management of labour pain in midwifery care

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Trudy Klomp

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Voor mijn ouders Dini Klomp-Casteel († 2001) en Joop Klomp

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Promotoren:
Prof. dr. A.L.M. Lagro-Janssen
Prof. dr. E.H. Hutton (Vumc)

Copromotor:
dr. A. de Jonge (Vumc)

Manuscriptcommissie
Prof. dr. F.P.H.A. Vandenbussche
Prof. dr. M.Y. Berger (UMCG)
Prof. dr. R de Vries (UM)

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Chapter 1

General Introduction

"Birth is as safe as life gets" – Harriette Hartigan

Prologue

As a midwife practicing until 2004 in the eastern part of the Netherlands I found that helping birthing women with their labour pain was always a great challenge. Above all, during the busy shifts, it seemed difficult to focus on the care of labouring women, and I required my full concentration to determine how the woman was coping with her labour pain and how I could effectively help her and her partner in order to contribute to their satisfaction with the childbirth. These midwifery experiences of helping women with labour pain inspired me to do research into understanding and improving management of labour pain.

First, this general introduction describes the maternity care system in the Netherlands followed by, literature on childbirth experience, labour pain and factors that influence experiences of labour pain. Furthermore, literature on the effectiveness and safety of inhaled analgesia for mother and child is described. Finally, this chapter presents the general aim of the study, research questions and the outline of this thesis.

Maternity care in the Netherlands

In the Netherlands, midwives are autonomous medical health care professionals with a four year Bachelor degree in Midwifery from one of the four Dutch Midwifery colleges. Additionally, midwives can choose to obtain a midwifery Master degree, and so far, 12 midwives finished a PhD degree at one of the universities (1).

Maternity care in the Netherlands is divided into primary – or midwife-led care for low risk women and secondary – or obstetrician-led care for women with an increased risk of complications. Low risk women who start their labour in midwife-led care will have: a term, singleton pregnancy; no (known) non-cephalic presentation; a spontaneous start of labour and no other obstetric risk factors for a normal, physiological birth. Medical interventions during labour such as medicinal pain relief, electronic foetal monitoring and augmentation of labour only take place in obstetrician-led care in hospital. Women who fear labour pain and who have decided that they will choose medicinal pain relief before going into labour may be referred by their midwife for a consultation with the obstetrician in order to discuss approaches to manage labour pain management. However, usually these women start labour in midwife-led care and they will make arrangements with their midwives that they will be referred to obstetrician-led care for medicinal pain relief as soon as required.

Around 80% of women start their prenatal care in midwife-led care and around 55% of women start labour in midwife-led care (2). Low-risk women give birth with supervision of a community midwife (midwife-led care) and they may choose to give birth at home or in a birth centre or midwife-led maternity care in hospital. Women will have care transferred to hospital and obstetrician-led care when complications arise during labour. Compared to other countries where midwives work autonomously, Dutch midwives have a relatively high caseload (3).
Research to support evidence-based practice in primary care midwifery in the Netherlands has been sparse and more research is urgently needed to evaluate this maternity care system and practice. To evaluate the quality of maternity care in the Netherlands with our focus on labour pain management, we will first describe some background about childbirth experiences of women.

Childbirth experience

In recent decades, the importance of assessing satisfaction with health care has become more obvious. Patients' experiences and perceptions are being used by managers and policy makers in evaluating the quality of care. Policy makers use these evaluations in decision making about health care services (4;5). Childbirth is the most common reason for women to access health services.
The degree of satisfaction with childbirth is influenced by several factors such as labour pain expectations and experiences (6;7). Remarkably, sense of control (over labour pain), which is an important determinant associated to labour pain experiences, and accessibility of pain relief seem more important than the degree of physical pain (6-8). Rijnders et al found that 'not being satisfied about coping with pain' and 'not having had a choice in pain relief' were important determinants for dissatisfaction with the childbirth experience three years after birth (8). Childbirth is a major life event that affects women's physical (9-11) and emotional wellbeing (8;12), and determines women's relationship with her newborn baby (13;14) and her partner (15). For most women, giving birth to a healthy child is the most important aim of childbirth. At the same time, satisfaction with the childbirth experience seems to be important for women's long term vivid memories of childbirth (8).
Experiences of women in labour are significant outcomes of maternity care and how women experienced dealing with labour pain is an important factor influencing childbirth experience (7;16). It is important to understand the physical dimensions of labour pain as well as how women experience pain in labour.

Labour pain

Labour pain is a very specific pain. In contrast to other acute and chronic pain, it is related to the most basic life experience of giving birth and it is unrelated to pathology (17). There are many religious and philosophic disputes about why labour should be painful (17;18). From a biological perspective, the meaning of labour pain might be explained as a mechanism to alert a women that she is about to give birth, so that she can prepare herself for her newborn and so that others around her may pick up the signal of her labour and help her in the labour process (19).

The International Association for the Study of Pain definition of labour pain is: "Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (20).

During the first stage of labour women experience the visceral pain of diffuse abdominal cramps and contractions of the uterus. In the second stage of labor, during pushing, there is a sharper and more continuous pain in the perineum by the pressure of the head of the baby that makes its way through the birth canal (21-23) Women might feel extensive and diffuse pain sensations, although others might feel much more localized pain in specific parts of their body (23).

While nearly all women in labour experience lower abdominal pain during labour contractions, some may also experience contraction-associated low back pain that for some is continuous, even between labour contractions (24;25). Pressure or nerve compression caused by the head of the fetus, might cause back or sometimes leg pain. Nulliparous women usually experience more intense sensory pain early during labour while parous women experience more intense pain during the late first stage partly because of a rapid descent of the head of the baby (26;27). Similar to other types of visceral pain, as labour progresses, the sensory pain is increasingly felt in the abdominal wall, lumbosacral region, iliac crests, gluteal areas, and thighs (21). The intensity of sensory pain is not linearly related to women's experiences of labour pain (16;23). Other factors than the sensory sensation play an important role in how women experience pain (28).

Experiences of labour pain

Women's experiences of labour pain vary greatly (16;29). Some women feel little pain while other women classify the pain as extremely stressful. In exceptional cases, women feel no pain at all and can give birth unexpectedly. However for the majority of women, labour is ranked as the most painful experience in their life (30).

The neuroscience of labour pain provides interesting insights into the meaning of labour pain (28). Labour pain is an intense, personal interpretation of the sensory pain stimuli during labour. Many factors play a role in this interpretation of the meaning of labour pain: important emotional, motivational and cognitive components are involved (19;29). Catastrophizing of pain is described in the field of pain research to illustrate persons who had a tendency to increase or overstate the pain feelings (i.e., "I'm afraid that my pain might get worse"). Pain catastrophizing by women increases the need for pain medication during labour among low-risk women (31;32). Variations in level of pain experienced might be explained, at least in part, by this phenomenon. Additionally, culture plays an important role in the personal expression and interpretation of labour pain (19;33) and along with other aspects of personal interpretation results in a subjective and abstract experience of labour pain (19;28;29).

Another explanation of the variations in women's labour pain experiences is that pain can be temporarily put aside in stressful situations in order to achieve a specific goal, such as winning or survival. If goals are uncertain or not concrete enough for women during childbirth than the pain inhibition response will be less activated and consequently women will experience more pain (28). If the woman does not know what is going on and she is uncertain about the outcome then all sensory windows open to obtain additional information resulting in increased anxiety and possibly more pain (28).

Personal expectations about labour pain also seems to play a major role in how women experience childbirth (34). Negative expectations such as fear of labour pain – caused by a negative labour pain experience with previous childbirth or by fear of the unknown – or perineal damage when the baby is born may lead to a so-called nocebo effect that can influence the pain experience. A nocebo effect is the opposite of a placebo effect and is described as a negative effect that occurs after patients or clients incorporated certain (negative) conceptions about their health state. The pain of labour is enhanced by this effect (28;32).

A physical hormonal explanation of labour pain variations might be that the laboring woman can create natural endorphins during labour, that are endogenous opiates, which act as natural analgesia to make the pain more manageable (28). Women have to feel in control and feel comfortable with the situation to release a cascade of labour hormones which include endorphins, cortisol and oxytocin.

Sense of control

Pain experienced during labour can give women opportunities for positive growth. At the same time, women can have a negative birth experience if labour pain was overwhelming and stressful and if women have experienced little sense of control or guidance during labour (35). Sense of control during labour is a major contributor to women's birth experience (7;36-38). It contributes to the degree of satisfaction with childbirth experience both short and long term (39-41). There are different definitions of sense of control in labour. Women's control during labour implies active involvement, personal responsibility, qualified and fair information of caregivers and the ability to influence outcomes (42). Giving women a choice in methods of pain relief during labour gives them a feeling of being in control and affects the degree of satisfaction with childbirth positively (8). Women can experience sense of control at different levels. They can feel in control and at the same time "let go" during labour which seems contradictory. Women talk about their bodies being in control (434). Three types of control during labour might be distinguished during labour: 'sense of control over how maternity care professionals treat you'; 'sense of control over your own behavior'; and 'sense of control over your labour contractions' (6). All three types of sense of control seem to be important to women and contribute to psychological well-being both during labour and afterwards. If women feel supported in dealing with labour pain, it results in a positive effect on women's sense of internal control. The extent to which women in labour have the feeling that maternity care professionals actually have given more than just the basic medical care that is given to them, affects the external control of women (6). Sense of external control refers to being involved in decision making during labour (7).

Hodnett et al also concluded that women who give birth in their own environment or an environment which looks like home are more satisfied, use less pain medication and experience more normal vaginal births compared with women who have given birth in a hospital (7). One could argue that these women feel more in control because they feel comfortable and at ease in their home, or home-like environment.

However, little research has been done into the association between planned place of birth (home, hospital or midwifery unit) and sense of control among women in midwife-led care, There is a need for further research on this specific topic and women's sense of control and to explore if receiving medicinal pain relief or not, effects the association between planned place of birth and sense of control.

Maternity Care Culture

Differences between countries in the number of women who receive pain medication during labour, as well as the type of pain medication that is used by women illustrate differences in cultural views on management of labour pain (4). Culture plays a significant role in attitudes towards labour pain, the definition of the meaning of childbirth pain and in perceptions of pain and coping mechanisms used to manage pain in childbirth (44;45). Historical documents demonstrate that some cultures accepted pain as a part of their life and consider it as a fundamental element for growth and spiritual promotion (46). The study of Gibson [2014] suggests that the dominant medical approach towards labour pain in the United States which is also dominant in many other Western countries is based on the principle that obstetricians have the responsibility to provide medicinal management of labour pain (47). In several modern western societies, pain is not accepted any more as something you can handle or work with but is something which can be suppressed with the help of modern pain relief techniques (47).

Labour pain in Dutch maternity care

The Dutch maternity care system is characterised by the concept that pregnancy and childbirth are mainly physiologic processes in which women who experience natural birth can deal with labour pain. Most Dutch women and midwives believe in the working with pain approach – if labour proceeds well – rather than believing in the pain medication approach regardless of the labour process and coping techniques of women (48;49).

Maternity care in the Netherlands is divided into primary- or midwife-led care for low risk women and secondary- or obstetrician-led care for women with an increased risk of complications. When complications arise during labour including a painful labour requiring pain medication women have to be transferred from midwife-led care to obstetrician-led care. Women and midwives might experience this as an obstacle, which may result in reduced use of pain medication.

In 2008, a new Dutch guideline was implemented on the use of medicinal pain relief. This guideline advices that women's request on its own is sufficient as an indication for pain medication during labour. An epidural is the mode of choice for the elimination of labour pain (50). Despite the Dutch culture of natural childbirth, in the Netherlands the number of women having a vaginal birth who use pain medication in labour has risen from 5.4% in 2003 to 17.6% in 2012, since the implementation of this guideline (51).

Most research on labour pain has been conducted in countries where women have limited choice regarding their place of birth and a medical model with routine pain medication is the dominant approach to intra-partum care (31;52-54). Little is known about women's expectations and experiences of dealing with labour pain and the use of pain medication in the Dutch midwife-led care system.

Inhaled analgesia

One type of medical pain relief is inhaled analgesia. The effectiveness of this type of pain medication is still controversial (50;55-57). Nitrous oxide is most frequently used as the agent of inhaled analgesia and can easily be used by women as a method of pain relief during labour; safe equipment is available; and nitrous oxide gives no pungent smell like some other agents of inhaled analgesia. It is especially useful for those women who want to use a medicinal method of pain relief that is not invasive and has fewer side effects then for example an epidural or remiphentanyl infusion. Nitrous oxide as inhaled analgesia during labour involves the inhalation of sub-anaesthetic concentrations of agents while the swallowing reflex stays intact (57). Nitrous oxide is relatively easy to administer, can be started very quickly within a minute and works within a minute (57). It can be started whenever it is needed because it does not affect the mechanism of labour contractions. Although several studies reported on the efficacy and safety for mother and child, the findings are difficult to interpret because of the small sample size of the studies (57).

DELIVER study

Research to support evidence based midwifery care in the Netherlands has been limited. Therefore, it was important to set out a nationwide multi-center research project to evaluate the maternity care system and practice in order to get an understanding of the Dutch midwifery care and to provide knowledge for improvement. The Academy of Midwifery Amsterdam, Groningen, the Netherlands Institute for Health Service Research (NIVEL), and the EMGO Institute for Health and Care Research of VU University Medical Center initiated the national DELIVER study. DELIVER is an acronym of Data Primary Care Midwifery ('Data EersteLIjns VERloskunde'). The DELIVER study set out to evaluate the quality, organization and accessibility of Dutch Midwifery Care. Although the study had a broader overall focus, one important emphasis was the management of labour pain.

Research in the Netherlands, into management of labour pain might give interesting insights in women's and midwives perceptions of dealing with labour pain, because of the particular characteristics of the maternity care system; in spite of Dutch tradition of natural birth and the availability of homebirth at the same time perceptions in society are changing about dealing with labour pain (50;51).

The aim of these series of studies was to examine women's and midwives perceptions towards the perceived changing attitudes in society in dealing with labour pain. Knowledge on women's characteristics and expectations, preferences, and experiences regarding dealing with labour pain in a midwife-led model will provide important insights for midwifery care.
Our findings might be important for other countries that are encouraging midwife-led care to promote physiological birth (58-60).

General aim
The aim of this thesis was to examine management of labour pain from the point of view of women and midwives and to synthesize evidence on the effectiveness and safety of inhaled analgesia for mother and child.

Research questions

(1) DELIVER (data of primary midwifery care) study design article:
What is the research design and methodology of this multicentre multidisciplinary prospective study?
(2) Which factors are important to women receiving midwife-led care in the Netherlands regarding their expectations of dealing with labour pain?
(3) Which factors were important to women receiving midwife-led care in the Netherlands in their experiences of how they dealt with labour pain?
(4) What approach to pain relief do Dutch women – in midwife-led care at the onset of labour- prefer before they give birth and what methods do they use during labour?
(5) What is the association between planned place of birth (home versus hospital) and sense of control?
(6) What are midwives' perceptions of supporting women in dealing with pain in labour, and what is the response of midwives to changing attitudes in society on this subject?
(7) What is the efficacy and safety of inhaled analgesia as pain relief for women in labour planning a vaginal delivery?

Outline of this thesis

The main body of the thesis comprises a series of seven articles (chapter 2 to 8). The research questions are addressed in the subsequent chapters of this thesis.

Chapter 2. The DELIVER study was designed as a multicenter prospective dynamic cohort study to evaluate primary care midwifery in the Netherlands with the main focus on quality, organisation and accessibility of care. The article describes the design and methods of this study that provided data for two of the other papers.

Chapter 3. A qualitative method was used to enable in-depth exploration of women's perception towards dealing with labour pain to understand pregnant women's expectations of labour pain. Fifteen pregnant women were interviewed between 36 and 40 weeks gestation receiving primary midwife-led care in five midwifery practices across the Netherlands between June 2009 and July 2010.

Chapter 4. A qualitative method was used to enable in-depth exploration of women's perception of how they dealt with labour pain. Seventeen women who were in midwife-led care at the onset of labour were interviewed between four and eight weeks postpartum in five midwifery practices across the Netherlands between June 2009 and July 2010.

Chapter 5 describes a quantitative study as part of the DELIVER-study of women's preferences and actual use of pain medication during labour. We studied the association between the characteristics of the women and their preferences for and actual use of pain medication. All of these women were in midwife-led care at the onset of labour.

Chapter 6 reports the results of a quantitative study as part of the DELIVER-study about the association between planned birth setting and sense of control of women who were in midwife-led care at the start of labour. We also studied the effect of receiving medicinal pain relief, on the association between planned place of birth and sense of control.

Chapter 7 presents the findings of a qualitative study into the perceptions of Dutch primary care midwives toward working with women who experience pain in labour. In total 23 midwives took part in four focus groups.

Chapter 8 shows the findings of a Cochrane systematic review with meta-analyses of the efficacy and safety of inhaled analgesia during labour with regard to maternal and neonatal outcomes.

In *chapter 9,* I present and discuss the main findings from the present studies and describe clinical implications for practice and offer suggestions for further research.

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Chapter 2

Evaluation of primary care midwifery in the Netherlands: design and rationale of a dynamic cohort study (DELIVER)

Judith Manniën, Trudy Klomp, Therese Wiegers, Monique Pereboom, Johannes Brug, Ank de Jonge, Margreeth van der Meijde, Eileen Hutton, Francois Schellevis, Evelien Spelten

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Abstract

Background

In the Netherlands, midwives are autonomous medical practitioners and 78% of pregnant women start their maternity care with a primary care midwife. Scientific research to support evidence-based practice in primary care midwifery in the Netherlands has been sparse. This paper describes the research design and methodology of the multicenter multidisciplinary prospective DELIVER study which is the first large-scale study evaluating the quality and provision of primary midwifery care.

Methods

Between September 2009 and April 2011, data were collected from clients and their partners, midwives and other healthcare professionals across the Netherlands. Clients from twenty midwifery practices received up to three questionnaires to assess the expectations and experiences of clients (e.g. quality of care, prenatal screening, emotions, health, and lifestyle). These client data were linked to data from the Netherlands Perinatal Register and electronic client records kept by midwives. Midwives and practice assistants from the twenty participating practices recorded work-related activities in a diary for one week, to assess workload. Besides, the midwives were asked to complete a questionnaire, to gain insight into collaboration of midwives with other care providers, their tasks and attitude towards their job, and the quality of the care they provide. Another questionnaire was sent to all Dutch midwifery practices which reveals information regarding the organisation of midwifery practices, provision of preconception care, collaboration with other care providers, and provision of care to ethnic minorities. Data at client, midwife and practice level can be linked. Additionally, partners of pregnant women and other care providers were asked about their expectations and experiences regarding the care delivered by midwives and in six practices client consults were videotaped to objectively assess daily practice.

Results

In total, 7685 clients completed at least one questionnaire, 136 midwives and assistants completed a diary with work-related activities (response 100%), 99 midwives completed a questionnaire (92%), and 319 practices across the country completed a questionnaire (61%), 30 partners of clients participated in focus groups, 21 other care providers were interviewed and 305 consults at six midwifery practices were videotaped.

Conclusions

The multicenter DELIVER study provides an extensive database with national representative data on the quality of primary care midwifery in the Netherlands. This study will support evidence-based practice in primary care midwifery in the Netherlands and contribute to a better understanding of the maternity care system.

Background

In the Netherlands midwives are autonomous medical practitioners, qualified to provide full maternity care on their own accountability to all women whose pregnancy and childbirth are uncomplicated including prenatal, intrapartum and postnatal care to mother and child [1]. The first appointment at the midwifery practice usually takes place around the 8th week of gestation. Because of the frequent (on average 13) contacts throughout pregnancy and because of their expertise, midwives are considered to be important reliable providers of pregnancy-related health education and advice for pregnant women.

In the Netherlands about 175,000 births occur annually. In 2009 there were 2444 registered and practising midwives (one per 1630 women within the fertile age range), of which 77% worked in a primary care setting, in just over 500 midwifery practices [2]. The vast majority of pregnant women (78%) start their maternity care in a primary care setting, 44% start labour in primary care, and eventually 33% of women give birth under supervision of a primary care midwife [3]. In order to be allowed to practice midwifery, midwives in the Netherlands are educated in a four year Bachelor level program in one of the four midwifery colleges in the Netherlands. Additionally, midwives can choose to follow a midwifery Master program.

Up to now, scientific research to support evidence-based practice in primary care midwifery in the Netherlands has been sparse. It is essential to accomplish more research that evaluates the maternity care system and practice, in order to develop a better understanding of the maternity system and to provide scientific knowledge for improvement.

Therefore, the Academy of Midwifery Amsterdam-Groningen (AVAG), the Netherlands Institute for Health Services Research (NIVEL), and the EMGO Institute for Health and Care Research of VU University Medical Centre initiated the national DELIVER-study. DELIVER is the Dutch acronym for data primary care midwifery (Data EersteLIjns VERloskunde).

The DELIVER study aims to gain insight into the quality, organisation and accessibility of midwifery care in the Netherlands. Results of the Deliver study

should further improve midwifery care in the Netherlands and contribute to evidence-based practice. This paper describes the research design and methodology of this multicenter multidisciplinary prospective study.

