rarely

15. I felt like I was falling to pieces

Almost Always	O	O	O	O	O	O	O	Rarely
	1	2	3	4	5	6	7	

16. I had a feeling of constriction and of being confined

Almost Always	O	O	O	O	O	O	O	Rarely
	1	2	3	4	5	6	7	

17. I was in control

Almost Always	O	O	O	O	O	O	O	Rarely
	7	6	5	4	3	2	1	

18. I experienced a sense of being with others who care

Almost Always	O	O	O	O	O	O	O	Rarely
	7	6	5	4	3	2	1	

19. Everything made sense

Almost Always	O	O	O	O	O	O	O	Rarely
	7	6	5	4	3	2	1	

20. I felt like I was dying

Almost Always	O	O	O	O	O	O	O	Rarely
	1	2	3	4	5	6	7	

21. I felt like I was doing everything I should have been doing

Almost Always	O	O	O	O	O	O	O	Rarely
	7	6	5	4	3	2	1	

22. I felt helpless

Almost Always	O	O	O	O	O	O	O	Rarely
	1	2	3	4	5	6	7	

23. Everything seemed peaceful and calm

Almost Always	O	O	O	O	O	O	O	Rarely
	7	6	5	4	3	2	1	

24. I experienced a sense of success

Almost Always	O	O	O	O	O	O	O	Rarely
	7	6	5	4	3	2	1	

25. I felt powerless

Almost Always	O	O	O	O	O	O	O	Rarely
	1	2	3	4	5	6	7	

26. I experienced a sense of failure

Almost Always	O	O	O	O	O	O	O	Rarely
	1	2	3	4	5	6	7	

27. I was accepting of what was happening

Almost Always	O	O	O	O	O	O	O	Rarely
	7	6	5	4	3	2	1	

28. I felt capable

Almost Always	O	O	O	O	O	O	O	Rarely
	7	6	5	4	3	2	1	

29. I felt bad about my behaviour during labour

Almost Always	O	O	O	O	O	O	O	Rarely
	1	2	3	4	5	6	7	

A number of statements which people have used to describe themselves are given below. Read each statement and then put an "X" in the circle of the statement that best indicates how you *generally* felt during your labour.
For example:
1. If you felt calm most of the time place an "X" in "Very Much So".
2. If you felt calm more than half of the time place an "X" in "Moderately So".
3. If you felt calm less than half of the time place an "X" in "Somewhat".
4. If you rarely felt calm place an "X" in "Not at All".

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I felt calm	O 4	O 3	O 2	O 1
2. I felt secure	O 4	O 3	O 2	O 1
3. I was tense	O 1	O 2	O 3	O 4
4. I felt strained	O 1	O 2	O 3	O 4
5. I felt at ease	O 4	O 3	O 2	O 1
6. I felt upset	O 1	O 2	O 3	O 4
7. I was worrying over possible misfortune	O 1	O 2	O 3	O 4
8. I felt satisfied	O 4	O 3	O 2	O 1
9. I felt frightened	O 1	O 2	O 3	O 4

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
10. I felt comfortable	O 4	O 3	O 2	O 1
11. I felt self-confident	O 4	O 3	O 2	O 1
12. I felt nervous	O 1	O 2	O 3	O 4
13. I was jittery	O 1	O 2	O 3	O 4
14. I felt indecisive	O 1	O 2	O 3	O 4
15. I was relaxed	O 4	O 3	O 2	O 1
16. I felt content	O 4	O 3	O 2	O 1
17. I was worried	O 1	O 2	O 3	O 4
18. I felt confused	O 1	O 2	O 3	O 4
19. I felt steady	O 4	O 3	O 2	O 1
20. I felt pleasant	O 4	O 3	O 2	O 1

PART 3:

Listed below are a number of words which may describe what your _pain_ during labour felt like.

1. Try and recall what your pain felt like for the most part of the labour and place an "X" in the box under those words which describe it best.