Research questions

The DELIVER study is primarily a descriptive study with the following research questions:

– How is primary care midwifery organised in the Netherlands?
– What is the accessibility of primary care midwifery in the Netherlands?
– What is the quality of primary care midwifery in the Netherlands?

Regarding the organisation of care, the DELIVER study aims to provide evidence about the referring system ('gate-keeper function' of midwives), role and responsibilities of midwives, collaboration with other care providers (e.g. continuity of care), and time expenditure of midwives. Regarding the accessibility of midwifery care, the study will assess the uptake of care (e.g. number of appointments, number of ultrasound scans, postnatal maternity care), number of ethnic minority women and undocumented women under care of a midwife, and accessibility of the practice (e.g. appointment times). The quality of primary care midwifery in the Netherlands from the preconception to postnatal period will be assessed by describing communication and provision of health information (e.g. information on prenatal screening, lifestyle, pain management, place of birth, labour positions), adherence to standards and guidelines, training and education of (student) midwives, experiences and satisfaction of clients (e.g. confidence in their midwife), and pregnancy outcomes. Additionally, data on midwives' attitudes towards their job and emotions, feelings, health and lifestyle of clients were collected to enable exploration of a range of secondary research questions.

Methods

Study design

The DELIVER study was designed as a multicenter prospective dynamic cohort study to evaluate primary care midwifery in the Netherlands with the main focus on quality, organisation and accessibility of care. The maternity care system was assessed from the perspective of the clients as well as from the perspective of the midwives and other involved care providers. The dynamic cohort consisted of clients who completed up to three questionnaires between their first appointment in the midwifery practice and six weeks postpartum within an observation

period of one calendar year. Of these clients, data were also obtained from the national Netherlands Perinatal Registry and from electronic client records kept by midwives. Data on midwifery practice were assembled by questionnaires, by recording work-related activities during one week, and by video-recordings of intake consults with clients. In addition, focus groups with client's partners evaluated their expectations, needs and experiences regarding midwifery care. Finally, interviews were held with other maternity care providers to gain insight into their experience regarding collaboration with midwives. The learning experiences of two National Surveys of General Practice, which were conducted by the NIVEL institute, were used to develop the design of the DELIVER study [4].

Recruitment and enrolment of study participants

Recruitment and participation of midwifery practices

Midwives and their clients were recruited from twenty midwifery practices. Purposive sampling was used to select practices, using three stratification criteria: region (north, east, south, west), level of urbanisation (urban or rural area), and practice type (dual or group practice). Twenty of the 519 primary care practices in the Netherlands were approached and invited to participate in this study. The approached practices received a brochure with information on the study and were visited by two members of the DELIVER research team who explained the study in further detail. If a practice declined participation, a replacement was found taking region, urbanisation and practice type into account. Ultimately, fourteen practices declined participation, mostly because of time constraints. Each participating practice signed a contract through which they gave consent to cooperate in all parts of the study, including related studies by PhD students. The twenty participating practices comprised 108 midwives and about 8200 clients per year. Midwives were instructed to provide usual care to all their clients irrespective of their participation and to refer clients with questions about the study to the research team.

Of the twenty DELIVER practices, six gave permission to videotape intake consults with clients. Prior to taping, each client was asked for consent to videotape the consult.

Recruitment of clients

The client recruitment period at each midwifery practice was twelve months. Three practices started including patients in September 2009, two started in October 2009, thirteen in November 2009 and two in December 2009. In the first

month at each practice, all clients in care were invited to participate, irrespective of their gestational age or whether they recently (maximum 6 weeks before) gave birth. The following months only new clients were invited to participate. Clients were eligible to participate if they were able to understand Dutch, English, Turkish or Arabic. The midwives were instructed to inform all eligible clients individually about the study and invite them to participate. The midwives gave all women who were interested a brochure about the study with a link to the website of the study [5] where they could find additional information about the study.
To improve the overall response, a reminder was sent to all non-responders.
In addition, five research assistants were enrolled (student midwives) to call all clients who did not complete the questionnaire within one week and invite them once more to participate.

Recruitment of partners of clients
Partners of pregnant women were recruited in two midwifery practices in November and December 2010. During a consult, midwives informed the partners about the study and asked them whether they were interested. If the partners did not accompany their pregnant partner to a consult with the midwife, the midwife asked the woman whether she thought her partner might be interested in the study. Each practice sent a list of clients who were at least 28 weeks pregnant and whose partners were possibly interested in the study to a research bureau (Intomart GfK). The research bureau first sent a letter to the partners with information about the study and then phoned them to invite them to participate. One focus group was organised per practice for partners of women expecting their first child, and one for partners of women who already had at least one child. The four focus groups were undertaken and analysed by Intomart GfK.

Recruitment of other maternity care providers
Seven categories of maternity care providers were included: clinical midwives, gynaecologists, general practitioners, maternity care assistants, paediatricians, ambulance personnel, and Obstetrics&Gynaecology (O&G) nurses. Each of the twenty DELIVER practices provided information on three of their contacts per category. The research bureau Intomart GfK executed and analysed in total 21 telephone interviews (March and April 2011): four with general practitioners, two with ambulance personnel, and three for each other category. Care providers were selected randomly, stratified by urban and rural practices.

Measurement tools

Measurement tools administered among midwives

All midwives and practice assistants of the twenty participating practices were requested to keep a diary for one week sometime between February and April 2010 (Figure 1). The goal of this diary was to get detailed insight into the real time expenditure of midwives for different responsibilities. Within each practice, all midwives and practice assistants were required to complete the diaries in the same week, choosing a week without public holidays. In the diary they used time sheets to record all work-related activities 24 hours per day for 7 days, using a pre-structured format. This pre-structured diary had been successfully used before by the NIVEL Institute in studies evaluating time expenditure of Dutch midwives [6]. The activities were categorized as midwifery clinic (e.g. consultation during pregnancy, ultrasound scan, or 6 weeks postnatal consultation), being on call, intrapartum care, postnatal care visits, hospital visits, administrative tasks, or meetings.

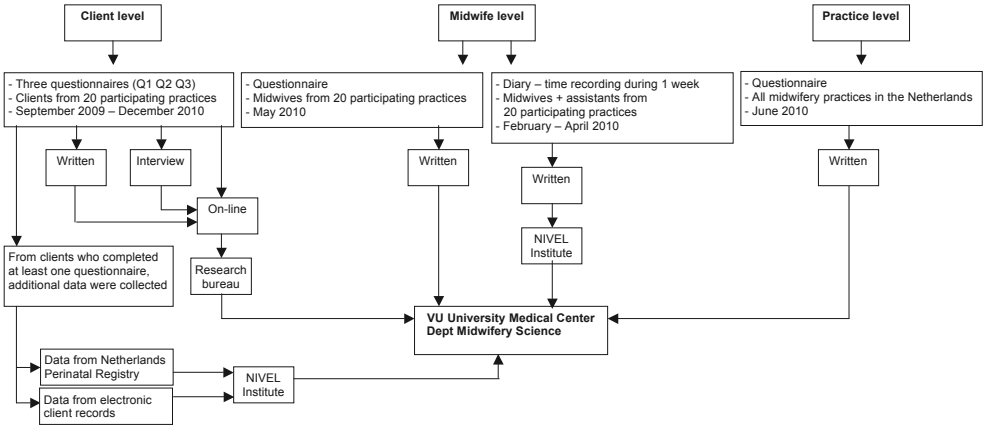

Figure 1 Flowchart of the questionnaires and diaries

In addition, all midwives from the twenty participating practices were asked to complete a written questionnaire in May 2010 (Figure 1). The aim of this questionnaire was to gain insight into collaboration of midwives with other care providers, their attitude towards their job, and their adherence to standards and guidelines (Table 1). Another questionnaire was sent to all midwifery practices in the Netherlands in June 2010 (Figure 1). The questionnaires provide description of the size and organisation of midwifery practices, provision of preconception care, collaboration with other care providers, education of students, and provision

of care to ethnic minority women and undocumented women (Table 1). Many questions from the midwife questionnaire and the practice questionnaire were derived from earlier studies [4,7].

Virtually all midwives in the Netherlands routinely submit data about mothers, newborns, and their care provision to the Netherlands Perinatal Registry [3]. The midwifery practices that participated in the DELIVER study sent these data, of all clients that completed at least one questionnaire, to the DELIVER research team electronically (Figure 1). These data included information on the mother (e.g., age, gravity, parity), birth (e.g., pain management, duration of labour, complications), baby (e.g., time of birth, birth weight, Apgar score at 5 minutes), and provided care (e.g., place of birth, referral to secondary care).
The midwifery practices also sent electronic client records data of participating clients to the research team including demographic information, medical history, progress of pregnancy (e.g., blood pressure of mother, foetal heart rate, position of baby, health status of the mother), and care plans (e.g., place of birth, breast or formula feeding) (Figure 1).

Measurement tools administered among clients
Clients received up to three questionnaires depending on their gestation at inclusion: one before 35 weeks gestation (completed on average around 20 weeks gestation), one between 35 weeks gestation and birth, one about 6 weeks postpartum. The primary aim of the questionnaires was to assess the expectations and experiences of clients regarding midwifery care. The questionnaires included validated instruments used in earlier studies (Table 2). The questionnaires were largely based on two National Surveys in general practice, which were conducted by the NIVEL institute [4]. The issues that were covered by the questionnaires as well as examples of items are given in Table 1.

A pilot study took place from May to July 2009 in three midwifery practices to test the client questionnaires. During the pilot study, 710 clients completed 774 questionnaires. The content of the questionnaires was adjusted according to comments made by clients during the pilot phase (e.g., too long, some questions were experienced as depressing) in August 2009.
As the response rate of clients from ethnic minority groups was relatively low in the pilot study, a lot of effort was put into reaching such women during the main part of the study, especially women with a Turkish or Moroccan ethnic

background. Primarily, the questionnaires were only offered on-line in Dutch. To enlarge participation of women from deprived areas and from ethnic minorities, written questionnaires were developed in Dutch and English [13]. As the largest groups of non-Western women in the Netherlands are from Turkish or Moroccan origin, the questionnaires were translated into Turkish and Arabic and the services of an interview bureau were enlisted to conduct telephone interviews in these languages.

Midwives and research assistants tried to collect information about all non-participating clients on age, parity, ethnicity, postal code (to determine socioeconomic position), and reason for non-participation. This information can be used to check the external validity of the data.

Video recordings of intake consults in primary care midwifery practices were used to gain insight into daily practice of primary care midwives, mainly on counselling regarding prenatal screening. The Roter Interaction Analysis System (RIAS) was used, which is a method of coding doctor-patient interaction during the medical visit [14]. In addition, content analysis was used for the following subjects: lifestyle (smoking, alcohol, weight (gain), nutrition), drug use during pregnancy, infectious diseases, and demographic information. Also, global affect ratings were recorded for the consult as a whole to rate the affect or the emotional context of the dialogues.

Focus groups with partners

The research team of the DELIVER study developed a topic list which was used to evaluate the expectations, needs and experiences of partners of pregnant women regarding the care provided by midwives. The topic list comprised amongst others midwives' characteristics, counselling regarding prenatal screening, preparation for labour, the midwife's role during labour, and postnatal care.

Interviews with other maternity care providers

Telephone interviews were held with health care professionals that work together with primary care midwives, namely clinical midwives, gynaecologists, general practitioners, maternity care assistants, paediatricians, ambulance personnel, and O&G nurses. The main aim of these interviews was to gain insight into the number of contacts, reasons for contact, and their views on the quality of the contacts. The aim was to interview three people per profession.

Data management

Data at midwife or practice level

The midwives and practice assistants sent their completed diaries with work-related activities to the NIVEL institute where the data were (partly) analysed. The data and results were then passed on to the department of Midwifery Science of VU University Medical Center (Figure 1).

The written questionnaires that were completed by the midwives of the twenty participating practices were returned to the department of Midwifery Science. Also the questionnaires that were completed by more than half of all midwifery practices across in the Netherlands were sent to the department of Midwifery Science. Data from these questionnaires were entered into SPSS by a research assistant.

Midwives received no information about study results during the course of the study to avoid bias in midwifery practice, with the exception of client response rates which were provided in order to promote further motivation in encouraging participation among their clients.

Data at client level

Client data from written questionnaires and from telephone interviews were entered into the on-line questionnaire by research assistants. The research bureau converted all data from the client questionnaires into an SPSS database, which was transferred to the department of Midwifery Science (Figure 1).

The midwifery practices sent the data of the Netherlands Perinatal Registry and the data of the electronic client records to the NIVEL institute at the end of the study (Figure 1). The NIVEL institute converted these data into an SPSS database before releasing the data to the department of Midwifery Science.

The video tapes were analysed using a special program at the NIVEL institute. The original tapes stayed at NIVEL, but the analysed data were converted into an SPSS database and sent to the department of Midwifery Science.

Focus groups with partners & Interviews with other maternity care providers

The focus groups with partners and the interviews with other maternity care providers were conducted and analyzed by the research bureau Intomart GfK. They processed the results of their analyses into reports which were sent to the department of Midwifery Science. Original data remained property of Intomart GfK but the anonymous transcriptions of the interviews with partners and other maternity care providers were sent to the department of Midwifery Science.

Check data entry
Data that were entered manually (on-line or into SPSS) by someone from the research team or by a research assistant were checked by another person.
A randomly selected sample of 5% of the questionnaires and client records was checked for errors and the error rate was below the maximum tolerated error rate of 1% at item level.

Data linkage
A crucial aspect of the data collection within the framework of the DELIVER study is the possibility to link the data. The overall database consists of data at three levels: individual client, individual midwife, and midwifery practice. These data were linked by unique anonymous client identifiers and anonymous midwifery practice identifiers.

Data analyses
Power
The number of included midwifery practices (*n*=20) was based on experience of two National Surveys of General Practice in the Netherlands [4]. A priori, we expected an average of 360 new clients annually per midwifery practice and therefore a total of 7200 women in the twenty participating practices during the course of the study. For about only a quarter of these clients (*n*=1800) it would be possible to complete all three questionnaires during the one-year study period. We aimed for a response rate of 60%, which was based on experience with the two National Surveys of General Practice.
Furthermore, we expected all midwives in the twenty practices to complete a questionnaire and expected all midwives and their practice assistants to complete a diary of work-related activities. Regarding the questionnaire that was sent to all midwifery practices in the Netherlands, we aimed for a response rate of 50%.
We aimed for at least ten video recordings of intake consults per midwife, because the reliability of the results increase with increasing number of video's per midwife. We decided to include six midwifery practices in order to be able to detect possible differences between practices.
Two focus groups were held with partners of women expecting their first child and two focus groups with partners of women who already had at least one child, because we wanted to have data from both groups separately. Besides, we aimed to do a qualitative survey, in other words, get an overview of themes that are

important to partners regarding maternity care. For this purpose, this sample was considered to be sufficient [15,16].
Regarding interviews with other maternity care providers, we interviewed people from a wide range of maternity care providers to get maximum variation in the research sample. It was decided to interview three people per category (21 in total), because we felt that there would be considerable overlap in themes between provider groups, and that saturation would be reached with this number of interviews.

Data analyses
The different modes of data collection require different types of data analyses, e.g. qualitative analyses for interviews and focus groups, quantitative analyses for questionnaires and diaries, and content and interaction analyses for video recordings. Subsequent publications reporting the study results will provide plans for the data analyses in detail. These subsequent publications will also report on representativeness of the clients, midwives, and midwifery practices that participated in the DELIVER study. For that purpose, characteristics of the participating midwifery practices will be compared with non-participating practices concerning region, urbanisation, and size of the practice (number of midwives and annual number of clients). In order to determine whether the midwives from the twenty participating practices are comparable with all other Dutch midwives, national data will be obtained from the NIVEL Institute on age, years of experience as a midwife, and weekly working hours. Data from Statistics Netherlands will be used to assess the representativeness of the participating clients regarding age, parity, social-economic status, education, religion, and ethnicity [17]. Because of all made efforts to obtain representative populations in the DELIVER study, we do not expect major selection bias. If comparisons with national populations do reveal selection bias, we will correct for this by adjusting results for relevant confounders. The available background information on clients and midwives will make it possible to adjust results for confounders such as age, parity, ethnicity, education, income, presence of a partner, and religion. The cluster design will be taken into account by applying multilevel modelling when necessary and possible.

Regarding the first research question (organisation of care), descriptive analyses will be conducted using data from midwives' diaries with work-related activities, the questionnaire they completed, and interviews with other maternity care

providers. These data sources reveal information on collaboration and meetings with health care providers within and outside the practice, number of employees/ associates, presence of a practice assistant, distribution of tasks, annual number of new clients and deliveries, frequency of preconception consults.
For the second research question (accessibility of care), descriptive analyses will be conducted with the main variables being timing of first consult, accessibility of practice by phone, accessibility of practice by public transport, availability of consults outside office hours, and the provision of care to ethnic minority women and undocumented women.
Regarding the third research question (quality of care), the main variables will be satisfaction of clients and their partners, midwives' adherence to standards and guidelines, quality and content of intake consults, quality of collaboration with other maternity care providers, and pregnancy outcomes.

Ethical approval and privacy issues
The design and conduct of the study were offered to the Medical Ethics Committee of the VU University Medical Centre Amsterdam. Participating midwifery practices were expected to participate in all aspects of the DELIVER study. Client participation was voluntary and they could withdraw at any time. Privacy was guaranteed in accordance with Dutch legislation. Clients' and midwives' anonymity was maintained by using anonymous patient and practice identifiers.

Incentives
We estimated that the time investment for midwives would be about 1.5 hours per week for an average practice. Each participating midwifery practice received on average €2,000 for their input, depending on their annual number of clients. In addition, the practices received several presents during the course of the study to keep them motivated. We also tried to keep the midwives enthusiastic by sending them regular news letters with stories from midwives or researchers, tips to increase the client response rate, clients' response rates per practice, and frequently asked questions.
All clients who complete at least one questionnaire received shower gel. Additionally, five coupons worth of 100 euro were raffled among all clients who completed at least two questionnaires. Client's partners who participated in one of the four focus groups received a gift certificate of 35 or 40 euro's.

Results

An overview of the collected data within the DELIVER study is given in Table 3. Ultimately, 34 midwifery practices were approached in order to achieve the sample of twenty practices that were willing to participate. The stratification criteria for selection of participating midwifery practices, led to a representative sample of twenty practices regarding region (5 north, 6 east, 3 south, 6 west), practice type (2 dual and 18 group practices), and level of urbanisation (5 urban area, 6 rural area, 9 combination of urban and rural area).

Of all 14418 invited clients, 7685 clients participated by returning at least one questionnaire and 1890 clients returned all three questionnaires. Most questionnaires were completed online, but 25% of the completed questionnaires after labour were print questionnaires. The interview bureau interviewed 183 Turkish and Moroccan clients. The overall crude client response rate was 53%. However, in this calculation women with an abortion or miscarriage were included in the denominator while these women were actually not part of our study population. Data from a part of the non-participants (n=922) showed that 30% of them did not want to participate in this study because of an abortion or a miscarriage. If we assume that 30% of all 6733 non-responders (n=2020) would have an abortion or a miscarriage, and therefore were not eligible for our study, the adjusted response rate is 62% (7685/12398). Data of the Netherlands Perinatal Registry could be linked to questionnaires for 5913 women, and the data of the electronic client records for 5895 women, and both registries for 5133 women. For each specific research question, different client data might be included. Therefore, the representativeness of the client population will be considered for each research question separately. Overall, the distribution of participating clients over the country (26% north, 30% east, 15% south, 30% west) was comparable with the distribution of the national population in the Netherlands. Seventeen percent of the DELIVER client population was of non-Dutch origin, compared with 25% of the national female population between 15 and 45 years of age in 2010 (p<.05). More specifically, the DELIVER client population comprised 4.3% Turkish and Moroccan clients, compared to 5.9% nationally (p<.05).
Regarding the questionnaire for midwives in the twenty practices, 99 of the 108 midwives completed the questionnaire (92%). All 108 midwives and 28 assistants in the twenty practices completed a diary. Regarding the questionnaire that was sent to all 521 Dutch midwifery practices, 319 practices returned the completed questionnaire (61% response rate).

In six midwifery practices, 310 video recordings were made of intake consults. This concerned in total 23 different midwives.
Thirty partners of pregnant women participated in one of the four focus group interviews. Twenty-one health care professionals that work together with primary care midwives were interviewed, namely four general practitioners, two ambulance personnel, and three of each of the remaining five professions (i.e. clinical midwives, gynaecologists, maternity care assistants, paediatricians, and O&G nurses).

Discussion

The DELIVER study is the first study evaluating the quality and provision of primary care midwifery in the Netherlands on such a large scale. The Dutch maternity care system is rather unique with a high number of homebirths and primary midwifery led births. In many countries midwives look at the Dutch system for inspiration. It is therefore crucial that the quality and characteristics of this system are described and that this information is put out in the public arena to inform people internationally about its advantages and disadvantages.
The DELIVER study protocol is presented in the present paper to offer researchers the opportunity to critically review the methodological quality of this study.
A discussion of the methodological issues of the DELIVER study follows below.
Research into primary care midwifery can make an important contribution to the improvement of prenatal, intrapartum, and postnatal care by midwives and thus contribute to the safety and satisfaction in childbirth. Midwives are considered to be important care providers of pregnant women in the Netherlands as 78% of clients start prenatal care at the primary care level and pregnant women have frequent contacts with midwives throughout pregnancy and after childbirth [3]. The DELIVER study provides evidence about the strengths and weaknesses of the current maternity care system regarding the quality, organisation and accessibility of primary care midwifery, which gives insight into areas for improvement that might lead to improved safety and satisfaction in childbirth. In addition, results of the DELIVER study should enhance evidence-based practice and may contribute to the start of a new continuous registration system in midwifery practices in the Netherlands. Such a continuous registration system will provide easy-accessible data for structural research on various aspects concerning primary care midwifery. Furthermore, data collection forms and experiences of the DELIVER study are currently used to establish a client panel of

1000 pregnant women in order to regularly collect data on their experiences with care and their health and well being.
By including exhaustive information from 7685 pregnant women and 108 midwives from 20 midwifery practices plus data from 299 other primary care midwifery practices, the DELIVER study has led to a rich and substantial dataset which will allow description of various aspects of maternity care from the perspectives of midwives as well as their clients, clients' partners, and other relevant maternity care providers, making it a multidisciplinary study.

Clients from ethnic minority groups were underrepresented in the pilot study, mainly because the questionnaire was only available in Dutch at that time. In the main study, many protocol adjustments and additional actions were executed to increase the response rate of this specific population: printed questionnaires were developed in Dutch and English and services of an interview bureau were enlisted to conduct telephone interviews in Turkish and Arabic. The inclusion of Dutch-speaking clients as well as non-Dutch speaking clients who could understand English, Turkish or Arabic in the main study, increased the external validity of the results because it enabled the four largest non-Western minority groups in the Netherlands to participate (women from Moroccan, Turkish, Surinamese and Antillean origin) as well as many other minority women who speak English.

The use of on-line questionnaires, which were used for the client questionnaires, was very advantageous because built-in checks and a logical follow-up of questions led to a low rate of missing data or errors (e.g., women could only give one answer and within the pre-set range of possible answers), and data could easily be uploaded to SPSS. However, in order to improve response rates for the client questionnaires, the clients were offered a choice between electronic and print questionnaires in either Dutch or English. The fact that many clients used this opportunity (25% of the completed questionnaires after labour were print questionnaires) indicates that this was a useful option to include.

The video recordings that we made of 310 client consults by 23 midwives in six practices provide unique data, and this method of data collection has hardly ever been used before in midwifery care research. It is probably the optimal way to objectively evaluate the daily practice of midwives.

Because not all data have been analysed yet, we cannot currently give insight in the strengths and weaknesses of the maternity care system in the Netherlands regarding the quality, organisation and accessibility of primary care midwifery. In process of time, results of the DELIVER study will describe the current level of service, which is the first step to improve midwifery care. The DELIVER study provides unique data on the activities of midwives, the variation between them and the evaluation of their care by clients and other maternity care providers. These data will enhance awareness among midwives about the care they give and this in itself may change clinical practice. For example, the results will show how many ultrasound scans women have on average and how this number varies between midwifery practices. If the variation is large, this will likely initiate a debate on when ultrasound is indicated. Secondly, the data from the client questionnaires will provide information on areas of care that could be improved. The Dutch Organisation of Midwives might use the results when developing their practice guidelines. Thirdly, if changes are introduced in midwifery practice, a repetition of the DELIVER study can show the extent to which these changes have materialised by making a comparison between the results of the first and second DELIVER study.
Certainly, the DELIVER study will enhance evidence-based practice in primary midwifery care in the Netherlands. And regarding the current global discussion about the organisation of maternity care (e.g. place of birth), this study provides a reliable basis for future research.

Conclusion

The multicenter multidisciplinary DELIVER study provides an extensive database with nationally representative data on the quality of primary care midwifery in the Netherlands. This study will support evidence-based practice in primary care midwifery in the Netherlands and will contribute to a better understanding of the maternity care system and provide scientific knowledge for improvement.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

ES, FS, and MM originated the idea for the study. ES and TK supervised the study. TK and MP recruited the midwifery practices. TW was responsible for

many measurement instruments (including diaries with midwives' work-related activities) and data linkage. JM monitored the data collection. All authors participated in discussing the design of the study and developing the research protocols and questionnaires. The core research team consisted of ES, TK, FS, TW, MP, and JM. JM drafted the manuscript, and all authors read and corrected draft versions of the manuscript and approved the final manuscript.

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Tables

Table 1 Content information of the questionnaires

Subjects	Moment	Number of items	Issues	Examples of questions
Clients	September 2009 to December 2010	Q0*: 32 Q1: 51 Q2: 73 Q3: 100	a. quality of midwifery care	a. Rate experiences with care provided by midwives / maternity care assistants (0=worst possible care to 10=best possible care; 10 steps)
			b. ultrasound scans and prenatal screening	b. Did you choose to undergo one or more ultrasound scans, and with hindsight, would you have chosen differently?
			c. (preparation for) childbirth	c. How much pain did you expect / experience? (0=no pain to 10= the worst imaginable pain; 20 steps) Have you drawn up a birth plan outlining your preferences and expectations during labour and delivery?
			d. emotions and feelings	d. Were you happy / afraid / worried during pregnancy? Did you feel tense / important / confident during labour?
			e. health	e. In general, how would you rate your current state of health? Do you suffer from any chronic illnesses, disorders or disabilities?
			f. lifestyle	f. Did you smoke, drink alcohol, use drugs during pregnancy? Do you take folic acid, vitamin B12, vitamin D?
			g. questions specifically for clients from ethnic minority groups	g. Are you planning to consult or have you consulted a midwife and/or gynaecologist in your or your parents' country of birth? Was your midwife and/or maternity care assistant sympathetic to ethnic differences in customs surrounding the birth?
Midwives from 20 participating practices	May 2010	115	a. collaboration with other health care providers	a. On average, how often do you have contact with a general practitioner, secondary care midwife, obstetrician, paediatrician, or maternity care assistant; for what reason do you have contact; who usually takes initiative for that; are you satisfied with the collaboration?

Subjects	Moment	Number of items	Issues	Examples of questions
			b. tasks	b. How often do you provide psychosocial care to clients? How often do you discuss lifestyle (eating, drinking, smoking) with clients? During the last 6 months, how much time did you spend on meetings /organised information activities / supervising midwifery students? Which tasks do you delegate to your practice assistant, and are you satisfied with that?
			c. attitudes towards job	c. Do you think that the following tasks should be executed by midwives? Advice in education possibilities, discuss relational or sexual problems, offer help in case of tendency towards suicide, discuss problems at work, discuss lifestyle (eating, drinking, smoking). Do you (dis)agree with statements on job satisfaction, e.g., my job is useful, my job makes me satisfied, I am enthusiastic about my job, my job is interesting, I have enough time to provide good care. With what items of your current job are you happy, and what can be improved?
			d. quality of care	d. How often do you look up information in guidelines of the Royal Dutch Organisation of Midwives (KNOV)? How much time do you spend on training / education for yourself? Are you registered in one of the quality registries of the KNOV? How much time do you reserve for: each intake, preconception consult, regular consult without ultrasound scan, regular consult with ultrasound scan, counselling regarding prenatal screening, postpartum consult?
			e. general information	e. How many years of working experience do you have as a midwife? How many hours per week are you currently working? Do you provide preconception care?

Subjects	Moment	Number of items	Issues	Examples of questions
Midwifery practices	June 2010	61	a. organisation of the practice	a. number of employees/associates, distribution of tasks, time reserved per client visit, computerised activities and databases, presence and tasks of a practice assistant
			b. size	b. annual number of new clients and deliveries
			c. provision of preconception information	c. frequency of preconception consults
			d. collaboration and meetings with health care providers within and outside the practice	d. frequency and duration of regular meetings with care providers within and outside your practice hospitals where clients are referred to and distance to hospitals
			e. placements and education of midwifery students	e. annual number of midwifery students, medical students, nursing students
			f. care provided to ethnic minority women and undocumented women	f. annual number of ethnic minority women and undocumented women

* Q0: socio-demographic characteristics, asked simultaneously with first questionnaire that a client completes; Q1: 1st questionnaire, before 35 weeks gestation; Q2: 2nd questionnaire, after 35 weeks gestation; Q3: 3rd questionnaire, postpartum.

Table 2 Validated measurements used in client questionnaires

Validated Measurement	Goal	Content	Client questionnaire*
Bologna score [8]	To determine whether the intrapartum care in case of a normal birth was according to the best evidence.	5 items: – presence of partner or friend during labour – use of a partogram (measure progression objectively) – absence of interventions – labour not in supine position – skin-to-skin contact between mother and child for at least 30 minutes during first hour postpartum	Q3
Dutch consumer quality index (CQI) treatment score [9]	To measure the actual experience of clients with structure and process aspects of health care, as well as the importance clients attach to each aspect.	6 items: – Does your *midwife* treat you with respect? – Do you feel that your *midwife* listens to you? – Does your *midwife* devote enough time to you? – Do you feel that your *midwife* takes you seriously? – Does your *midwife* explain things to you in a way that is easy for you to understand? – Do you feel you are in good hands with your *midwife*? (never/sometimes/usually/always)	Q2 + Q3

Validated Measurement	Goal	Content	Client questionnaire*
Labour Agentry Scale [10]	To measure personal control during childbirth (separately during first and second stage of labour).	10 items (shortened version): – I was tense – I felt important – I felt confident – I felt I was in control of myself – I was scared – I was relaxed – I felt I was doing a good job – I felt helpless – I felt powerless – I felt I was surrounded by people who cared for me – I felt a failure (the whole time or nearly the whole time/ About three quarters of the time/ Just over half the time/ Just under half the time/ About a quarter of the time/ Not or hardly at all)	Q3
EuroQol questionnaire [11]	To measure health-related quality of life, categorized by mobility, self-care, main activity, social relationships, pain and mood.	6 dimensions: – Mobility – Self-care – Main activity (eg work, study, housework) – Social relationships (pursue family and leisure activities) – Pain – Mood (anxious or depressed)	Q1 + Q2 + Q3
Visual Analogue Scale [12]	To measure pain	10 cm visual analogue scale, from 'no pain' to 'worst pain imaginable'	Q2 + Q3

* Q1: 1st questionnaire, before 35 weeks gestation; Q2: 2nd questionnaire, after 35 weeks gestation; Q3: 3rd questionnaire, postpartum.

Table 3 Collected data

Data collection	Measure	Subjects	Number of participants (%)
Client	Questionnaires (max 3)	All clients in 20 participating pract.(during one year)	7685 (53%*)
	Netherlands Perinatal Registry	All clients that completed at least one quest.	5913 (77%)
	Electronic client records	All clients that completed at least one quest.	5895 (77%)
	Video recordings	Midwives + clients during first consult	310 clients / 23 midwives / 6 practices
	Focus groups	Partners of clients	30
Midwife	Questionnaire	All midwives in 20 participating practices	99 (92%)
	Diary of work-related activities (one week)	All midwives + practice assistants in 20 participating practices	136 (100%)
Practice	Questionnaire	All 521 midwifery practices in the Netherlands	319 (61%)
Other	Interviews	Other maternity care providers (clinical midwives, gynaecologists, general practitioners, maternity care assistants, paediatricians, ambulance personnel, and O&G nurses)	21

* If women with an abortion, a miscarriage or intra uterine death were excluded from the denominator, the net response rate would be estimated to be 62%.

Chapter 3

What do midwives need to know about approaches of women towards labour pain management?

A qualitative interview study into expectations of management of labour pain for pregnant women receiving primary midwife-led care in the Netherlands

Trudy Klomp, Judith Manniën, Ank de Jonge, Eileen K. Hutton,
Antoine L.M. Lagro-Janssen

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Abstract

Objective: To investigate factors important to women receiving midwife-led care with regard to their expectations for management of labour pain.
Design: Semi-structured ante partum interviews and analyses using constant comparison method.
Participants: Fifteen pregnant women between 36 and 40 weeks gestation receiving primary midwife-led care.
Setting: Five midwifery practices across the Netherlands between June 2009 and July 2010.
Main outcome: Women's expectations regarding management of labour pain.
Results: We found three major themes to be important in women's expectations for management of labour pain: preparation, support and control & decision-making. In addition, three distinct approaches to women's planning for pain management in labour were identified: the *'pragmatic natural',* the *'deliberately uninformed'* and the *'planned pain relief'* approach. These approaches clustered within women's other expectations around pain management.
Conclusion: Midwives need to recognise that women take different approaches to pain management in labour in order to adapt care to the individual woman.

Keywords: Labour Pain, Expectations; Childbirth; Midwife-led Care

Background

Labour pain is a complex, subjective and multidimensional phenomenon with not only sensory components but also an important emotional, motivational and cognitive dimension (1;2). Labour pain ranks high in order of severity when compared to other experiences of pain in life (3;4). Many pregnant women have concerns about the level of pain they will experience and how they can manage this pain during labour (4). At the same time, many women have described their childbirth as a difficult but empowering experience and that they were proud especially of their ability to cope with the labour pain (5;6). Management of labour pain encompasses pharmacological, non-pharmacological and other approaches such as the woman's relationship with the health professional (7-10).
Hodnett et al. (2002) showed in a systematic review of 'Pain and women's satisfaction with the experience of childbirth' that four main factors are associated with childbirth satisfaction: 1] personal expectations, 2] the amount of support from caregivers, 3] the quality of the caregiver–patient relationship,

and 4] the involvement in decision-making (11). These factors appear to be so important that they override the influence of age, socio-economic status, ethnicity, childbirth preparation, the physical birth environment, pain, immobility, medical intervention and continuity of care when women evaluate their childbirth experience. Involvement and participation in the birthing experience was also identified as a significant theme by Fenwick et al. in the study of a self-selected cohort of Western Australian women; these authors concluded that involvement in the birthing process had an important influence on women's childbirth experience (Fenwick et al., 2005).

Use of some form of pharmacological pain relief has become the norm in developed countries with the number of women who prefer epidural analgesia as a means of pain relief in labour increasing during the past two decades (12;13). Although the Netherlands has a tradition of birthing without pharmacological pain management, the number of women using pharmacological pain relief is rising in this country over the past decade as well (14).

The Netherlands has a community-based maternity care system, with approximately 80% of all pregnancies starting in primary midwife-led care (14). Low-risk women in primary care may choose to give birth at home, in a birth centre or in hospital. If risk factors or complications arise, women are referred to secondary care. Medical interventions such as pharmacological pain relief, electronic foetal monitoring and augmentation of labour only take place in secondary care.

New guidelines on the use of pharmacological pain relief introduced in the Netherlands state that women's request is a sufficient medical indication for pharmacological pain relief during labour and that epidural analgesia is the method of choice for the elimination of labour pain (15). In addition the guidelines of the Royal Dutch Organisation of Midwives (KNOV) recommend that midwives should make concrete care plans together with pregnant women based on the women's expectations and preferences regarding pain management during labour (16). These guidelines together with the influence of Dutch and international media and friends and family of women have probably had an influence in raising the usage of pharmacological pain management in the Netherlands (17). Nevertheless, among developed countries the Netherlands still has a relatively high rate of physiological births not involving the use of pharmacological pain relief. This makes it an ideal time and setting to study women's expectations regarding the management of labour pain. People's expectations of specific items are shaped by knowledge of this item and personal preferences.

An investigation of this topic in the Netherlands may generate important insights for countries that are currently encouraging midwife-led care in order to support physiological birth (18).
This study set out to explore pregnant women's expectations of labour pain and labour pain management including preparation of labour pain management; the amount of support from caregivers; the quality of the caregiver-woman relationship; and the involvement in decision-making.

Methods
We conducted semi-structured ante partum interviews with clients from five midwifery practices across the Netherlands between June 2009 and July 2010 for the purposes of this qualitative study. Our study was approved by the Medical Ethical Committee of the Vrije Universiteit (VU) University Medical Center (VUmc) in Amsterdam.
The practices selected were located in different parts of the country, in both rural and urban areas. We chose these eligibility criteria in view of the explorative nature of the study. We included women who spoke Dutch, were between 36 and 40 weeks pregnant, and were receiving primary midwife-led care at the time of the interview. In the Netherlands, only low-risk pregnant women can receive primary midwife-led care; this means they must have singleton pregnancies with cephalic presentation, no previous caesarean section and no other delivery risk factors according to the Dutch Obstetric Indication List (19). We chose the lower pregnancy limit of 36 weeks because midwives usually discuss childbirth with their pregnant clients between 32 and 36 weeks of pregnancy. The characteristics of the 15 respondents are presented in Table 1. Apart from Dutch women, we intended to include Turkish, Moroccan and Surinamese women in the study sample because they represent the largest groups of non-Dutch ethnic background in the Netherlands. It has been shown that ethnic background influences health behaviour and engagement with health care services (20;21). We also intended to include women who varied as regards age, parity, level of education and intended place of birth, because these factors are expected to affect expectations of pain management (22;23).

In each of the five participating practices, the midwife or her practice assistant asked eligible pregnant women at their prenatal care visit for consent to be approached by the researcher. We continued to look for more participants until data saturation was reached.

Table 1 Characteristics of study sample

Resp.	Age	Level of education	Cultural background	Parity	Intended place of birth	Approaches*
01	30	Intermediate	Dutch	Nulliparous	Home	PN
02	26	Secondary	Dutch	Parous	Home	DU
03	34	Higher	Dutch	Parous	Home	PN
04	24	Intermediate	Turkish	Nulliparous	Hospital	DU
05	27	Secondary	Turkish	Nulliparous	Hospital	DU
06	35	Higher	Dutch	Parous	Hospital	PN
07	30	Higher	Dutch	Nulliparous	Home	PN
08	32	Higher	Dutch	Nulliparous	Home	PN
09	35	Higher	Dutch	Parous	Home	PN
10	23	Secondary	Turkish	Nulliparous	Hospital	DU
11	30	Secondary	Surinamese	Parous	Hospital	PN
12	36	Higher	Dutch	Parous	Hospital	PN
13	28	Secondary	Dutch	Parous	Hospital	PN
14	34	Higher	Dutch	Parous	Hospital	PN
15	27	Intermediate	Dutch	Parous	Hospital	PP

*Approaches: PN=Pragmatic Natural, DU=Deliberately Uninformed, PP=Pro Pain relief

All interviews were conducted in Dutch at the women's homes by the main researcher (TK). The researcher explained to each participant that all information from the interview would be strictly confidential. The women gave informed consent for participation in the study and the interview was taped by a digital voice recorder. The interviewer kept field notes in a logbook, referring to the context of the interview, the circumstances of the interviewee and reflections on her own role as interviewer.

The interviews were guided by a topic list based on literature on expectations and satisfaction with childbirth generally and with pain management during labour (8;24;25;26). Although the studies of Hodnett et al. (8) and Rijnders et al. (26) are based on actual experience of labour pain management, it was considered that the themes they identified would provide a useful basis for our study because expectations influence experience in birth and labour pain management as in other fields. Our semi-structured interviews contained the following topics: expected labour pain during labour and childbirth; expected methods of pain relief, involvement in decision-making about pain management during labour; plans and agreements with care-giver and partner, preparation for management of labour pain and expectations of the role of health professionals and partner in pain management during labour. If necessary, further exploratory questions were asked (see Appendix 1 for topic list).

All interviews were transcribed by the first author (TK) and an assistant. The transcripts were coded and analysed with the aid of the qualitative software program ATLAS.ti and further analysed by the constant comparison method (27). The following baseline information was collected for all study participants: age, level of education, country of birth of the woman and of her parents, parity and intended place of birth. The level of education was categorised into 1] no education, 2] primary school only, 3] secondary school only, 4] 'intermediate' (post-secondary but below university level) and 5] 'higher' or university level. The first five interviews were coded separately by the first author (TK) and the second author (JM).We ensured the reliability of our results by comparison and discussion of the coding of the interviews between the researcher (TK) and two of the other authors (JM, AdJ). The subsequent interviews were analysed by TK and four of these interviews chosen at random were reviewed by JM. When any disagreement was found, TK and JM tried to reach consensus and consulted AdJ if necessary to this end. The validity of our data was ensured by monitoring the research role of the first author and by a systematic search for disconfirming cases during data collection and analysis. All the interviews were analysed using open codes and the following thematic codes: 1) personal expectations; cognitive and personal preferences, 2) the anticipated quality of the caregiver/client relationship; attitude and behaviour, 3) the anticipated amount of support from caregivers, 4) the expected involvement in decision-making during labour; feeling of control, 5) preparation (8;24-26).

Results

We asked 24 women to participate in the ante partum interview. Four refused, four gave birth before the interview could be held, and one forgot the appointment for the interview and was on holiday abroad on the date in question. The fifteen participating women varied in age, parity, educational level, cultural background and intended place of birth as shown in Table 1.

We explored the data according the five pre-existing themes from the literature, then used open coding and derived one new main theme addressing the approaches women used to planning the management of labour pain. The main themes that we identified are discussed below and quotes, translated from the Dutch verbatim transcript into English, are given to illustrate them. The following information was added in connection with the quotes: Px = participant No. x; [ ] = explanation added by authors; […] = text omitted.