	NONE	MILD	MODERATE	SEVERE
THROBBING	▢ 0	▢ 1	▢ 2	▢ 3
SHOOTING	▢ 0	▢ 1	▢ 2	▢ 3
STABBING	▢ 0	▢ 1	▢ 2	▢ 3
SHARP	▢ 0	▢ 1	▢ 2	▢ 3
CRAMPING	▢ 0	▢ 1	▢ 2	▢ 3
GNAWING	▢ 0	▢ 1	▢ 2	▢ 3
HOT-BURNING	▢ 0	▢ 1	▢ 2	▢ 3
ACHING	▢ 0	▢ 1	▢ 2	▢ 3
HEAVY	▢ 0	▢ 1	▢ 2	▢ 3
TENDER	▢ 0	▢ 1	▢ 2	▢ 3
SPLITTING	▢ 0	▢ 1	▢ 2	▢ 3
TIRING-EXHAUSTING	▢ 0	▢ 1	▢ 2	▢ 3
SICKENING	▢ 0	▢ 1	▢ 2	▢ 3
FEARFUL	▢ 0	▢ 1	▢ 2	▢ 3
PUNISHING-CRUEL	▢ 0	▢ 1	▢ 2	▢ 3

2.   Circle the number associated with the one word group that best describes the duration and intensity or strength of your pain for the most part of the labour.

1	2	3
Continuous	**Rhythmic**	**Brief**
Steady	**Periodic**	**Momentary**
Constant	**Intermittent**	**Transient**

3.   Place an "x" in the box that best describes the intensity of your labour pain for the most part of the labour.

0	1	2	3	4	5
None	**Mild**	**Discomforting**	**Distressing**	**Horrible**	**Excruciating**

PART 4: LABOUR SUPPORT

Instructions

Listed below are types of support which some women have found helpful during labour. You probably experienced some but not all of the supportive activities on the list. Consider the first activity on the list. How often did a *Nurse* provide for you - Never, Occasionally or Frequently? Place an "X" in the appropriate box beside the activity.

"Occasional" is defined as one or more times, but not often.
"Frequent" is defined as several times, quite often and/or repeatedly.

ACTIVITY	NURSE		
	NEVER	OCCASIONAL	FREQUENT
1. Giving me cool cloths or warm compresses	☐ 1	☐ 2	☐ 3
2. Helping me with my breathing	☐ 1	☐ 2	☐ 3

ACTIVITY	NURSE		
	NEVER	OCCASIONAL	FREQUENT
3. Light comforting touch, such as holding my hand, stroking my brow	☐ 1	☐ 2	☐ 3
4. Reassuring me	☐ 1	☐ 2	☐ 3
5. Offering me ice chips or fluids to drink	☐ 1	☐ 2	☐ 3
6. Giving me information about my progress in labour	☐ 1	☐ 2	☐ 3
7. Interpreting the doctor's assessment to me	☐ 1	☐ 2	☐ 3
8. Giving advice, such as suggesting relaxation or comfort measures	☐ 1	☐ 2	☐ 3
9. Being with me to keep me company	☐ 1	☐ 2	☐ 3
10. Explaining what was happening to me	☐ 1	☐ 2	☐ 3
11. Supporting my decisions	☐ 1	☐ 2	☐ 3
12. Acting on my behalf	☐ 1	☐ 2	☐ 3
13. Massaging my back or other parts of my body	☐ 1	☐ 2	☐ 3
14. Giving me encouragement	☐ 1	☐ 2	☐ 3
15. Assisting me with walking	☐ 1	☐ 2	☐ 3
16. Interpreting my needs to other staff members	☐ 1	☐ 2	☐ 3
17. Changing my underpads or sheets	☐ 1	☐ 2	☐ 3
18. Having a social conversation with me	☐ 1	☐ 2	☐ 3
19. Helping me to find a comfortable position	☐ 1	☐ 2	☐ 3

Instructions

Just as no two women are exactly alike, no two women experience the same physical feelings during labour. Please try and recall you labour as vividly as you can. Think about your physical sensations during labour. Of course, you had many different sensations, but try to remember what you generally felt like during this time.

To rate your physical feelings follow the instructions as outlined *in Part 1: Childbirth Feelings Scale.* Please mark an X in the circle that corresponds to what you generally felt.

1)   How nauseated were you during labour?

Worst possible nausea   O   O   O   O   O   O   O   No nausea
                     7   6   5   4   3   2   1

2)   How hungry were you during labour?

Worst possible hunger   O   O   O   O   O   O   O   No hunger
                     7   6   5   4   3   2   1

3)   How thirsty were you during labour?

Worst possible thirst   O   O   O   O   O   O   O   No thirst
                     7   6   5   4   3   2   1

4)   How tired were you **during labour?**

Worst possible fatigue   O   O   O   O   O   O   O   No fatigue
                     7   6   5   4   3   2   1

5)   How tired were you the **first day after you delivered?**

Worst possible fatigue   O   O   O   O   O   O   O   No fatigue
                     7   6   5   4   3   2   1

Please try to recall and list what you ate or drank **during your labour.**
     1) While you were at home in the earlier stages of labour

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

2) While you were in the hospital during labour

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

3) What food or drinks did you enjoy the most?