Approaches to management of labour pain

We found that women take one of three main approaches to planning the management of labour pain. The first is a '*pragmatic natural'* approach which we identified in 10 women. Here, the woman is confident that she will be able to give birth without pharmacological intervention if labour proceeds naturally and does not last too long. She believes the labour pain will be intense but something she can probably manage; she sees birth as a tough but natural challenge. At the same time she appreciates the availability of pharmacological pain relief if it is needed. This was the largest group in our study population.

The second is a '*deliberately uninformed'* approach which we identified in four women. Here, the woman prefers to receive as little information as possible because she fears that too much information will cause anxiety and undermine her confidence. She believes that receiving extensive information about the childbirth process will frighten her too much; she would rather experience her own labour as it presents. The three women of Turkish ethnicity in our study all seemed to belong to this group.

The third is a '*planned pain relief'* approach where the woman decides before giving birth that she will make use of some form of pharmacological pain relief. Only one woman in our sample fell into this group.

We found the following *three major themes* of expectations of pain management related to the five pre-existing themes: 1] preparation, 2] support, 3] control and decision-making.

The above mentioned three approaches to expectations of labour pain management were clustered within each of these three major themes.

1] Preparation

With the exception of the women who used a deliberately uninformed approach, the women interviewed wanted information about management of labour pain. They sought information from many sources, including their midwives, family or friends who had given birth themselves, the internet and books about pregnancy.

P07, Nulliparous woman, pragmatic natural approach: *Yes, I asked my mother and mother-in-law about their experiences of childbirth. They have two different stories, so I hope my story will fall in the middle of theirs. I also have a book about pregnancy [….] which contains a section on childbirth at the end, so I read this.*

P04, Nulliparous woman, deliberately uninformed approach: *I don't want to be too well informed in advance. I would rather just wait and see what happens.*

[…] So I didn't read much about it…. Otherwise I'd get very stressed, which isn't necessary. I'd be too worried, too scared, and that isn't what I want. I'll see – it has to come out anyway.

Women varied in the way they prepared themselves for managing labour pain, ranging from minimal preparation to attending antenatal birthing classes even if they had given birth in the past and felt confident about the management of labour pain. This variation seems to be in line with their approach to labour pain management, as discussed above.
P09, Parous woman, pragmatic natural approach: *Every labour will proceed in its own way but I'm really confident about it. Of course the labour pain will be intense whether you give birth in hospital or at home. […]. I did go to the prenatal birthing classes because I really wanted to prepare myself with other mothers and to focus for myself on the coming birth. This time will be more challenging, since we already have one little child to look after.*

2] Support
The advocacy role of the woman's partner or sometimes a family member or friend was mentioned by many women. Women planned to rely on this during labour even if they didn't discuss it with their partner in advance. Many women said that they would rely on their partner to speak for them and ask for help if they were unable to be assertive themselves.
P12, Parous woman, pragmatic natural approach: *Look, it's very nice to have a calm person that you know by your side…..to know that nothing that I really don't want will happen … Because in that case, he'd speak up. And that is very good to know.*

Women mentioned they would like their midwife to be there well in time before the baby was born, to be able to stay with them during labour, give them advice on how to handle labour pain and support them throughout labour by giving them information about the progress of labour. All nulliparous women in our study with a pragmatic natural approach expected that the midwife would just be with them during labour.
P01, Nulliparous woman, pragmatic natural approach: *Well, you know for sure that the midwife will be there then [during birth]. And I presume that she will direct and guide me. At that moment, I will rely on that. That she will tell me, you should do this and this. […] I expect her to support me in moments that I find difficult. […] and*

when she is finally present I expect that the two of them [husband and midwife] will both do it, together.
The parous women with a pragmatic natural approach had varying expectations of the supporting role of the midwife, from just being there to being pro-active in coaching them through labour pain.
P13, Parous woman, pragmatic natural approach: *The midwife is there to help me through labour with a little bit of humour, not too serious and offering a positive example. That's just about all she has to do; the rest is up to me.*

In case of unbearable pain during labour, most women said they have great confidence in their supporting midwives to be their advocate in pain management.
P11, Parous woman, pragmatic natural approach: *Yes, you have to listen carefully to your midwife [during birth]. […]. The midwife will really help you to get through labour, she will really support you […]. I mean your husband as well, but that's different. You will listen to him in a different way than to your midwife. She will call you to order at some point, and tell you to concentrate and listen to her and then we will go on, […] whatever happens*.

Most women expected a lot of support from their partners and coaching midwife, and sometimes from close family members or friends. They expected these people to provide reinforcement and company.
P02, Parous woman, deliberately uninformed approach: *Yes, my mother and partner will be there [during labour and childbirth]. My mother and I are very much in tune with each other in that respect. My mother is a very reassuring person, which is why I want her to be there with me […] If I panic, I know that she'll know whether there is real cause for concern. Yes.*

3] Control and decision-making
In our study, the type of control of labour pain management expected varied from internal control to external control (if requested). Most women thought they would control their own labour pain as long as they were able to, and then wanted to have the option of handing over control to the midwife. This construction gave women the feeling that they never lost control completely, since the decision of whether to hand over to the midwife was up to them. Women with a pragmatic natural and a deliberately uninformed approach trusted the midwives' expertise and professional knowledge to advise them on pharmacological pain relief if necessary.

P07, Nulliparous woman, pragmatic natural approach: *Yes, she [midwife] knows that I want to give birth at home, but she also knows that at a certain point when I have the feeling that I will not be able to handle the pain anymore, yes in that case we will go to the hospital,[….] she will guide me….*

Women's expectations of decision-making concerning pain management during labour included a management strategy agreed on in advance. The women made these agreements with their midwives, partner, family or friends before they went into labour. Women in our study indicated that they wanted the healthcare professionals attending to listen to them during labour. Some stated that they wanted to be able to opt for some method of pharmacological pain relief themselves. The same women mentioned that they approved of the change in labour pain management policy in the Netherlands, which makes pharmacological pain relief more readily available.
P12, Parous woman, pragmatic natural approach: *Yes, if it [labour] were to last quite long again then I would probably like an epidural very much. And in that respect many things have just changed because of course many years ago you couldn't ask for it yourself. In the weekend or in the evening there was nobody to do it. […] Fortunately, things are very different now […]. I can ask for it [pain relief] myself. I am in charge of it. Yes, it is written in my notes, it is. I don't think we have a real birth plan, but they have recorded it clearly in my notes. Well…then I just have a very good feeling about this…. that nothing will happen that I don't agree with.*

Women who discussed labour pain management during their antenatal consultations with their midwives were appreciative of the approachable attitude of the midwife and of the pain management plans agreed with her.
P10, Nulliparous woman, deliberately uninformed approach: *Of course, I am the best judge of what I need. But… they [midwives] can mean a lot to me during birth. I know one midwife the best; she's very open […], she's a very special lady. I hope she will be there with me [during labour and birth] but OK that's in my heart what I want most. She's great, just like a mother. If I could explain that…, a bit exaggerated, I know. She does not have to explain anything and my feelings tell me 'it will all end well'.*

One woman in our study chose to go to the hospital in early labour to have pharmacological pain relief.

P15, Parous woman, planned pain relief approach: *I want to give birth in the hospital anyway and again I arranged to have an epidural, I was very pleased with this [epidural] the last time. The midwives know this and the hospital knows this.[…] So, she really has to come when I give her a phone call and she has to send me to the hospital in time […] that's important to me. My husband has to be with me of course… and he will, I'm sure.*

Discussion

The results of our study showed that most women interviewed believed that, contrary to the increased use of pain medication in the Dutch maternity care system, they would be able to handle labour pain without pharmacological pain relief in a normal labour. These findings were applicable across age groups, parity of women groups and intended place of birth groups. This finding is consistent with those of other studies, which showed that the ability to manage labour pain is more important than actual avoidance of labour pain (28). Fear of pain during labour is strongly associated with fear of pain in general, regardless of parity (29). The pain avoidance model introduced by Lethem et al. (1983) assumes that people learn to avoid or escape from situations that are potentially painful (30). Pain avoidance mechanisms have been shown to have a powerful effect in producing more pain (30;31).

Most of the women in our study had confidence in themselves and in their care provider. Women believed that with support from family members or close friends and coaching from their midwives they would have no trouble in managing labour pain. Although increasingly women in the Netherlands use pharmacological pain relief during labour, our results indicate that most women still intend to labour without medication if possible. This finding has not previously been reported.

We found three main approaches to the management of labour pain: the pragmatic natural approach used by women who were confident that they do not need pain relief if labour and birth proceeds naturally but at the same time appreciated with the availability of pharmacological pain relief if it is needed; the deliberately uninformed approach used by women who did not want too much information and would prefer to see how things turned out and the planned pain relief approach used by one woman who definitely wanted pain relief on forehand. Women approaching pain in labour in these different ways may need different information, support and encouragement from their midwife during pregnancy and labour. Healthcare workers should try to explore each client's

approach to labour pain management and adapt care to the individual concerned. Several members of our study sample belonged to the second group of deliberately uninformed women. This finding was unexpected. Healthcare providers generally believe that giving information to women about labour and about the availability of pain relief before birth will reduce anxiety (32;33). Women using a deliberately uninformed approach may be prepared to accept labour as it comes and accept whatever management of labour pain they will experience. On the other hand these women may also avoid exposure to information based on fear of labour pain in which case they may experience more pain during labour than women who have no fear avoidance beliefs who confront their pain (30;31). Maternity healthcare workers should explore women's knowledge and possible misconceptions during counselling in order to help them to make adequately informed decisions (34). If women have fear avoidance beliefs, they need corrective information that might reduce their fear of labour pain.

The present findings seem to be consistent with other studies of women's expectations of pharmacological pain relief which found that women want access to effective pain relief if that is needed (35;36). Some of our findings also seem to be consistent with other research which found that while women are unsure what to expect from labour pain, they hope it will be manageable, with or without pharmacological pain relief (37).

One limitation of our study is the possibility of selection bias due to the probability that women who were more interested in the topic of labour pain management would be more likely to participate. However, the fact that we searched for any disconfirming cases and reached data saturation suggests that such bias may not exist.

Although it was beyond the scope of this project to explore subgroups, we did observe that the women of Turkish decent in our study all used the deliberately uninformed approach; had a relatively low education level; and spoke Dutch as their second language. The only woman of Dutch decent with a deliberately uninformed approach also had a relatively low level of education. The only woman with a Dutch Surinamese background in our study used the pragmatic natural approach, like most of the native Dutch women we interviewed. Further studies of ethnic variations in women's attitudes to labour pain management are desirable to explore the factors involved.

Our study was conducted in the Netherlands, which has a strong community-based maternity care system with a relatively high rate of 'natural' birth as defined by the National Institute for Health and Clinical Excellence (38). The results will thus be relevant for countries that have a comparable obstetric system, or are implementing midwifery led-care with the goal of supporting natural birth (14;38).

Kangas and Kangas (1994) concluded that women would be disappointed if their wishes regarding pain management were not fulfilled (39). A majority of the women in our study used a pragmatic natural approach to labour pain management, in other words they hoped to have a natural birth but were happy to accept pharmacological pain relief if this proved necessary. This strategy would seem to guard them against disappointment, as long as their wishes are made known in advance and are followed. The women in our study who used a deliberately uninformed approach seemed to have no specific expectations and therefore they could not be disappointed either. Finally, the woman who planned to have pain relief in advance prevented the pain from getting too unbearable. One could argue that all women seemed to be disappointment averse but they varied in the way they avoided disappointment.

Future research is required to determine the extent to which women's expectations regarding labour pain management are met, and to measure their satisfaction with the pain management process.

In conclusion, midwives should individualise counselling and information around labour pain management to accommodate the different approaches of women towards this process in the interests of woman-centred care.

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Chapter 4

A qualitative interview study into experiences of management of labor pain among women in midwife-led care in the Netherlands

Trudy Klomp, Anke B. Witteveen, Ank de Jonge, Eileen K. Hutton,
Antoine L.M. Lagro-Janssen

Submitted

Abstract

Introduction: Many pregnant women are concerned about the pain they will experience in labor and how to deal with this. This study's aim was to explore aspects of dealing with labor pain that are important to women in midwife-led care in the Netherlands.
Methods: Semi-structured postpartum interviews were analyzed using the constant comparison method. Using purposive sampling, we selected seventeen women from five midwifery practices across the Netherlands, from August 2009 to September 2010.
Results: Women reported that control over decision-making during labor (about dealing with pain) helped them to deal with labor pain, as did continuous midwife support at home and in hospital, and effective childbirth preparation. Most women adopted a 'Pragmatic Natural' approach to labor pain, i.e. they preferred to go through labor without pain medication but were happy that medication would be available if needed. Women with a 'Deliberately Uninformed' approach would rather experience their labor as it occurs and 'Pro Pain Relief' women definitely planned to use pain medication. However, during labor, some women switched their approach to labor pain from 'Pro Pain relief' to 'Pragmatic Natural'. Some of these women implicitly or explicitly indicated that midwives should know which method of pain management they need during labor and arrange this in good time.
Discussion: It may be difficult for midwives to discriminate between women who need continuous support through labor without pain medication and those who genuinely desire pain medication at a certain point in labor, and who will be dissatisfied postpartum if this need is unrecognized and unfulfilled.

Introduction

Labor pain is a varied phenomenon not restricted to the sensory mechanism alone. Emotional, motivational and cognitive dimensions all contribute significantly to the way in which labor pain is experienced (1). Many pregnant women worry about the pain they will experience and about how they will deal with it (2). The management of labor pain includes medicinal and non-medicinal pain relief. It is also influenced by factors such as a woman's relationship with the health professional involved (3,4,5,6). A new guideline on the use of pain medication in labor was introduced in the Netherlands in 2008. It states that a women's request is a sufficient medical indication for pain medication in labor

and that epidural analgesia is the method of choice (7). This guideline, together with the influence of Dutch and international media, has probably helped to boost the use of pain medication in the Netherlands (8,6). There have been no previous studies in the Netherlands of how women receiving midwife-led care from the onset of labor perceived their ability to deal with labor pain.
In the Netherlands, around 80% of women start their pregnancy in midwife-led care and around 55% of women start their labor in midwife-led care (9).
The Netherlands' relatively high rate of physiological births (around 82% of all women who have a vaginal delivery use no medicinal pain relief) (9) lends itself to investigations of women's' perceptions of their ability to deal with labor pain.
Midwife-led care systems focus on helping women to work with their labor pain, unlike many obstetrician-led care systems which routinely offer medicinal pain relief at an early stage of labor (10). An in-depth exploration of women's perceived pain during labor in midwife-led care in the Netherlands may generate important insights for countries that are supporting midwife-led care to encourage physiological birth (11,12).
This study's aim was to explore aspects of dealing with labor pain that are important to women in midwife-led care in the Netherlands.

Methods

This study was designed as a qualitative interview study, as we feel that this is well suited to an exploration of women's perceptions and views (13). The choice of interviews over focus groups was driven by the private nature of the topic of labor pain. Furthermore, this setting allows women to discuss their intimate, personal experiences with the interviewer, if they so wish.

Participants and procedure

We conducted semi-structured postpartum interviews with clients from five midwifery practices across the Netherlands, between August 2009 and September 2010.
We selected practices in both rural and urban areas. Our goal was to include women who varied in terms of age, parity, level of education, cultural background and intended place of birth. This was because these factors are expected to affect women's expectations and experiences of pain management (14,15).
We included women who spoke Dutch, were between four and eight weeks postpartum, and who received midwife-led care at the onset of labor. The Dutch maternity care system is community-based (16). Midwife-led care is restricted

to women with a low level of risk at the onset of labor, i.e. singleton pregnancy with cephalic presentation, no previous caesarean sections, and no other risk factors on the Dutch Obstetric Indication List (17). Those opting for midwife-led care may choose to give birth at home, in a birth Center or in hospital. If risk factors or complications arise, then the subject is referred to obstetric-led care. Medical interventions such as induction or augmentation of labor, electronic fetal monitoring and pain relief only take place in obstetric-led care. Interviews were held at least four weeks after women had given birth, as we wished to allow them some time to reflect on their experiences of labor. The final deadline was eight weeks after birth, as a woman's memory may change over time (18), and we wanted to interview women who still had vivid memories of their labor pain.
In each of the five participating practices, the midwife or her practice assistant identified eligible pregnant women. During prenatal care visits (after 36 weeks of gestation), these women were asked if they would consent to a researcher contacting them around three weeks postpartum. Later, the midwives were asked to invite subjects with specific, under-represented characteristics, such as women with Surinamese, Antillean or Moroccan cultural backgrounds, women who had decided beforehand to use some form of pain medication during labor, and women who had originally intended not to use pain medication but who actually did so in the end. When data saturation was reached, subject recruitment was discontinued. All interviews were conducted in Dutch, at the women's homes, by the principal researcher (removed for blind review). The researcher explained to each participant that all information obtained during the interview would be strictly confidential. The interviewer kept field notes in a logbook, about the context of the interview, the interviewee's circumstances, and her own role as the interviewer.
The opening question was:

We would like to know how you dealt with labor pain, what can you tell me about it?
Additional open questions helped women to talk freely, describing events in their own words (see Appendix 2, Chapter 4 for details of the interview guide).

Ethical approval
Ethical approval was obtained from the Institutional Review Board of the University where this study took place.

Analysis

All interviews were transcribed by the first author (removed for blind review) and an assistant. The transcripts were coded and analyzed using ATLAS.ti version 5.2 (qualitative data analysis software), and further analyzed using the constant comparison method (19). The following baseline information was collected for all study participants: age, level of education, country of birth of the subject and of her parents, parity, intended- and actual place of birth. The subject's level of education was categorized as 1] no education, 2] primary school only, 3] secondary school only, 4] 'intermediate' (post-secondary but below university level) and 5] 'higher' or university level. We explored the data using open coding. The first three interviews were coded separately by the first author (removed for blind review) and second author (AW). We ensured the reliability of our results by comparing the results they obtained. Subsequent interviews were analyzed by (removed for blind review), three of which (chosen at random) were reviewed by (removed for blind review). The final analyzes were discussed by all of the authors. To avoid socially desirable answers, the women were not told that the interviewer was a former midwife. She told them she was a lecturer of midwifery and a researcher interested in improving the quality of care, and asked them to be honest about their labor experiences. The information was coded as follows: Px = participant no. x; XX = woman's approach (Pragmatic Natural (PN), Deliberately Uninformed (DU), Pro Pain relief (PP)); [ ] = explanation added by authors; […] = text omitted. Quotes were translated from the Dutch verbatim transcript into English by a professional translator.

Results

We asked 23 women to participate in the postpartum interview. Six refused, mostly due to time constraints. As shown in Table 1, the seventeen participating women varied in age, parity, educational level, cultural background and planned place of birth. The interviews lasted from 45 to 105 minutes.

After open coding, three new main themes emerged from the data: 'control over decision making in labor', 'midwives' continuous support in labor' and 'childbirth preparation'. Next, we found the same three approaches previously seen in a group of women interviewed antepartum about their expectations regarding labor pain (6).

Table 1 Characteristics of study sample

Resp.	Age	Level of education	Cultural background	Parity	Intended place of birth	Actual place of birth	Framework: exp. labor pain approach*
01	32	Intermediate	Dutch	Primiparous	home	hospital	DU
02	29	Intermediate	Dutch	Primiparous	home	home	PN
03	32	Higher	Dutch	Parous	home	home	PN
04	27	Intermediate	Dutch	Primiparous	home	home	PN
05	41	Lower	Moroccan	Parous	hosp./indec.	home	PP/PN
06	22	Secondary	Moroccan	Primiparous	hospital	hospital	DU
07	28	Secondary	Dutch	Parous	home	home	PN
08	33	Secondary	Moroccan	Parous	home	home	PN
09	29	Higher	Other Eur.	Parous	home	home	PN
10	18	Secondary	Antillean	Primiparous	hospital	hospital	DU
11	19	Secondary	Surinamese	Primiparous	hospital	hospital	DU
12	28	Higher	Dutch	Primiparous	indecisive	hospital	PP
13	32	Higher	Dutch	Primiparous	home	hospital	PN/PP
14	36	Intermediate	Dutch	Parous	indecisive	hospital	PN
15	27	Lower	Turkish	Parous	hospital	hospital	DU
16	30	Intermediate	Turkish	Parous	hospital	hospital	DU
17	35	Higher	Dutch	Parous	hospital	hospital	PP

*Labor pain approaches: PN = Pragmatic Natural; DU= Deliberately Uninformed; PP = Pro Pain relief

Approaches to dealing with labor pain

The first of these was 'Pragmatic Natural', i.e. women planning to give birth naturally, without pain medication, provided that labor was straightforward. Nevertheless, they were not opposed to the use of pain medication if labor were to become too exhausting and painful. The second approach was 'Deliberately Uninformed', i.e. women who did not want too much information and preferred to see how things turned out. Finally, there was the 'Pro Pain relief' approach, i.e. women who definitely planned to use pain medication (6). In this study, as in the antepartum study before, the 'Pragmatic Natural' approach was the most common way of dealing with labor pain during childbirth. The three themes identified in the current study cut across the approaches to pain management, which will be discussed below.

Control over decision-making in labor

Most women preferred to be in control when dealing with labor pain. Those in our study preferred to be informed by their midwife or other hospital staff about their

options, and about what they could expect. Subjects whose labor process did not proceed as expected, expressed very strong feelings.

[…] Until labor became very stressful and I became very tired, at which point the hospital staff took action. And just said 'we have to arrange something or a drip with pain medication so you can control the dose slightly each time or just an epidural'. And we opted for the latter. When I was connected to all the tubes, I could not control that part of my body anymore and I think that this made me feel emotional. That I just could not follow my original birth plan anymore [planned to give birth without medicinal pain relief], [P14, PN parous woman who had to go to the hospital for augmentation and request for pain medication

A few women had a 'Pragmatic Natural' approach towards anticipated labor pain and felt disappointed when this did not work during childbirth. They expected their body to cope with giving birth naturally, and felt disappointed when they realized that they couldn't work with the labor pain any more. Their thoughts on the progress of labor and on labor pain itself seemed to catastrophize the pain involved.

I thought that all my efforts were for nothing. I find that very hard, that you do not know when it is all over. […] I could not rest between my contractions […], I thought the baby just does not want to come out. So then, I started to scream for an epidural because I could not bear it any more. She [midwife] saw that […]. In fact, my body really let me down during labor. She phoned the hospital and they were prepared to admit me. [P13, PN/PP primiparous woman who had to go to the hospital for prolonged labor and request for pain medication].

Some women blamed the Dutch maternity care system's culture of dealing with labor pain and the traditional Dutch culture of accepting pain in labor. They believed this resulted in poor accessibility to pain medication in hospital. For example, one woman expressed disappointment with her supporting midwives because they failed to recognize her need for support and her calls for pain medication. She was unable to control her labor pain and had no control over the decision-making process.

I really felt that I had to call out for it [pain medication]. I expected that the midwife would be able to assess how much pain I had to endure and I expected that she […] would be sympathetic to your plight, thinking 'she can't do this anymore' and that she would transfer you to the hospital [without hesitation], […]. I believe that I should have actually, yes, should have had it already. I actually think that they should have taken the initiative. That really upsets me, and I really feel that that is typical of the Netherlands [with emphasis on the Netherlands]. […] It was a bit as if she was just looking at me, no matter how much pain I had. And I find that very disappointing. [P13, PN/PP primiparous woman who had to go the hospital for prolonged labor and request for pain medication].

Other women expressed their satisfaction with the new policy on the provision of pain medication, which allowed them to make their own decisions during labor.

I am really happy with the changes in the pain relief policy. Now, you just have to ask for it and that you will be taken seriously [P12, PP, primiparous woman who gave birth in hospital with pain medication].

Many women described their cognitive coping style as encouraging themselves to work with labor pain as it occurred. Their 'Pragmatic Natural' approach to labor pain helped them to remain in control.

But at that point [pushing phase], basic instinct took over and you had to go through with this…at that point there was no panic at all, I just thought: 'OK you have to go on, be in control and go on…[P2, PN primiparous woman who gave birth at home].

One woman did not feel in control, either during the process at home or after being transferred to hospital for pain medication. She expressed her feelings of helplessness and of not being listened to.

I could only shout 'I want an epidural' […] The only thing I heard was that I would not get an epidural, I was so deeply disappointed […] I wasn't prepared to listen to the reasons why I couldn't get it, I just kept on shouting for that epidural. […]. They told us but I was too exhausted. My partner understood them though. [P13, PN/PP, primiparous woman who had to go to the hospital for prolonged labor and request for pain medication].

A few women explained why, during labor, they changed their mind about how to deal with labor pain. One woman trusted her midwife, whose support helped her to continue without pain medication.

Yes, I wanted an epidural but she [midwife] said 'you really do not need to do this, I know you're afraid, you just have to be patient then everything will be fine and I was fine […], really it was a good decision, I was very proud of myzelf [P5, PP but changed her approach to PN, parous woman who first planned to give birth in hospital with medicinal pain relief but who changed her plan to 'indecisive' and, on starting labor, switched to 'home birth'

Another women accepted pain medication, despite initially being against it, because her labor was more difficult than she had anticipated.

I had a [urine] catheter inserted. In the meantime, I still had vaginal examinations again to see, okay, can we do that, how many centimeters do you have to go ahead with it. Because that is of course also dependent on whether you get an epidural or that drip […]. And that is actually not what you want but that is then necessary and eh… yes, you have to let it happen like that. [P14, PN parous woman who had to go to the hospital for augmentation and request for pain medication].

Midwives' continuous support in labor

The study participants appreciated the continuous support of their midwives. They felt well cared for if they had direct access to the midwife, and if a midwife that they knew cared for them both at home and in hospital. They also appreciated midwives with a communicative, supportive and pro-active attitude. Some stated that midwives provided the best guidance through labor pain. They trusted their midwives to act as their advocate if their labor did not proceed as expected.

Yes, I knew her [midwife] from my consultations at the midwifery practice and that was nice. She stayed very calm and in control and that calmed me, so that was fine wasn't it? […]. She kept on talking to me when contractions came and when she noticed that I was in severe pain she just said nothing and waited until the pain was over. Good communication with your midwife because in the end, she's the one you'll have to trust/ [P11, DU primiparous woman who gave birth in hospital with her community midwife].

A few women who were transferred from primary midwife-led care to secondary obstetrician-led care, due to prolonged labor and a request for pain medication, expressed negative emotions about their birth experiences. These women felt abandoned by the caregiver whom they knew very well. Their criticism of the Dutch maternity care system was that the primary care midwife is no longer responsible for their care once they have been referred.

The midwife said to us 'maybe this time your labor will go fast' and I just thought that maybe this time [second child] I would just be able to stay at home but I had to let go of that dream. […]. I believe it is just not right that your midwife can't stay, that she has to hand you over, I did not like that because that person knows you very well and I know her [P14, PN parous woman who had to go to the hospital for augmentation and request for pain medication].

Similarly, women experiencing many changes of midwife during labor said they felt abandoned by these individuals, and disappointed by the support they gave.

And then I got another midwife [woman's face expresses disappointment]. For a long time, it really bothered me that three different midwives were looking after me, which was not OK [P1, DU primiparous women who had to go to the hospital for prolonged labor and request for pain medication].

Childbirth preparation

Many women saw antepartum preparation as important to the approach they used during labor. They placed great importance on childbirth stories by women with experience of labor, and on antenatal classes. Concerning the latter, women often stressed the importance of breathing exercises, of becoming familiar with the physical and cognitive aspects of the labor process, and of developing a birth plan.

Stories told by other women, about their labor pain, can help women to prepare for childbirth. Yet some women said too much information made them feel unsecure and more fearful about working with labor pain.

I think that all that information about pain relief actually makes women afraid of giving birth. While reading the information, I was thinking 'Gosh, this is all such scaremongering'. […] I would prefer to believe that I can just do it. I have to

empower myself. And if something happens [during birth] that means I cannot handle the pain any more, then the midwife will know what to do [P3, PN parous woman who gave birth at home].

Most felt prepared and empowered by antenatal classes during pregnancy. Some especially appreciated cognitive preparation and breathing exercises to help control pain during labor.

I was very happy with my yoga childbirth classes, they helped a lot, it meant that I could really control my breathing so, no matter how much pain I had, my mind stayed clear; then there is less tendency to panic …, with fewer stressful moments and I was more in control [P2, PN primiparous woman who gave birth at home].

Some participants in our study said that they had used cognitive coping strategies, such as believing that natural childbirth is positive and special.

I am convinced that, well fear makes your body stiff. Fear does not allow you to be open to things, so you always have to try […]. And I also said a few times [during prenatal classes]: yes, wait a minute, just try to face it in a relaxed manner because it is also beautiful [birth]. It's something very special that you are allowed to do; to try and develop that kind of attitude. [P9, PN parous woman who gave birth at home].

Likewise, those with a 'Deliberately Uninformed' approach said they just planned to their best, believing that the birth of their child would be compensation enough.

I just tried to do my best, knowing that later on I would be rewarded for my hard labor, for all that pain, being patient is also painful but if you are more patient then everything will be fine [P5, DU parous woman who gave birth in hospital without pain medication with support of her community midwife].

Discussion

Summary of findings

The participants said their involvement in decision making during labor helped them to deal with labor pain, as did their midwives' continuous support and effective, helpful birth preparation. In these postpartum interviews, the three

approaches actually used by women to deal with labor pain coincided with those described in our study of antepartum expectations of labor pain in another group (6). However, during labor, some women switched their approach to labor pain from 'Pro Pain relief' to 'Pragmatic Natural'.

Interpretation

As in other studies (2,10), when their antenatal approach towards labor pain did not work out as planned, some women felt lost and not in control during labor. These women felt confused and let down by their own bodies, and might have tended to catastrophize labor pain (20,21). Catastrophizing involves focusing on and overstating the significance of pain in specific circumstances, and a lack of belief in the ability to work with it (22,23). Those women who catastrophized their labor pain also focused on its physical dimension, which may have caused them to overstate its importance. They also said they had difficulty accepting that their bodies were able to work with labor pain. In line with the studies conducted by Whitburn et al. [2014] and Escott et al. [2009], we found that the cognitive coping strategies instilled in women as part of their childbirth preparation appeared to help them to work with labor pain (20,21). Some felt strengthened and empowered by seeing themselves as capable of working with pain.

Other studies found that most women wanted to wait and see before they decided about the use of pain medication during labor (24). In our study, too, many preferred to defer decisions about pain medication until labor, as they trusted their maternity care professional to guide them through labor pain (24,25). Haines et al., (2012) found that women's approaches to childbirth (or profiles) were broadly similar, i.e. 'take as it comes', 'fearful' and 'self-determination' (26). However, the framework of approaches that we previously identified is more specific to labor pain (6). Other studies (27,28) found that women's approaches to birth are not based purely on their personal characteristics. Situations arising during pregnancy and labor can also influence women's approach to a subsequent pregnancy and labor (28). Interestingly, we found that some women even changed their approach early in labor from 'Pro Pain relief' to 'Pragmatic Natural'. This change may be prompted by information from their midwife. Some women who adopted a 'Pragmatic Natural' approach and changed their approach to labor pain to a subsequent labor in the future may have been so focused on natural birth without pain medication that they failed to take the unpredictability of birth into account, and were unable to request pain medication when they actually needed it. This finding has not previously been reported.

Dutch culture seems to be an important determinant for women's approach to labor pain (29). Previous studies suggest that Dutch women have more positive attitudes towards labor pain than women in other developed countries (29,30). Most women still believe in natural childbirth – including working with labor pain – provided that labor proceeds well (6). This is in line with the results of the present study. Most subjects adopted a 'Pragmatic Natural' approach to labor pain, i.e. they preferred to go through labor without pain medication but were happy that medication would be available if needed. 'Deliberately Uninformed' women would rather experience their labor as it occurs, and express no specific expectations about dealing with labor pain. Nevertheless, the change in Dutch culture and the greater availability of pain medication is important for many women (7).
Women who are 'Deliberately Uninformed' and those adopting the 'Pro Pain relief' approach are most likely to have their expectations about dealing with labor pain fulfilled. Many women had high expectations of their midwives, in terms of helping them through labor pain. At the same time, some of these women implicitly or explicitly indicated that midwives should know which method of pain management they need during labor and arrange this in good time.
In other studies, continuous support from one maternity care professional, has been shown to have a positive effect on women's birth experiences (4,31). The Dutch guideline of 'failure to progress in labor' recommends continuous support during labor to facilitate the labor process, to reduce the need for pain medication and to reduce labor interventions (32). In our study, too, women preferred continuous support from one midwife to deal with labor pain.
It may be difficult for midwives to assess whether pain medication should be provided. In this respect, it seems important that midwives should help women to have realistic expectations about dealing with labor pain. Antepartum, midwives should discuss potential difficulties in deciding whether or not to switch to pain medication, as some may find that working with labor pain is not what they expected. In discussions with clients, midwives should indicate that they may change their mind about dealing with labor pain, and that they are free to state their needs during labor, in order to manage their labor pain.

Limitations and strength

Our study has some limitations. One potential limitation is that the interviewer was a former midwife, so some subjects may have given socially desirable answers. Although there were some critical stories about the care provided by midwives and hospitals, we cannot entirely rule out the possibility of information bias.

All of the women interviewed were in midwife-led care, so the results of our study cannot be generalized to those in obstetrician-led care.
One major strength of our study is that -given the delicate nature of the subject of labor pain- a different group was involved than the one interviewed antepartum about labor pain (6). Had we interviewed the same women both antepartum and postpartum, then the antepartum interview might have acted as an intervention, focusing them on the subject of labor pain. Women with this acquired focus on labor pain may then have prepared themselves differently to those who had not been interviewed. At the same time, one could argue that this is a limitation, as the subjects involved might not adequately remember their antepartum approach to labor pain once they had given birth.

Further research
Further research is needed to identify areas for improvement in working with labor pain in 'Pragmatic Natural' subjects, e.g. coping techniques and the support needed to balance giving birth without pain medication versus getting medication in time, when necessary.

In conclusion, women in our study appreciated the option of requesting pain medication, and they expected this would be available when they request it, either explicitly or implicitly. The women wanted continuous support from their maternity care professional during labor, to enhance the communication of needs, such as switching approaches to labor pain. They also felt that this would provide real support in working with the pain, and when care switches from being midwife-led to being obstetrician-led. It may be difficult for midwives to discriminate between women who need continuous support through labor without pain medication and those who genuinely desire pain medication at a certain point in labor, and who will be dissatisfied postpartum if this need is unrecognized and unfulfilled.

Acknowledgement
We thank all the midwifery practices for recruiting women for our interviews. We also thank all the women who gave us their time and were prepared to share their intimate labor experiences with us.

Declaration of interest
All the authors declare that they have no conflicts of interest.

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Chapter 5

Dutch women in midwife-led care at the onset of labour: which pain relief do they prefer and what do they use?

Trudy Klomp, Ank de Jonge, Eileen K Hutton, Antoine LM Lagro-Janssen

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Abstract

Background
Pain experienced during labour is more extreme than many other types of physical pain. Many pregnant women are concerned about labour pain and about how they can deal with this pain effectively.
The aim of this study was to examine the associations among low risk pregnant women's characteristics and their preferred use and actual use of pain medication during labour.

Methods
Our study is part of the DELIVER study: a dynamic prospective multi-centre cohort study. The data for this study were collected between September 2009 and March 2011, from women at 20 midwifery practices throughout the Netherlands. Inclusion criteria for women were: singleton pregnancies, in midwife–led care at the onset of labour and speaking Dutch, English, Turkish or Arabic. Our study sample consisted of 1511 women in primary care who completed both questionnaire two (from 34 weeks of pregnancy up to birth) and questionnaire three (around six week post-partum). These questionnaires were presented either online or on paper.

Results
Fifteen hundred and eleven women participated. Prenatally, 15.9% of women preferred some method of medicinal pain relief. During labour 15.2% of the total sample used medicinal pain relief and 25.3% of the women who indicated a preference to use medicinal pain relief during pregnancy, used pain medication. Non-Dutch ethnic background and planned hospital birth were associated with indicating a preference for medicinal pain relief during pregnancy. Primiparous and planned hospital birth were associated with actual use of the preferred method of medicinal pain relief during labour. Furthermore, we found that 85.5% of women who indicated a preference not to use pain medication prenatally, did not use any medication.

Conclusions
Only a small minority of women had a preference for intrapartum pain medication prenatally. Most women did not receive medicinal pain relief during labour, even if they had indicated a preference for it. Care providers should discuss

the unpredictability of the labour process and the fact that actual use of pain medication often does not match with women's preference prenatally.

Background

Pain experienced during labour is a complex, subjective and multidimensional phenomenon. Aside from sensory components, it involves major emotional, motivational and cognitive dimensions [1,2]. Labour pain is more extreme than many other types of physical pain [3,4] and many pregnant women are concerned about the pain of labour and about how they can deal with it effectively [4]. On the other hand, women have also described their experience of giving birth as an empowering experience which gave them a sense of pride in their ability to deal with the pain [5,6]. Labour pain can be managed through medicinal and non-medicinal approaches. Non-medicinal methods of pain relief include relaxation techniques, distraction techniques and continuous support [7-9]. Epidural analgesia, pethidine or morphine injections, and remiphentanil infusions are examples of medicinal pain relief [9]. Christiansen et al. [10] and Hodnett et al. [11] reported an association between involvement in decision making and satisfaction with the experience of childbirth. Involvement in decision making and the ability to choose between different methods of pain relief contributes to childbirth satisfaction [12].

In recent years there has been an increase in the number of women opting for epidural analgesia during labour [13,14]. The use of some method of medicinal pain relief has become standard procedure in many developed countries [15,16]. The Netherlands has a community-based maternity care system, with approximately 84% of all pregnancies starting in midwife-led care [17]. Low-risk women in midwife-led care may choose to give birth at home, in a birth centre or in hospital with their own midwife. If risk factors or complications arise, women are referred to obstetrician-led care. Medical interventions such as medicinal pain relief, electronic fetal monitoring and augmentation of labour only take place in obstetrician-led care. Women who fear labour pain and who have decided that they will choose for medicinal pain relief before going into labour may be referred by their midwife for a consultation with the obstetrician in order to discuss about their labour pain management. However, usually these women will start their labour in midwife-led care and they will make arrangements with their midwives that they will be referred for pain medication as soon as labour starts [18].

The Dutch guideline concerning medicinal pain relief was introduced in 2008 [19]. This guideline states that a woman's request is a sufficient medical indication

for medicinal pain relief during labour, and that epidural analgesia should be the method of choice for the elimination of labour pain. Despite the Dutch tradition of a 'natural' birth without medicinal pain relief, the number of women using medicinal pain relief in this context is increasing every year [17]; 13.9% of women without a primary caesarean section used epidural analgesia in 2009 [17].
Little is known about pregnant women's prenatal preference regarding pain relief and their actual pain relief in the Netherlands during labour. In addition, little is known about women's socio-demographic and personal characteristics that are associated with a preference for medicinal pain relief during pregnancy.
The aim of this study was to examine the associations between women's characteristics and their preferred use and actual use of pain medication during labour.

Methods

Study population

Our study was part of the DELIVER study: a dynamic prospective multi-centre cohort study [20]. This study was approved by the Medical Ethical Committee of VU University Medical Center Amsterdam (VUmc). The data for this study were collected between September 2009 and March 2011, from women at 20 midwifery practices throughout the Netherlands.
We approached twenty of the 519 primary care practices in the Netherlands and invited them to participate in this study. We purposively selected practices using three stratification criteria: region: north, middle, south; level of urbanisation: urban, rural or combined urban/rural; practice type: dual or group practice (Table 1). The approached practices received a brochure with information on the study and were visited by two members of the DELIVER research team who explained the study in further detail. If a practice declined participation, a replacement was found taking region, urbanisation and practice type into account. Ultimately, fourteen practices declined participation, mostly because of time constraints. Midwives invited all women in their practices who spoke Dutch, English, Turkish or Arabic. Those pregnant women who were prepared to participate in the study gave informed consent to their midwife. For the purposes of the study, these women received three questionnaires: the first early in pregnancy (at around 12 weeks), the second between 34 weeks of pregnancy and birth. and the third at around six weeks post-partum. Depending on the preferences of the women, these questionnaires were presented either online

or on paper. In an attempt to boost the response rate, successive reminders were sent to non-responders one week after the initial invitation, and student-assistants called non-responders between three to four weeks of non-responding. Non-responders from other cultural backgrounds were offered an opportunity to participate in the study by means of a telephone interview in Dutch, Turkish, Berber or Arabic (depending on their preference). The DELIVER client data were linked to primary care data from the Netherlands Perinatal Register ('Landelijke Verloskundige Registratie'. LVR1).

Table 1 Characteristics of the 20 midwifery practices

Practice	Region	Level of urbanisation	Practice type (n = number of practising midwives)
1	South	Rural/Urban	Group (4)
2	South	Rural/Urban	Group (6)
3	Centre	Rural/Urban	Group (7)
4	North	Rural	Group (3)
5	Centre	Urban	Group (5)
6	Centre	Rural	Group (5)
7	North	Urban	Group (3)
8	North	Rural	Group (4)
9	South	Rural/Urban	Group (5)
10	Centre	Rural/Urban	Group (6)
11	North	Rural	Duo (2)
12	North	Urban	Group (4)
13	Centre	Rural/Urban	Group (5)
14	Centre	Rural	Group (6)
15	Centre	Rural/Urban	Group (5)
16	North	Rural	Group (3)
17	Centre	Rural/Urban	Group (5)
18	Centre	Urban	Group (5)
19	South	Rural/Urban	Duo (2)
20	Centre	Urban	Group (6)

For this study, all women with singleton pregnancies who were in midwife–led care at the onset of labour and who completed both questionnaires two (from 34 weeks of pregnancy until delivery) and three (around six weeks after delivery) were selected. We excluded women who did not meet the criteria for midwife-led care at the onset of labour. Thus we excluded women who were referred to obstetrician-led care during pregnancy; gave birth before 37 weeks and 0 days or after 42 weeks and 0 days gestation and were referred for prolonged rupture of membranes (> 24 hrs without being in active labour). Women who had an induction of labour or planned Caesarean section start labour in obstetrician-led care and were therefore not included in our sample.