_____
_____
_____
_____
_____
_____
_____

4) What food or drinks did you not enjoy?

_____
_____
_____
_____
_____
_____
_____

5) Other: Please comment on any other aspect of providing food and fluids during labour which you think is important.

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Part 6: Start of Labour Information

1. **What time do you feel your labour first started?**

   Year _____ Month _____ Date _____
   Time (hour:minute) _____

2. **How frequent were your contractions at this start time?**

   Approximately one contraction every _____ minutes.

3. **Do you feel your contractions were regular at this start time?**

   Yes _____   No _____

4. **What time did you go to the hospital?**

   Year _____ Month _____ Date _____
   Time (hour:minute) _____

Pregnancy Information

Listed are a few questions about your pregnancy. Please answer as best you can.

1. **What was your weight before you became pregnant?**

I weighed _____ gms or _____ pounds.

2. **What was your weight just before you delivered?**

Just before delivery, I weighed _____ gms or _____ pounds.

3. **How tall are you?**

My height is _____ cm or _____ feet/inches.

4. **Did you experience any nausea during pregnancy?**

Yes _____ No _____

5. **Did you experience any vomiting during pregnancy?**

Yes _____ No _____

6. **Did you smoke during your pregnancy?**

Yes _____ No _____ If yes, I smoked about _____ pack per day.

7. **Did you drink any alcohol during your pregnancy?**

Yes _____ No _____

If yes, I had about _____ drink(s) per day or _____ drink(s) per week.

Part 7: Sociodemographic Information

Listed below are a few questions about your background. This information is needed to help compare study findings in both groups. As with all your responses on this questionnaire, this information is completely confidential.

Question	Response
What is your age in completed years? Give the exact date of your birth.	_____ years Year _____ Month ____ Day ____
What is your marital status? . 1. Married 2. Common-law 3. Single 4. Separated/divorced	O Enter number that applies.
What is your highest level of education completed? 1. Completed primary school 2. Completed secondary school 3. Completed community college, technical college, or nursing program 4. Completed undergraduate university degree 5. Completed postgraduate degree (Masters, PhD)	O Enter number that applies
What is the language most often spoken at home? 1. English 2. French 3. Italian 4. Portuguese 5. Spanish 6. Chinese 7. Vietnamese 8. Other (specify)	O Enter number that applies _____
What was your main activity during the last 12 months? 1. Working at a job 2. Looking for work 3. Going to school 4. Keeping house 5. Other (Specify) If you worked at a job what was your occupation?	O Enter number that applies _____ _____

What was your approximate total combined income for the last 12 months? 1. No income 2. Less than $14,999 3. $15,000 - $29,999 4. $30,000 - $44,999 5. $45,000 - $59,999 6. $60,000 - $74,999 7. Greater than $75,000	O Enter number that applies
What is your ethnic or cultural identity? 1. Canadian 2. French 3. English 4. Italian 5. Chinese 6. East Indian 7. North American Indian 8. Other (specify)	O O O Enter all numbers that apply _____

A) Did you receive the information book "You Need Energy: Food and Fluids During Labour"? YES O   NO O

B) If you received the book, did you have an opportunity to speak with a member of the investigative team about the information in the book? YES O   NO O

C) If you did not receive the book, did you have an opportunity to speak with a member of the investigative team about the information in the book? YES O   NO O

PLEASE NOTE ANY OTHER COMMENTS IF YOU WISH

_____
_____
_____
_____

THANK YOU FOR TAKING THE TIME TO RESPOND TO THIS QUESTIONNAIRE.
IF YOU HAVE ANY CONCERNS OR FURTHER COMMENTS PLEASE CALL:
Joan Tranmer 613-548-3232 Extension 4952.