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The variables used in the study

Data of socio-demographic and personal characteristics were used in the analyses as independent variables. Based on prior studies, we used five variables known to be associated with medicinal pain management use; age, level of education, ethnic background, parity and planned place of birth [21-23].

Women reported their date of birth; age was subsequently categorized into ‘under 25’, ‘from 25 to 35’ and ‘over 35’. Women’s highest level of education was recoded into low (no education, only primary education or lower vocational education), medium (only secondary school education or medium vocational education) and high (college, university or post-graduate education). Women were asked about the country of birth of both parents. Women’s ethnicity was based on the definition used by Statistics Netherlands [24], which considers someone to be of non-Dutch ethnicity if at least one of the parents was born in a country other than the Netherlands. If the parents were born in two different countries,

then the mother's country of birth is considered the 'country of origin'. Finally, women reported their number of children, which was then dichotomized into 'primiparous' and 'parous'.
Planned place of birth (home or hospital) was taken from the perinatal registration form of the Netherlands Perinatal Registry which was filled in by the midwife during pregnancy.
In the prenatal questionnaire, women were asked whether they had a preference in terms of pain management during labour and, if so, what would be their preference in terms of medication; pethidine, remiphentanil, epidural or no medication (Additional file 1). In the questionnaire, women were informed that they would have to be referred to obstetrician-led care if they would choose to use medicinal pain relief. In the postnatal questionnaire, women were asked whether they used any method of medicinal pain relief during labour and, if so, what method of medication: pethidine, remiphentanil, epidural or no medication (Additional file 2).
For the analyses regarding women who used their preferred method of medicinal pain relief, age and education were dichotomised because of limited numbers in some categories (age: ≤35, >35 and education: low/medium, high).
Women who had a preference for medicinal pain relief were compared with women who did not have a preference for medicinal pain relief. The following three groups were created for the analysis regarding women who used their preferred method of pain relief: no medication; epidural and pethidine or remiphentanil. Women who used epidural in combination with pethidine or remiphentanil were placed in the epidural group. For the multivariable analyses, women who used any form of pain medication were combined as one group.

Statistical analyses
We used descriptive statistical methods to determine frequencies and percentages. Univariable logistic regression methods were used to calculate crude odds ratios and multivariable logistic regression methods for adjusted odds ratios with 95% confidence intervals. Because women in our study population were clustered into twenty different midwifery practices. We used multi-level analysis to control for the dependency of measurements within these practices. Except for multi-level analyses, all analyses were carried out in IBM SPSS, version 20. Multi-level analyses were carried out in Stata IC 20.

Results

The overall net response rate of the DELIVER study was 62% [20]. Of all 7685 women that participated in the DELIVER study, 3334 women completed the second questionnaire and 3952 completed the third questionnaire. The DELIVER client data were successfully linked in 86.3% of the cases with data from the Netherlands Perinatal Registry. Of all women who started their pregnancy in midwife-led care, 2398 individuals filled in both the second and third questionnaires. Of these, 1511 women started labour in midwife-led care (Figure 1). The characteristics of the women in the study are shown in Table 2. Highly educated women and those of Dutch ethnic background were over-represented in our study population compared to the overall Dutch perinatal registration of midwife-led care and obstetrician-led care in total (56.5% versus 48.2% and 88.5% versus 74.2% respectively).

Women's preferences regarding medicinal pain relief

Prenatally, 15.9% of women preferred to use some method of medicinal pain relief (Table 3). Women with a non-Dutch background were more likely to prefer using medicinal pain relief than women with a Dutch background (OR 1.96 CI 1.31 to 2.94), and women with a planned hospital birth were more likely to prefer using a medicinal method of pain relief than women with a planned home birth (OR 3.37 CI 2.46 to 4.63) (Table 4).

Figure 1 Flowdiagram of women in midwife-led care

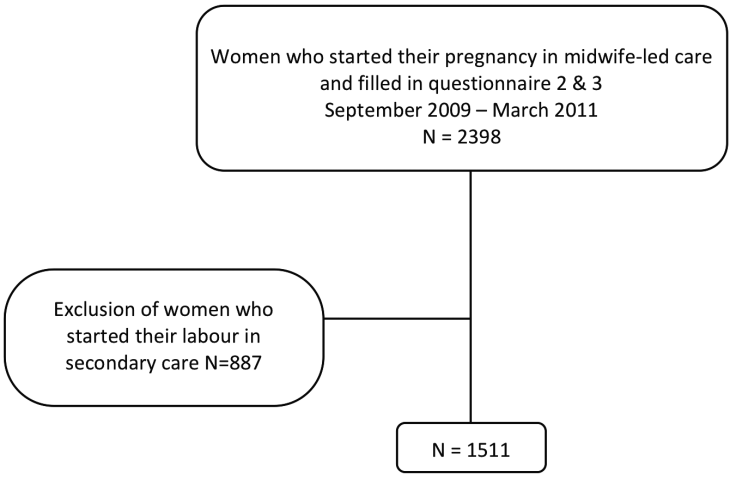

Table 2 Study sample

Characteristics of the study sample (N = 1511)			
	N	**%**	**PRN [a] data%**
Age group (years)			
<25	100	6.6	-
25-35	1191	78.8	-
>35	220	14.6	-
Education level			
Low	157	10.4	15.5
Medium	501	33.2	36.4
High	853	56.5	48.2
Ethnic background [b]	n = 1509		
Dutch	1336	88.5	74.2
Non - Dutch	173	11.5	20.8
Planned place of birth [c]	n = 1470		
Home	910	61.9	-
Hospital	565	38.1	-
Parity			
Nulliparous	686	45.4	45.8
Parous	825	54.6	54.2

[a] Data of the Dutch pregnant population (PRN. 2009).
[b] Missing ethnic background n = 2
[c] Missing planned place of birth n = 41.

Table 3 Women's preferences* and women's used pain relief

			Used method of medicinal pain relief		
			Epidural	**Pethidine.or remiphentanil**	**No medication**
		No (%)	**No (%)**	**No (%)**	**No (%)**
Preference	Medication	233 (15.9)	35 (15.0)	24 (10.3)	174 (74.7)
	No medication	1231 (84.1)	109 (8.9)	70 (5.7)	1052 (85.5)
	Total	1464	144 (9.8)	94 (6.4)	1226 (83.8)

* Missing 'women's preferences' n = 47.

Table 4 Association between age, education level, ethnicity, planned place of birth, parity and women's preference to use medicinal pain (N = 1511)

	Total N [b]	No (%)	Univariable OR (CI)	Multivariable [a]OR (CI)
Age groups (years)				
<25	100	9 (9.2)	0.55 (0.27-1.11)	0.60 (0.29-1.27)
25-35	1191	181 (15.6)	1.0	1.0
>35	220	43 (20.2)	1.37 (0.95-1.99)	1.11 (0.74-1.67)
Level of education				
Low	157	22 (14.3)	0.97 (0.58-1.62)	0.93 (0.54-1.60)
Medium	501	72 (14.7)	1.0	1.0
High	853	139 (16.7)	1.17 (0.86-1.59)	1.11 (0.79-1.56)
Ethnic background[c]				
Dutch	1336	186 (14.2)	1.0	1.0
Non-Dutch	173	47 (28.8)	2.45 (1.69-3.56)**	1.96 (1.31-2.94)**
Planned place of birth[d]				
Home	910	85 (9.5)	1.0	1.0
Hospital	560	142 (26.2)	3.37 (2.51-4.52)**	3.37 (2.46-4.63)**
Parity				
Primiparous	686	108 (16.0)	1.03 (0.78-1.36)	0.90 (0.66-1.22)
Parous	825	125 (15.6)	1.0	1.0

[a] Adjusted for age, education, ethnic background, planned place of birth and parity.
[b] Missing 'women's preference to use medicinal pain relief n = 47.
[c] Missing ethnic background n = 2.
[d] MISSING place of birth n = 41, ** $p < 0.05$, $R^2 = 10\%$.

Use of medicinal pain relief

Of the women who started labour in midwife-led care 16.2% of the women used some method of medicinal pain relief during labour, 9.8% used epidural analgesia; 6.4% used pethidine or remiphentanil (Table 3). Of the women preferring no medication for pain relief prenatally, 85.5% used no medication. Of the women preferring medicinal pain relief 25.3% used medicinal pain relief (Table 3). Women with a planned hospital birth who indicated a preference to use medicinal pain relief were more likely to use it than women with a planned home birth with the same preference (OR 2.14 CI 1.04 to 4.39). Primiparous women who indicated a preference to use medicinal pain relief were more likely to use it than parous women with the same preference (OR 4.60 CI 2.27 to 9.13) (Table 5).

Table 5 Association between age, education level, ethnicity, planned place of birth parity, and use of medicinal pain relief method that was preferred prenatally (N = 1511)

	Total N [b]	No (%)	Univariable OR (CI)	Multivariable[a] OR (CI)
Age groups (years)				
≤35	1291	14 (32.6)	1.56 (0.76-3.20)	1.96 (0.87-4.43)
>35	220	45 (23.7)	1.0	1.0
Level of education				
Low-Medium	658	17 (18.1)	1.0	1.0
High	853	42 (30.2)	1.96 (1.04-3.71)**	1.66 (0.83-3.34)
Ethnic background[c]				
Dutch	1336	47 (25.3)	1.0	1.0
Non-Dutch	173	12 (25.5)	1.01 (0.49-2.11)	0.74 (0.33-1.68)
Planned place of birth[d]				
Home	910	17 (20.0)	1.0	1.0
Hospital	560	42 (29.6%)	1.68 (0.88-3.19)	2.14 (1.04-4.39)**
Parity				
Primiparous	686	41 (38.0)	3.64 (1.93-6.85)**	4.60 (2.27-9.13)**
Parous	825	18 (14.4)	1.0	1.0

[a] adjusted for age, education level, ethnic background, planned place of birth and parity. [b]Missing 'use of medicinal pain relief which was preferred prenatally' n = 10, [c]missing 'ethnic background' n = 2, [dmissing] 'planed place of birth' n = 41, ** $p < 0.05$, $R^2 = 18\%$.

Discussion

One of the main findings was that 85.5% of the women in our study indicated prenatally a preference to use no medication for pain relief during labour. Secondly, our study showed that women with a non-Dutch ethnic background were more likely to indicate a preference for medicinal pain relief prenatally compared to women with a Dutch ethnic background. Thirdly, our study found that women with a planned hospital birth were more likely to indicate a preference for medicinal pain relief compared to women with a planned home birth. Finally, our study showed that women with a planned hospital birth who preferred to use medicinal pain relief were more likely to use medicinal pain relief compared to women with a planned home birth. Primiparous women were more likely to use their preferred method of medicinal pain relief compared to parous women.

Women's preferences regarding medicinal pain relief

Despite the growing numbers of medicinal pain relief in labour worldwide and the introduction of guidelines that should ensure access to epidural analgesia for all Dutch women, most women in midwife-led care in our study still preferred prenatally not to use medicinal pain relief. This finding has not previously been reported. It might be that most women in midwife-led care with low-risk profiles believe they will have a natural birth which they can manage without medicinal pain relief. Another reason might be that the guideline of medicinal pain relief in labour, which was introduced in 2008, is not implemented in every midwifery practice [25]. This would mean that not all women are informed about their options regarding medicinal pain relief.

We found that women with a non-Dutch ethnic background were more likely to indicate a preference for, and to use the preferred medicinal pain relief. These women might be more accustomed to use medicinal pain relief in labour compared to women with a Dutch ethnic background because of the maternity culture in their country of origin [5,26,27]. It is also possible that women from non-Dutch cultures might have a more negative attitude towards labour pain [27].

We found that women with a planned hospital birth were more likely to indicate a preference to use medicinal pain relief compared to women with a planned home birth. Women who choose a planned hospital birth might feel less secure and more anxious around their ability to give birth 'naturally' without medicinal pain relief. Therefore it is more likely that these women would choose a hospital setting for birth so as to avoid transport from home to hospital in case they would need medicinal pain relief.

Surprisingly, 9.5% of the women with a planned home birth indicated a preference to use medicinal pain relief, even though this is never administered at home. It might be that women take into account different scenarios that may occur during labour. They might plan to stay at home without medicinal pain relief as long as labour progresses well. However, at the same time women might choose for medicinal pain relief if labour is more difficult than anticipated. This finding is in line with the interview study of Klomp et al. [18]. In this qualitative study most women indicated prenatally that they did not want to make use of medicinal pain relief during labour but at the same time they had thought of their preferred method in case they would need some pain medication after all.

Use of medicinal pain relief

Other studies have suggested that the use of medicinal pain relief is not solely dependent on the preferences and backgrounds of the women in question; it also seems to depend on the culture of the maternity care system in the country, in the region or even at the individual delivery unit [26,27]. Christeans et al. [27] suggest that Dutch women have more positive attitudes towards labour pain compared to women in Belgium who have more negative attitudes. Our finding of relatively low actual use of some method of medicinal pain relief is consistent with these findings.

Surprisingly, only 25.3% of the women who indicated prenatally a preference to use medicinal pain relief during labour actually used a medicinal method. It might be that women's preferences regarding medicinal pain relief are unmet by their care-providers. Although a multidisciplinary Dutch guideline states that women who request pain medication should receive this, it is possible that not all professionals adhere to this recommendation. Since research has shown that women's involvement in decision making on the use of pain relief contributes to childbirth satisfaction [11], further studies are needed into the decision making process regarding pain relief in the Netherlands. On the other hand, it is also likely that women take into account different scenarios that may occur during labour as formulated before. Medicinal pain relief during labour does not seem to be a dichotomous choice for women but to comprise a continuum of choices. Furthermore, we found that 85.5% of women who indicated a preference to use no medication for pain relief prenatally, did not use it. These findings are in line with studies of Walsh & Devane [28] and Begley et al. [29] which found that women in midwife-led care during labour and birth use less medicinal pain relief compared to women in other models of care. All our women started their labour in midwife-led care.

Our study also showed that primiparous women who indicated a preference to use medicinal pain relief were more likely to use it than parous women. It might be that parous women are more likely to have a fast labour and therefore these women have little time and also feel less need to use their preferred medicinal pain relief.

Women with a planned hospital birth who indicated a preference to use medicinal pain relief were more likely to use it than women with a planned home birth. If women give birth in hospital medicinal pain relief is more readily available and it might be that these women are more likely to use their preferred method because of this availability [30,31].

Limitations

The women in this study filled in the post-partum questionnaire at different points in time from two weeks post-partum until three months post-partum. This study, therefore, does not take into account that some women may have changed their memories of the used method of pain relief in labour due to recall bias.

Due to the limited numbers of women in each different ethnic group we decided to dichotomize ethnic background into two groups: Dutch and non-Dutch. Further study is needed into the preferences and use of pain relief among different ethnic minority groups.

Strengths

A major strength of our study is that women were asked to indicate their preferred method of pain relief before they went into labour and their used method of pain relief after they gave birth. In some studies [23,32] women were asked after birth which method of pain relief they preferred when they were still pregnant but experience of labour may have influenced women's recall in these cases.

Our large study provides a good cross-sectional insight into the characteristics associated with women who indicate a preference for medicinal pain relief at some point between 35 weeks of pregnancy and start of labour and the characteristics of women who prefer to use and who used medicinal pain relief.

Conclusions

Even though the prevalence of women preferring medicinal pain relief was low (15.9%), surprisingly, only one quarter of this group actually received pain medication. Of the women who did not indicate any preference for medicinal pain relief prenatally (84.1%) a small proportion (14.6%) used medicinal pain relief. With regard to counselling for labour pain management, care providers should discuss the unpredictability of the labour process. Labour can be easier or more difficult than anticipated. This can help women to have realistic expectations towards labour pain management.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TK and AdJ designed the study of labour pain questionnaires as part of the DELIVER study. TK recruited the midwifery practices, Judith Manniën monitored data collection and TK supervised data collection. TK conducted data analyses and was also primarily responsible for data interpretation. TL, EH and AdJ assisted with data interpretation. All authors read and corrected draft version of the manuscript and approved the final manuscript.

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Chapter 6

Birth setting, transfer and maternal sense of control: results from the DELIVER study

Caroline C. Geerts, Trudy Klomp, Antoine L.M. Lagro-Janssen, Jos W.R. Twisk, Jeroen van Dillen, Ank de Jonge

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Abstract

Background In the Netherlands, low-risk women receive midwife-led care and can choose to give birth at home or in hospital. There is concern that transfer of care during labour from midwife-led care to an obstetrician-led unit leads to negative birth experiences, in particular among those with planned home birth. In this study we compared sense of control, which is a major attribute of the child birth experience, for women planning home compared to women planning hospital birth under midwife-led care. In particular, we studied sense of control among women who were transferred to obstetric-led care during labour according to planned place of birth: home versus hospital.
Methods We used data from the prospective multicentre DELIVER (Data EersteLIjns VERloskunde) cohort-study, conducted in 2009 and 2010 in the Netherlands. Sense of control during labour was assessed 6 weeks after birth, using the short version of the Labour Agentry Scale (LAS-11). A higher LAS-11 score indicates a higher feeling of control. We considered a difference of a minimum of 5.5 points as clinically relevant.
Results Nulliparous- and parous women who planned a home birth had a 2.5 (95% CI 0.7, 4.2) and a 2.9 (1.5, 4.3) higher LAS score during first stage of labour respectively and during second stage a higher score of 2.7 (0.8, 4.7) and 2.3 2.2 (0.5, 3.9), compared with women who planned a hospital birth. Overall, women who were transferred experienced a lower sense of control than women who were not transferred. Nullliparous women who planned a home birth and actually gave birth at home experienced a higher sense of control during second stage of labour compared to women who planned a hospital birth and who gave birth in hospital (3.3 95%CI 0.2, 6.5).
Conclusion We found no clinically relevant differences in feelings of control among women who planned a home or hospital birth. Transfer of care during labour lowered feelings of control, but feelings of control were similar for transferred women who planned a home or hospital birth.
As far as their expected sense of control is concerned, low-risk women should be encouraged to give birth at the location of their preference.

Introduction
The Dutch maternity care system is characterised by the concept that pregnancy and childbirth are basically physiologic processes. Maternity care is divided into midwife-led care, for low risk women and obstetrician-led care for women with

an increased risk for complications. Low-risk women give birth under supervision of a community midwife and have the choice between home or hospital birth. When complications occur during labour, a woman will have care transferred to an obstetrician-led unit.

Recently it was shown that a substantial proportion of Dutch women look back negatively on their birth experience three years after childbirth [1]. This finding is worrisome and needs further exploration, particularly since childbirth is an important life event that may influence women's well-being in the short- and long-term [2,3].

The experience of childbirth has several attributes, of which sense of control is a major one [4]. Sense of control is an important predictor of satisfaction with the birth experience [5]. Evaluation of control during labour can be used as a proxy for birth experiences.

Looking back more negatively on the birth experience has been associated with transfer during labour [1]. In the Netherlands the rate of transfer to obstetrician led care has risen over the last decades. Transfer rates during labour have risen for nulliparous women from 50% in 2008 to 60.3% in 2010 and from 17% to 26.2% for parous women [6, 7]. Since transfer of care during labour has become more common, this may affect the birth experience of women.

Recent studies confirm the association between transfer and a negative birth experience, but they did not compare the effect of transfer between a planned home and hospital birth [8, 9]. In an older Dutch study, rating of the birth experience after transfer during labour was similar in women planning a home birth compared to women planning a hospital birth [10]. However, currently, it is unknown how the birth experience of women planning a home birth and who are transferred, compares to those planning a hospital birth and who are transferred. Although it has been stated that "the high rate of transfer undercut the raison d'etre of planned home birth" with regard to satisfaction with the birth experience [11], there is no evidence to support this.

To measure sense of control a reliable and valid instrument has been developed: the Labour Agentry Scale (LAS) [12]. Canadian studies using the LAS to compare birth experiences between different birth settings, concluded that planned home birth was related to a higher sense of control during labour compared to planned hospital birth [13, 14]. However, in the Netherlands, this has, to our knowledge, never been studied. And, although the Canadian maternity care system shows similarities with the Dutch system, home birth in the Netherlands is much more common (17.1 per cent) [7], compared to Canada (Ontario, 1.6 per cent) [15]. It is

important for women to know whether the planned place of birth is associated with sense of control when choosing their birth setting.
Giving birth at home was reported to lead to preserved authority and autonomy whereby the women themselves rule the situation [16]. Women choose home birth to enhance their sense of control over their surroundings. However, the current thought is that positive experiences associated with planned home birth might be overshadowed by negative experiences of women who are moving to hospital if transfer of care to an obstetric-led unit is required [11]. In the Netherlands rates of transfer are relatively high and this might affect the birth experience in the total group of women who plan home birth. Therefore, the hypothesis of this study was that among the total group of women who plan a home birth, whether or not they experienced a transfer, overall feelings of control during labour are lower than women who plan a hospital birth. Women who plan a home birth and who are transferred might be more disappointed if care is transferred to an obstetric-led unit because it means they have to move to hospital and thus not give birth in their chosen setting.
We formulated two research questions (RQ):

1. What is the association of planned place of birth, home or hospital in midwife-led care, with feelings of control during labour experienced by low risk women.
2. What is the association of planned place of birth with feelings of control among women who were in midwife-led care at the onset of labour and who had care transferred to an obstetrician-led unit during labour.

Methods

In the Netherlands, low-risk women receive midwife-led care from community midwives, unless complications arise. For routine antenatal care, a woman visits the midwife in the midwifery practice.

Study design and study population

The DELIVER study is a multicenter prospective cohort study into the quality, organisation and accessibility of midwifery care in the Netherlands, which was described extensively elsewhere [17].
Briefly, the means of recruitment of clients was through midwifery practices. Purposive sampling was used to select practices, using three stratification criteria: region (north, centre, south), level of urbanisation (urban or rural area), and practice type (dual or group practice). Twenty of the 519 midwifery practices

across the Netherlands participated in this study. Between September 2009 and December 2010 client data were collected using questionnaires. Clients who received antenatal care and who gave informed consent were given a brochure by their midwife, with a link to a website where women could fill in up to three questionnaires: one before 34 weeks gestation (the 1st questionnaire), one between 35 weeks gestation and birth (the 2nd questionnaire), one approximately 6 weeks postpartum (the 3rd questionnaire). To improve the overall response, a reminder was sent to all non-responders. In addition, clients who did not complete the questionnaire within one week were called by the research team, and they were invited once more to participate. The response rate of the DELIVER study was 62%.

The DELIVER client data were linked to midwife-led care data from the Netherlands Perinatal Register (PRN, "Landelijke Verloskundige Registratie", LVR1). Linkage was successful in 86% of the women included in this study. Women with and without linked data were similar with regard to maternal age and ethnic background. Women with LVR1 data linked had a higher socioeconomic status than women without LVR1 data available.

Agreement between LVR1 and DELIVER data for women who started labour in midwife-led care was 99.1% for vacuum or forceps extraction, 99.9% for caesarean section and 99.4 (hospital) to 94.7% (home) for actual place of birth. In case of disagreement, we used data from the DELIVER study.

For this study, participants with singleton term pregnancies that were in midwifery care at the onset of labour were selected. Onset of labour was based on information from LVR1. Women who were transferred for prolonged rupture of membranes (> 24 hrs without contractions) were excluded. Among these women, transfer to secondary care occurred before start of the dilation (first) stage, and thus planned place of birth is unlikely to have affected sense of control. Women who were transferred to secondary care during pregnancy and women who were advised to give birth in hospital in midwife led care because of a condition that would increase the risk of complications for the woman or baby were also excluded. These conditions are listed in the obstetric indication list ("Verloskundige Indicatielijst; VIL").

Planned place of birth and transfer of care during labour

Planned place of birth (home or hospital under midwife-led care) is recorded on the LVR-1 form at some point during pregnancy.

When complications arise such as listed in the VIL, care is transferred from midwife-led to obstetrician-led care. When a woman is at home, this requires transport to a hospital facility prior to transfer of care, either by car, or in case of an emergency, by ambulance. Transfer of care for women who planned a hospital birth may require transportation from home to hospital in early labour or from a hospital room to another room or another floor within the hospital. However, often no physical transport is necessary, and only the caregiver changes. In this study, both transfer of care during labour or immediately postpartum, were defined as transfer.

Sense of control

To measure personal control during childbirth the women filled in a shortened version of the Labour Agentry Scale (LAS), in the postpartum period (on average 6 weeks) on the 3rd questionnaire, twice, concerning feelings of control during the first, the dilatation stage, and the second, the expulsion stage.

The LAS, a self-report scale designed to measure sense of control during childbirth has demonstrated robust psychometric properties with an internal reliability coefficient of 0.97 and evidence of construct validity demonstrated through factor analysis and dual scaling procedures [12]. The LAS has been used in several studies on sense of control in maternity care [13,14,18-20]. The original LAS consists of 29 short affirmative statements (e.g. 'I felt confident' and 'I felt relaxed'). The shorter version of the LAS contains 10 items [21]. We used the LAS-10 to gain insight in feelings of control during both the first and second stage of labour. Translation to Dutch resulted in 11-items, because the English item 'I felt helpless (powerless)' was translated into two separate items due to the difference in meaning between 'helpless' and 'powerless' in the Dutch language. The translated LAS-11 was back-translated into English to check on accuracy of translation. Respondents were asked to rate each statement on a 7-point Likert-scale from (7) 'never, or almost never' to (1) 'almost always'. However, 'almost always' was coded as 1 point, and 'never', or 'almost never' as 7 points. Coding was reversed on positively worded items, so that a high score reflected in a higher sense of control on all items. The separate items were summated to a total score; possible total scores for LAS ranged from 11 (indicating feeling rarely in control) to 77 (reflecting feeling almost always in control). We considered a difference of a minimum of 5.5 points on the 11 item LAS score measured on a 7 points scale as clinically relevant. This is based on studies concerning self-report (quality of life) instruments, which reported that the minimal clinically important difference is half a point on a 7 point scale (0.5 * 11 items is 5.5 points) [22,23].

Confounding factors

Maternal age, ethnic background, and social status were taken into account, because of their relation with planned place of birth [24-26] and feeling in control during labour or satisfaction with childbirth [27-30].

For social status we used a score based on postal code, developed by the Netherlands Institute for Social Research (SCP), based on education, income and employment rates, and we linked it to the client data file. A low score equals low social status [31]. Ethnic background was based on the definition of Statistics Netherlands: Dutch (both parents born in the Netherlands), Western background (at least one parent born in another country in Europe except for Turkey, or born in Oceania, Indonesia, North-America or Japan) or non-Western background (at least one parent born in Africa, Latin-America, Asia or Turkey) [32]. This categorisation identifies three separate groups (Dutch, Western and non-Western) based on socioeconomic and cultural aspects.

The birthing process is usually quite different for nulliparous compared to parous women. For parous women the duration of labour is often shorter, they feel more in control during labour [33] and they are far less likely to be transferred to secondary care. We therefore stratified our results for parity.

Potential explanatory factors

The effect of transfer (yes/ no) on the association between planned place of birth and sense of control was evaluated.

Furthermore, we evaluated the effect of receiving medicinal pain relief (yes/ no), because it might be a factor in the causal pathway of the association between planning a hospital birth [34], and sense of control [35]. In addition, anxiety during pregnancy, measured with the Pregnancy Related Anxiety Questionnaire-Revised version (PRAQ-R) score, was assessed as potential explanatory factor, in the relation between planned place of birth and sense of control. Our hypothesis was, that women who are more anxious during pregnancy, both might be more likely to opt for a hospital birth and might be less likely to feel in control during labour. The PRAQ-R score measures anxiety and specific fears related to pregnancy and consists of three subscales [36]. Pregnant women filled in the PRAQ-R in the first questionnaire. The three scales were ‘fear of giving birth’ (3 items for nulliparous women and 2 items for parous women), ‘fear of giving birth to a handicapped child’ (four items) and ‘concern about one’s appearance’ (three items). Items were scored on a four-point scale (4 = very true, 3 = true, 2 = not true, 1 = certainly not true). Higher scores indicated a higher level of anxiety.

The role of medical interventions, including augmentation, vaginal instrumental childbirth and caesarean section were investigated [26,30,37]. Finally, the impact of the baby's health postpartum on the relation between planned place of birth and feeling in control was evaluated, because that might negatively influence the recall of the birth experience, including sense of control.

Data-analysis

Baseline and pregnancy related characteristics of low risk women who planned to give birth at home were compared with women who planned to give birth in hospital using mean and standard deviation for continuous variables and numbers with percentages for categorical variables.

For the primary aim of this study (RQ1), the relation between planned place of birth (home/ hospital) as independent variable and LAS score of first stage and second stage of labour separately as dependent variables were analysed using multilevel analysis with 2 levels; the midwifery practice level and individual level, to account for clustering of women within midwifery practices. Besides crude analysis, adjustments were made for ethnicity (categorical), maternal age (categorical) and social status (in quartiles). Next, in an additional analysis, possible explanatory factors (i.e. receiving medicinal pain relief, anxiety during pregnancy, transfer, augmentation, mode of birth and complications with baby) were added to the model in addition to the confounders, one at a time. Dummy variables were created for all variables with more than two categories. To deal with missing data for anxiety during pregnancy (in the other variables there were only few missings), multiple imputation was performed according to the Predicted Mean Matching method. With this method, each missing value is imputed randomly from a set of nearest observed values in the dataset. Number of imputations was based on the percentage of missing values [38]. Data for PRAQ-R were missing in 31.4% of nulliparous and 23.3% of parous women. All items for anxiety were imputed when missing.

From information on place of birth and transfer of care (extracted from LVR1 forms) we identified women who planned home birth and who were transferred to obstetric-led care during labour or immediately postpartum, (home - transfer); and the women who planned hospital birth in midwife-led care and who were transferred to obstetric-led care during labour or immediately postpartum, (hosp - transfer). With regard to RQ2, we compared the mean LAS score of first and second stage of labour for women who planned a home birth and who were transferred (home-transfer), to women who planned a hospital birth and who

were transferred (hosp-transfer). This analyses were adjusted for ethnicity, social status and maternal age.
Furthermore, women who opted for giving birth at home and did (home-home) and women who opted for a hospital birth in midwife-led care and did (hosp-hosp) were identified, as well as women who planned a hospital birth in midwife-led care and who gave birth at home (hosp-home), to gain insight in sense of control among these groups of women in relation to their birth setting using a similar multivariable multilevel model. The group who planned a home birth but actually gave birth in hospital in midwife led care was too small for meaningful analysis (22 nulliparous women and 30 parous women).
For the main analyses we used data from women who started labour in primary care. For some women start of labour in primary care seems likely, but information of the LVR1 data shows discrepancies for the onset of labour. We conducted sensitivity analyses for women with and without discrepancies in the definition for start of labour in primary care.
Since the option for home birth is being questioned with regard to women's experiences [11], we used hospital birth as the reference group. All analyses were performed using SPSS version 20.0. Statistical significance was considered with a p-value < 0.05.

Results

In the DELIVER study, LVR1 data were available of 5749 participants. Of these, 2188 were excluded for medium risk pregnancy, prolonged rupture of membranes without effective contractions, preterm or overdue birth date or start of labour in obstetrician-led care. Of the 3561 remaining women, 3479 started labour in midwife-led care, for 82 women this could not be defined with confidence. The postpartum questionnaire (PPQ) was not filled in by 1301 women and in 66 questionnaires the Labour Agentry Scale was not filled in completely. Of the remaining 2112 eligible women, 1279 women planned a home birth (60.6%) and 781 (36.9%) women planned a hospital birth. Planned place of birth was unknown in 52 women (2.5%) (Appendix 4, Chapter 6).
The Cronbach's alpha of the Labour Agentry Scale during first stage and the second stage was 0.85. The mean LAS during first stage and second stage respectively, was 59.6 (SD 12.7)/ 58.0 (SD 13.9) for nulliparous women and 62.3 (SD 11.4)/ 59.3 (SD 13.7) for parous women. The ratio nulliparous and parous women was 44:56%. Transfer to secondary care during labour or directly postpartum occurred in 60.6% for nulliparous women and 18,0% for parous women. Main reasons included

meconium stained fluid (22%), medicinal pain relief (17%) and failure to progress during first (16%) and second stage of labour (16%).
Table 1 shows that women who choose to give birth in hospital were more likely to be nulliparous, of ethnic minority background and below 25 years or above 35 years, compared to women who choose home birth. Women planning a hospital birth more often had augmentation or were transferred to obstetric-led care and they had a higher rate of instrumental vaginal childbirth and medicinal pain relief. Women in the home birth group were less anxious during pregnancy about giving birth.

All women

Table 2 shows that planning a home birth is associated with a higher mean score of sense of control, for nulliparous and parous women, during both the first and second stage of labour, taking account of clustering of women within each midwifery practice. Adjusting the multilevel model for ethnicity, social status and maternal age did not influence the association.
The explanatory analysis showed that for nulliparous women, the association between planned place of birth and sense of control during the first stage of labour was partly explained by medicinal pain relief: after adjustment the difference was 1.5 (95% CI -0.2, 3.2). Additional adjustment for, separately, transfer during labour, anxiety during pregnancy, medical interventions (e.g. vaginal instrumental childbirth, caesarean section and augmentation) or neonatal complications within one hour postpartum did not have an effect on the association. In multiparous women, separate adjustment for the abovementioned factors did not change the associations (not shown).

Women who were transferred

Table 3 (transfer) shows that parous women who planned a home birth and who were transferred to secondary care had higher feelings of control during the second stage of labour compared to parous women who planned a hospital birth and who were transferred. However, this difference in sense of control is no longer signifcant after adjustement of counfounders. Among nulliparous women who were transferred, feelings of control during second stage of labour were similar for both women who planned a home birth or a hospital birth after adjustment for maternal age, ethnic background and socioeconomic status. During first stage of labour feelings of control among women who were transferred were similar, regardless whether they planned a home or hospital birth.

Table 1. Baseline and pregnancy related characteristics and labour outcomes for planned place of birth of women in the midwife-led care setting at the onset of labour.

	Planned home birth n = 1279	Planned hospital birth n = 781	Test statistic X^2 (df)	p-value
Baseline characteristics				
Parity, n (%)			11.4 (1)	
nulliparous	528 (41.3)	382 (48.9)		0.001
parous	751 (58.7)	399 (51.1)		
Gestational age, n (%)			1.83 (2)	
37 weeks	35 (2.7)	28 (3.6)		0.40
38 - 40 weeks	996 (77.9)	614 (78.6)		
41 - 42 weeks	248 (19.4)	139 (17.8)		
Maternal age, n (%)			8.8 (2)	
< 25 years	99 (7.7)	72 (9.2)		0.01
25-35 years	966 (75.6)	544 (69.7)		
> 35 years	213 (16.7)	165 (21.1)		
Ethnic background, n (%)			54.5 (2)	
Dutch	1160 (90.9)	623 (80.1)		<0.001
Western background	71 (5.6)	74 (9.5)		
Non-western background	45 (3.5)	81 (10.4)		
Social status, n (%)				
1st quartile	342 (26.8)	222 (28.6)	1.1 (3)	0.78
2nd quartile	322 (25.3)	190 (24.5)		
3rd quartile	290 (22.8)	179 (23.1)		
4th quartile	320 (25.1)	184 (23.7)		
Pregnancy related characteristics				
Pregnancy related anxiety^, median (min – max)				
Fear of bearing a handicapped child	8.0 (4 - 16)	8.0 (4 - 16)	-1.6*	0.11
Concern about one's appearance	6.0 (3 - 12)	6.0 (3 - 12)	-1.3*	0.18
Fear of giving birth				
nulliparous women	6.0 (3 - 12)	7.0 (3 - 12)	-3.1*	0.002
parous women	3.0 (2 - 8)	4.0 (2 - 8)	-4.0*	<0.001
Labour outcomes				
Medicinal pain relief†, n (% yes)	129 (10.1)	171 (22.0)	54.8 (1)	<0.001
Transfer during labour, n (% transferred)	395 (30.9)	362 (46.5)	50.6 (1)	<0.001
Medical interventions, n (%)				
Vacuum-/ forceps extraction	111 (8.7)	88 (11.3)	8.1 (2)	0.02
Secondary caesarean section	38 (3.0)	36 (4.6)		
Augmentation, n (% yes)	188 (14.7)	160 (20.5)	11.8 (1)	0.001
Complications baby postpartum, n (%)	21 (1.6)	14 (1.8)	0.067 (1)	0.80

^ This item was missing in 31.4% of nulliparous and 23.3% of parous women. † Medicinal pain relief includes epidural (172), remiphentanyl (90) and opioids (85). * z statistic of U (Mann Whitney U test)

Table 2. Relation between planned place of birth and sense of control (LAS) among women in midwife-led care at start of labour (RQ1).

		Nulliparous women			Parous women	
LAS* 1st stage						
	N	**Estimated Mean LAS**	**Difference (95% CI)**	**N**	**Estimated Mean LAS**	**Difference (95% CI)**
Crude						
Home	520	60.7	2.8 (1.0, 4.5)**	736	63.5	3.5 (2.1, 4.9)**
Hospital	370	57.9	-	390	60.0	-
Adjusted						
Home	515	60.6	2.5 (0.7, 4.2)**	732	63.3	2.9 (1.5, 4.3)**
Hospital	365	58.1	-	386	60.4	-
LAS* 2nd stage						
	N					
Crude						
Home	500	59.3	3.1 (1.2, 5.1)**	726	60.3	2.8 (1.1, 4.5)**
Hospital	351	56.2	-	386	57.5	-
Adjusted						
Home	495	59.1	2.7 (0.8, 4.7)**	722	60.1	2.2 (0.5, 3.9)**
Hospital	346	56.4	-	382	57.9	-

* Labour Agentry Scale (LAS): measured with 11 items on a 7-point Likert scale (min. score 11, max. score = 77)
** $p < 0.01$
Crude: multilevel analysis with 2 levels (midwifery practice and pregnant women)
Adjusted: for maternal age, social status, ethnicity (Dutch, western background, non-western background).

Overall, feelings of control for women who were transferred were lower than feelings of control in women who were not transferred (difference in LAS-11 score in 1st stage of labour was 5.3; 95% CI 4.3 - 6.4 and 2nd stage of labour 4.3; 3.1 - 5.6).

Women who were not transferred

Table 4 (no transfer) shows that women who planned a home birth and who actually had a home birth had statistically significantly higher feelings of control compared to women who planned a hospital birth and who actually gave birth in the hospital in midwife-led care. Parous women who planned a hospital birth under midwife-led care and who actually gave birth at home under midwife-led care had a statistically significant higher LAS score during second stage of labour,

Table 3. Planned place of birth in relation to sense of control (LAS) among women in midwife-led care at start of labour and who were transferred to obstetric-led care during labour (RQ2).

Transfer						
			Nulliparous women			**Parous women**
LAS* 1st stage						
	N	**Estimated Mean LAS**	**Difference (95% CI)**	**N**	**Estimated Mean LAS**	**Difference (95% CI)**
Crude						
Home-transfer	294	58.6	2.2 (-0.1, 4.5)	95	59.7	3.1 (-0.4, 6.5)
Hosp-transfer	244	56.4	-	108	56.6	-
Adjusted						
Home-transfer	292	58.3	1.4 (-0.9, 3.6)	95	58.9	1.5 (-2.2, 5.1)
Hosp-transfer	241	56.9	-	106	57.3	-
LAS* 2nd stage						
	N					
Crude						
Home-transfer	275	57.1	2.6 (0.1, 5.2)**	91	59.0	5.1 (1.2, 9.0)**
Hosp-transfer	226	54.5	-	104	53.9	-
Adjusted						
Home-transfer	273	56.8	2.1 (-0.5, 4.87)	91	58.2	3.7(-0.4, 7.8)
Hosp-transfer	223	54.7	-	102	54.4	-

* Labour Agentry Scale (LAS): measured with 11 items on a 7-point Likert scale (min. score 11, max. score = 77)
** $p < 0.05$
Crude: multilevel analysis with 2 levels (midwifery practice and pregnant women)
Adjusted: for maternal age, social status, ethnicity (Dutch, western background, non-western background).
Home-transfer: women who planned a home birth and who had care transferred during labour.
Hosp-transfer: women who planned a hospital birth and who had care transferred during labour

than women who planned a hospital birth and who actually gave birth in hospital under midwife-led care.

Sensitivity analyses

Sensitivity analysis for sense of control and planned place of birth of the 2112 eligible women plus 82 women of which start of labour was unsure, yielded similar results (data not shown).

Table 4. Planned place of birth in relation to sense of control (LAS) among women in midwife-led care at start of labour and who were not transferred during labour.

No transfer						
		Nulliparous women			**Parous women**	
LAS* 1st stage						
	N	**Estimated Mean LAS**	**Difference (95% CI)**	**N**	**Estimated Mean LAS**	**Difference (95% CI)**
Crude						
Home-home	204	63.8	3.4 (0.6, 6.2)**	610	64.2	3.6 (1.8, 5.4)**
Hosp-hosp	89	60.4	-	184	60.6	-
Hosp-home	34	63.2	2.9 (-1.6, 7.3)	98	62.8	2.2 (-0.4, 4.8)
Adjusted						
Home-home	202	63.6	3.0 (0.2, 5.8)**	606	64.1	3.2 (1.4, 5.0)**
Hosp-hosp	88	60.6	-	182	60.6	-
Hosp-home	33	62.7	2.1 (-2.4, 6.5)	98	63	2.1 (-0.5, 4.7)
LAS* 2nd stage						
Crude						
Home-home	203	62.2	3.9 (0.8, 7.0)**	605	60.6	3.3 (1.1, 5.5)**
Hosp-hosp	87	58.3	-	184	57.3	-
Hosp-home	35	61.8	3.5 (-1.4, 8.3)	98	61.5	4.1 (0.8, 7.4)**
Adjusted						
Home-home	201	62	3.3 (0.2, 6.5)**	601	60.4	2.8 (0.5, 5.0)
Hosp-hosp	86	58.7	-	182	57.7	-
Hosp-home	34	61.2	2.5 (-2.4, 7.5)	98	61.7	4.0 (0.8, 7.3)**

* Labour Agentry Scale (LAS): measured with 11 items on a 7-point Likert scale (min. score 11, max. score = 77)
** $p < 0.05$
Crude: multilevel analysis with 2 levels (midwifery practice and pregnant women)
Adjusted: for maternal age, social status, ethnicity (Dutch, western background, non-western background).
Home-home: women who planned birth at home and actually gave birth at home
Hosp-hosp: women who planned a hospital birth and actually gave birth in the hospital under midwife-led care
Hosp-home: women who planned hospital birth in midwife-led care and actually gave birth at home.