Appendix D: Statistical Analysis Program for the Calculation of Dystocia

```
ptions ls=78 ps=50;
libname study 'c:\data\perinatal';
proc access dbms=xls;
create study.perinat.access;
path='c:\data\perinatal\newborn2.xls';
getnames=yes;
list all;
create study.perinat.view;
select all;
proc access viewdesc=study.perinat out=study.newborn2;
run;

proc sort data=study.labourh nodupkeys; by studyno; run;
proc sort data=study.groupass nodupkeys; by studyno; run;
proc sort data=study.anxiety nodupkeys; by studyno; run;
proc sort data=study.control nodupkeys; by studyno; run;
proc sort data=study.support nodupkeys; by studyno; run;
proc sort data=study.painphys nodupkeys; by studyno; run;
proc sort data= study.newborn2 nodupkeys; by studyno; run;
proc sort data = study.descript nodupkeys; by studyno; run;

data study.all; merge study.labourh study.groupass
study.anxiety study.control study.support study.painphys study.newborn2
study.descript ; by studyno;

     speed=round(.5/60,.000001);
    examo=.;dilato=.;
    examf=.;
    dilatf=.;
    dysto=0;
intv=.;
slope=.;
timea=.;
timeb=.;
dilata=.;
dilatb=.;
exama=.;
examb=.;
dati1=.;
support = .;
anxiety = .;
painper=.;
control=.;



     if dil1=0 then dil1=.;
if dil2=0 then dil2=.;
if dil3=0 then dil3=.;
if dil4=0 then dil4=.;
if dil5=0 then dil5=.;
if dil6= 0 then dil6=.;
if dil7=0 then dil7=.;
if dil8=0 then dil8=.;
if dil9=0 then dil9=.;
```

```
if dil10=0 then dil10=.;
if dil11=0 then dil11=.;
if dil12=0 then dil12=.;
if dil13=0 then dil13=.;
if dil14 = 0 then dil14=.;
if dil15=0 then dil15=.;
if dil16=0 then dil16=.;
if dil17=0 then dil17=.;
if dil18=0 then dil18=.;
if dil19=0 then dil19 = .;
if dil20=0 then dil20=.;

     array cervix {*} diln1-diln20;
     array minuts {*} timen1-timen20;


dtime1= date1*24*60*60 + time1;
dtime2= date2*24*60*60 + time2;
dtime3= date3*24*60*60 + time3;
dtime4= date4*24*60*60 + time4;
dtime5= date5*24*60*60 + time5;
dtime6= date6*24*60*60 + time6;
dtime7= date7*24*60*60 + time7;
dtime8= date8*24*60*60 + time8;
dtime9. = date9*24*60*60 + time9;
dtime10 = date10*24*60*60 + time10;
dtime11= date11*24*60*60 + time11;
dtime12= date12*24*60*60 + time12;
dtime13= date13*24*60*60 + time13;
dtime14= date14*24*60*60 + time14;
dtime15= date15*24*60*60 + time15;
dtime16= date16*24*60*60 + time16;
dtime17= date17*24*60*60 + time17;
dtime18= date18*24*60*60 + time18;
dtime19 = date19*24*60*60 + time19;
dtime20 = date20*24*60*60 + time20;

     timen1 = dtime1;
     timen2 = dtime2;
     timen3 = dtime3;
     timen4 = dtime4;
     timen5 = dtime5;
     timen6 = dtime6;
     timen7 = dtime7;
     timen8 = dtime8;
     timen9 = dtime9;
     timen10 = dtime10;
     timen11 = dtime11;
timen12= dtime12;
timen13=dtime13;
timen14=dtime14;
timen15=dtime15;
timen16=dtime16;
timen17= dtime17;
```

```
timen18= dtime18;
timen19= dtime19;
timen20= dtime20;

     diln1  = dil1;
     diln2  = dil2;
     diln3  = dil3;
     diln4  = dil4;
     diln5  = dil5;
     diln6  = dil6;
     diln7  = dil7;
     diln8  = dil8;
     diln9  = dil9;
     diln10 = dil10;
diln11= dil11;
diln12= dil12;
diln13 = dil13;
diln14 = dil14;
diln15= dil15;
diln16 = dil16;
diln17 = dil17;
diln18 = dil18;
diln19 = dil19;
diln20 = dil20;




 do i = 1 to 19;
   if cervix(i) >= 3 and dysto=0 and cervix(i)<=10 then do;
      examo=minuts(i);
      dilato=cervix(i);
      do j=2 to 20;
          if dysto=0 and cervix(j-1)<=10 then do;
              dilatf=cervix(j);
              examf=minuts(j);
              intv=(examf-examo)/60;
              if intv > 0 then slope=round((dilatf-dilato)/intv,.000001);
              if intv >= 240 and slope < speed then do;
dysto=1; timea=i; timeb=j; dilata=dilato; dilatb=dilatf; exama=examo; examb=examf;
          end;
       end;
     end;
end;
end;


oossdys =.;
stimgr=.;
alldys = .;
failprog =.;
totaldys = .;
```