Discussion

In this study we showed that women in midwife-led care at the start of labour who planned a home birth with their midwife experienced a higher mean sense of control during labour, than women who planned a hospital birth. Among women who were transferred during labour, sense of control was similar for both women who planned a hospital birth or a home birth.

Our study had some strengths and limitations which need to be addressed. We used data from a prospective cohort study. A randomised controlled trial was shown not to be feasible, because women do not accept randomisation for place of birth [39]. Therefore, in this study we have controlled the analyses for confounders to deal with unequally distributed characteristics. Furthermore, in the analysis, we accounted for clustering of women within midwifery practices. For few women planned place of birth was unknown. Some do not choose their place of birth until they are in labour. In some cases the midwife might have forgotten to fill it in. LAS score was not available in all eligible women. It seems, however, unlikely that among non-responders the association between planned place of birth and sense of control would be in the opposite direction. The LAS was filled in an average of 6 weeks postpartum and this raises the possibility of recall bias. However, adjustment for neonatal complications postpartum did not change the results. Furthermore, it has been reported that the LAS remains stable until 3 months postpartum [12]. In the DELIVER study, more participants were highly educated compared to the national female population and between 15 and 45 years of age in 2010 and fewer participants were of non-Dutch origin [17]. With regard to the proportion of nulliparous and parous women and transfer rates, the results in our study were comparable to national rates from 2010 apart from the transfer rate of 18.0% for parous women which was lower than the national rate of 2010 (26.2%) [7]. Women planning a home birth were slightly overrepresented, 60.6% compared to the national percentage of 54% [6], which may be explained by the higher educational level of the participants [25]. A reliability analysis of the 11-item LAS score in our study revealed a high internal consistency.

A good sense of control during labour, is a major contributing factor to a positive childbirth experience [4,5,40]. We found a significant association between a planned home birth and a higher mean score of sense of control during labour. This association was not explained by differences in social status, ethnicity or maternal age. Results of previous studies are consistent with our findings [13,14]. Hodnett found that women who planned birth at home scored 23.8 points higher on the 29-item LAS. However, their hospital births were obstetrician-led at the start, instead of supervised by a midwife, which was the case in our study. Janssen found a higher LAS score of 11.9 on the 29 item LAS scale, for women with a planned home birth. They did not compare sense of control for women who planned a home or hospital birth and who were transferred during labour. Although we found a statistically significant difference in LAS score between a planned home and hospital birth in our study, the difference was very small and

it might not be clinically relevant. In our study a difference of 5.5 points was considered as a clinical important difference [22,23]. Likewise, the difference that was found by Janssen can be considered not clinically relevant, since the difference did not exceed 14.5 points on the 29 item LAS. Among the women who were transferred in our study, no clinically relevant differences were found either. The sense of control scores of women in second stage of labour in our study was higher (mean 58.6) than the LAS-11 reported in a Dutch study into the influence of birthing positions on sense of control during labour (mean 56.2) [41]. Nevertheless, the difference is small and not clinically relevant (< 5.5 points).
In our longitudinal study, information was available from women concerning their pregnancy as well as information concerning labour, which provided insight in background characteristics and labour factors that might give insight in the association between planned place of birth and sense of control. Among nulliparous women, receiving medicinal pain relief explained the difference in sense of control during first stage of labour between women planning home and hospital birth. This could suggest that medicinal pain relief is in the causal pathway: women who plan a hospital birth more often receive medicinal pain relief (our results) and medicinal pain relief has been associated with a lower sense of control [42]. Women who planned a hospital birth but who gave birth at home, had a LAS-11 score similar to women who planned a home birth and who actually had a home birth. This is interesting and could perhaps mean that expectations were surpassed, resulting in a higher sense of control.
A previous study reported that women who were transferred during labour looked back more negatively on their birth compared to women who were not transferred [1]. In particular, it can be hypothesized that unplanned transfer from home to hospital may lead to a reduced feeling of being in control. Since many women with a planned home birth are transferred during labour, these negative experiences might overshadow the positive experiences of women giving birth at home, resulting in an overall reduced sense of control for women planning a home birth. This was also suggested recently, in a clinical opinion report [11]. However, there was no evidence until so far to support this. Our results are not in agreement with this assumption, and show that the mean score of sense of control among women with a planned home birth was not lower than sense of control in planned hospital births. Moreover, we showed that transfer had a similar impact on feelings of control among women who planned a home or hospital birth. Our hypothesis, that transfer would affect birth experiences of women who plan home birth in particular, could not be confirmed.

In our study, feelings of control were lower among women who were transferred during labour, compared to women who were not. We found that birth setting had no influence on this decline. This is in line with previous findings, showing that women who were transferred from midwife-led care at home to obstetrician-led care in hospital during labour, were as positive about the childbirth experience as women who were transferred within the hospital, although this study did not use the LAS [10]. Possibly no clinically relevant difference was found because all women who give birth in hospital need to travel to hospital during labour at some point. However, it is also possible that discontinuation of care as a consequence of transfer might have contributed to the decrease in feelings of control during labour for both groups [19,20]. Unfortunately this could not be explored further, since no data were available on continuous support during labour. Overall, when complications arise and transfer is necessary, levels of fear during labour may increase, which is related to a decreased sense of control [18]. Women hope for or expect a natural birth and do not expect to be transferred. For many women this is disappointing [42]. In addition, women who are transferred have a higher risk of medical interventions, such as augmentation and vaginal instrumental childbirth, which on their own have been reported to reduce feelings of control [30], although the association may be weak [33]. In our study medical interventions did not explain the difference in feeling in control between a planned home and hospital birth.

Our findings can be used when informing women who are in midwife-led care, about the advantages and disadvantages of different places of birth, so that they can make an informed choice. Many women choose a home birth because of a desire of greater personal autonomy [43]. However, there is a considerable chance that they will be transferred during labour, in particular for nulliparous women. It is important for women to know that there is no clinically significant association between planned place of birth and sense of control, and that, when transfer is necessary, feelings of control might decline, but the choice for birth setting has no influence on this decline. Therefore, as far as their expected sense of control is concerned, they should be encouraged to give birth at the location of their preference.

This study focuses on low-risk women. To get a broader view of birth experiences of women, it would be useful for future research to compare sense of control among women who receive obstetrician led care with women in midwife-led care. In addition, with regard to the decrease in sense of control in case of transfer, a qualitative study may provide more in depth insight in the experiences of these women.

Conclusion
The difference in sense of control during labour was not clinically relevant for low-risk women in midwife-led care who planned a home birth compared to women who planned a hospital birth. In women who had care transferred feelings of control were lower. But feelings of control were similar for women who planned a home versus a hospital birth and who were transferred during labour. Low-risk women should be informed that planned home or hospital births are associated with similar levels of feeling in control during labour.

Competing interests
We declare that we have no conflict of interest.

Authors' contributions
All authors contributed substantially to the design of the study, C.C. Geerts prepared the manuscript and analyzed the data. T. Klomp is project leader of the DELIVER study. A. de Jonge is the initiator of this study. All authors critically revised earlier concepts of the paper and gave final approval of the version to be published.

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Details of ethical approval
The design and conduct of the DELIVER study was approved by the Medical Ethics Committee of the VU University Medical Centre Amsterdam (2009/284). All participants were informed about the study and they were asked to participate by their consulting midwife. Inclusion of participants occurred on an opting-out basis.

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Chapter 7

Management of labour pain; perceptions of labour pain by Dutch primary care midwives, a focus group study

Trudy Klomp, Ank de Jonge, Eileen K. Hutton, Suzanne Hers,
Antoine L.M. Lagro-Janssen

Submitted

Abstract

Background: Labour pain is a major concern for women, their partners and maternity health care professionals. However, little is known about Dutch midwives' perceptions of working with women experiencing labour pain. The aim of this study was to explore midwives' perceptions of supporting women in dealing with pain during labour.
Methods: We conducted a qualitative focus group study with four focus groups, including a total of 23 midwives from 23 midwifery practices across the country. Purposive sampling was used to select the practices. The constant comparison method of Glaser and Straus (1967, ren. 1995) was used to gain an understanding of midwives' perceptions regarding labour pain management.
Results: We found two main themes. The first theme concerned the midwives' professional role conflict, which was reflected in their approach of labour pain management along a spectrum from "working with pain" to a "pain relief" approach. The second theme revolved around how midwives saw their professional role being influenced by the situational context, including factors such as time constraints; discontinuity of care; the important role of the partner; and various cultural influences.

Conclusion:
Midwives felt challenged by the need to balance their professional attitude towards normal birth and labour pain management, which favours working with pain, with the shift in society towards a wider acceptance of pharmacologic pain management during labour. This shift compelled them to redefine their professional identity.
Keywords: midwifery, midwife-led care, labour pain, pain management, childbirth

Background
Labour pain is a major concern for women, their partners, and maternity health care professionals and has received intense coverage in the Dutch nationwide media. Although the Netherlands has a tradition of birthing without the use of pharmacological pain management, such as epidural analgesia, the number of Dutch women using epidural analgesia has risen over the past decade [1;2]. In 2012, 17.6% of women without a planned caesarean section used epidural analgesia compared with 5.4% and 11.3% in 2003 and 2008, respectively. The Netherlands has a community-based maternity care system, with approximately

84% of all pregnant women starting prenatal care in midwife-led care and around 55% of women starting their labour in midwife-led care [1]. Women with low-risk pregnancies undergoing midwife-led care can choose to give birth either at home, in a birth centre or in a hospital at the onset of labour while being attended by their own midwife. If risk factors or complications arise, women are referred to obstetrician-led care. Medical interventions such as pain medication during labour, epidural analgesia, continuous foetal monitoring and induction or augmentation of labour only take place in obstetrician-led care in hospital settings. In these situations, community midwives transfer patient care to the responsibility of an obstetrician. Typically after the transfer of care from community midwives, clinical midwives take over care under the supervision of obstetricians. If women indicate during their pregnancy that they want to undergo analgesia with pharmacological agents, including epidural or other pain medication, they may have a consultation with an obstetrician, but most of them will start their labour in midwife-led care. As soon as they are in active labour and still choose to undergo pharmacological pain relief, the midwife will refer them to an obstetrician in the hospital setting. In this situation, there is no or hardly any implication for midwives in terms of diminishing caseloads.

Dutch midwives emphasise that labour is a physiological process and that labour pain may be a significant factor in the empowerment of women and in their relationship with their new born babies [3]. This concept is in line with a specific cultural perception among Dutch women that is connected with the concept of natural childbirth [4]. Leap introduced two distinct approaches to manage labour pain that have been widely adopted by health professionals [5]. The first is the "working with pain approach", which involves providing women with support to help them cope with labour pain. The second is the "pain relief" approach, which involves offering pharmacological management to women in labour in order to minimise labour pain.

In 2008, a Dutch guideline concerning pain medication (or an epidural) was introduced [6]. This guideline states that a woman's request for pain medication during labour is, of itself, an adequate medical indication to provide pain relief. It also states that epidural analgesia should be the method of choice for the elimination of labour pain. The guideline has changed attitudes towards labour pain management of women, their partners and maternity health care professionals in the Netherlands [1, 2]. Midwives, too, may have changed their perception, possibly shifting from the traditional "working with pain" approach towards a "pain relief" approach. However, to the best of our knowledge, there have been no previous

studies of Dutch midwives' perceptions regarding working with women undergoing labour pain. The aim of this study was to explore primary care midwives' experiences while providing support to women undergoing labour pain and to determine whether midwives consider that their own attitude towards labour pain have changed in response to the changing attitudes towards this topic in society.

Methods

Ethical approval

Our study was approved by the Medical Ethical Committee of VU University Medical Center (VUmc) in Amsterdam. All midwives gave informed consent prior to participation in the study.

Design

We used a qualitative design and conducted four focus groups with a total of 23 midwives from 23 midwifery practices across the Netherlands.

Data collection

A total of 26 practices across the country were asked to participate in the focus groups. Three declined because of time constraints.

Procedure

Participating midwives were self-selected from within each practice. We included only one midwife per practice, to obtain a broad view of midwives' attitudes. The decision to use focus groups was based on the fact that professionals are better able to share knowledge in social interactions. It was also thought that this approach might elucidate details of professional values and culture [7]. We used purposive sampling, and the selected practices were located in various parts of the country, in rural, rural/urban, and urban areas. We included midwives who worked in solo, duo, and group practices. The researcher informed each practice and each midwife that any information obtained in the focus group discussion would be handled confidentially. The discussions were taped using a digital voice recorder. The first author kept field notes in a logbook, giving details of the context of the discussion, conditions in the focus group and reflections while carrying out her own role as an interviewer.

Midwives were asked to fill in a form containing questions about their personal characteristics. All focus group proceedings were conducted face-to-face in Dutch by the first author (TK) and one trained midwifery student (SH) as moderator

and co-moderator. Midwifery students were involved in the study as part of their midwifery research education programme. They signed a confidentiality statement before they were involved in the study. Some midwifery students acted as hostesses while others audiotaped the group discussion. The focus groups were conducted in a range of settings, such as midwives' practices, a cultural centre, and meeting rooms both at the university and at a midwifery school. The intention was to continue with the focus groups until we reached data saturation.

Focus group topic list

Focus group discussions were guided by a topic list. The questions were not formally phrased but key topics were formulated to help the moderator structure the discussions (Appendix 1). These key topics were selected on the basis of input related to the two approaches to women in labour pain formulated by Leap [5]. The opening question was:

"We are interested in your perception towards working women who are experiencing labour pain. What do you think is the best way to help women in labour with their labour pain?"

Analyses

The constant comparison method was used to elucidate midwives' perceptions of labour pain management [8, 9].

All of the discussions were transcribed by three midwifery student researchers. The micro-analytic process of developing concepts from the data involved repeated reviews of the transcripts (both written and taped) by TK, assisted by two midwifery student researchers. The transcripts were coded by the researchers (TK, SH and SB). Data were analysed and discussed at regular meetings attended by all the researchers, by which repetitive ideas, similarities, and differences were identified. Events that shared common characteristics were cross-linked, while key phrases were identified and coded. The analyses generated new information that was explored in subsequent discussions [7, 10].

The iterative process of constantly comparing text fragments enabled any research bias to be minimised. We used memo writing to extract explanations from the data (9). During regular research team meetings, we discussed and explored theories in order to ensure the validity and accuracy of our analysis. The main themes that we identified are discussed below. These are illustrated by quotes from the Dutch verbatim transcript, translated into English by

a professional translator. The following details were added to the quotes: participant number (Px); explanation added by authors is in square brackets [ ]; and omitted text, indicted by […].

Findings

We held four focus groups between June 2011 and July 2012. Midwives ranged in age from 24 to 56 years. They came from various types of practices (two solo, five duo and 15 group practices) located in areas with varying degrees of urbanisation (nine urban, seven urban/rural and six rural areas). The length of midwives' experience ranged from 1 to 35 years. The characteristics of all participants are outlined in Table 1. Each focus group session lasted approximately 90 minutes.

Table 1. Characteristics of focus group participants

Focus group no. (Fx)	Participating midwife no. (Px)	Age (yrs.) from-to	Number of practice organisation solo/duo/group (x midwives)	Midwifery experience in years from–to
F1	P1–6	24-52	2 solo 1 duo 1 group (3) 2 group (4)	1-30
F2	P7-12	24-56	2 duo 1 group (3) 2 group (4) 1 group (5)	5-35
F3	P13-16	27–50	2 duo 1 group (4) 1 group (5)	3-23
F4	P18-23	29-56	1 duo 2 group (3) 1 group (4) 1 group (5) 1 group (6)	5-24

The following two overarching themes emerged from the analysis:

1. Midwives' professional role conflict, which was reflected in their approaches to labour pain. These approaches were bound within midwifery care and connected with the predominate beliefs of natural childbirth.
2. Midwives' perception of that professional role was influenced by the following factors: situational context of discontinuity of care; time constraints; important partner's role; and various cultural influences.

Midwives' professional role conflict

Perceptions of the working with pain and pain relief approaches

Midwives whose approach was to work with pain described childbirth as a natural biological process. They believed that important birth hormones are released, which allow women to manage labour pain without the need of pharmacological pain management, including the use of epidural analgesia. Midwives described these hormones as essential for labour pain management, for allowing labour pain to be tolerable for women, for mother-child bonding, and for women's self-esteem. This is exemplified by the following quotes:

"Pain is an essential part of the labour process […]. Your body will release those endorphins and these [hormones] will influence mother and child bonding … will influence the awareness of pain. Overall, moments of pain are potential opportunities for inner growth. If women are supported in their labour pain, I believe, that this can be very important for them. We have to consider very carefully whether we should sedate all those important moments in women's lives…… (P5)."

"As if pain medication is the solution to everything (P7)."

For most midwives in our study, "working with pain" was seen as preferable to providing pain medication or an epidural to women. Conversely, these midwives faced the inherent ambiguity of childbirth, not knowing how long labour will last nor how well an individual woman might be able to tolerate labour pain.

"… It is very hard to assess [intensity of labour pain]; … this is manageable and this not… With one woman you feel 'this is horrible' but she says 'well it was all right actually'. For another you think that 'she will manage' yet she perceives labour as hellish….. (P16)."

At the same time, some midwives said that their perceptions of pain medication and epidurals had changed in the years since the introduction of the pharmacological pain relief guideline in 2008 [6]. This was because of women's changed attitudes toward labour pain, which in turn was reflected by the way midwives supported women in labour pain. Midwives stated that they had shifted towards a more pain-relief oriented approach than the one they applied before the introduction of the guideline.

"……*the client has already made a personal decision to use pain medication, so I just arrange this for her … this is really different compared with 10 years ago…* (P3)."

All the midwives in our study were happy with the availability of pharmacological agents for pain management, including epidural analgesia, for women who need it, such as those who have been traumatised by previous childbirth experiences of labour pain suffered in a previous or those whose labour did not progress. Nevertheless most midwives believed that they play an important role in helping women manage their labour pain without the use of pain medication or epidural analgesia.

"Above all, it is fantastic that pain medication exists and that it is relatively easy to obtain if a woman really wants to use it, but our attitude also has a big effect. If we also take the view that labour pain is quite normal, this will make it more manageable for women (P5)."

Midwives said that they would like to have more influence on the process of labour pain management. Some said that women do not always accept the supporting role of a midwife because their assessment of their own ability to work with pain differs from that of the midwife.

"[…] this is a woman who I could have supported through labour pain but she decided to have pain medication and I find that difficult. At that point I think 'If we could have waited for just one more hour then she would have been fine', but yes, women are no longer prepared to accept 'just one more hour'…… (P21)."

Another factor that worried midwives seemed to be the prevalence of the 'pain relief' view, in the media and among women, their partners, and maternity health care professionals. This results in an excessively low threshold for the provision of pain medication or an epidural. In a situation where the support of women in labour seems to be losing ground as the standard management of labour pain to pain medication or use of epidural analgesia, midwives felt that they were no longer able to use their training in midwifery standards to provide such support.

"Pain medication seems to be a substitute for coaching women in labour pain, I believe this development is a major cause of concern (P4)."

"I caught myself thinking very unkind thoughts: 'what a fussy woman you are, everything has to be totally organised, you don't want any pain, you don't want to breastfeed… only then do you want a child! (P14)."

However, most midwives in our study expressed the view that facilitating women's satisfaction with the childbirth experience was the most important aspect of labour pain management, overriding their own beliefs about normal labour. They seemed to feel that pain relief during labour should be seen as a spectrum of pain management, and not as a simple dichotomous choice.

"When they have given birth, I know that it is incredibly important for women to be able to look back at a satisfying birth process rather than thinking 'that was sheer hell'. I'd be the first one to approve pain relief, and to offer effective counselling and consultation (P21)."

Midwives in our study realised that the world is changing. With these changes, and women being more outspoken now, they may request medical interventions even before they are actually in labour.

"We have to keep up with the times and admit that women now have access to various forms of labour pain medication. It's a sign of prosperity to be able to give birth with less labour pain or none at all (P22)."

Nevertheless, according to the midwives, most women prefer to undergo natural labour without pain medication or epidural analgesia if possible, but they feel comfort and assurance in knowing that it is available if they should need it during labour. They expressed the opinion that, once the methods of pain relief available in the region have been explained to them, women have enough confidence to start their labour process without fear.

"Women often tell us: 'These midwives won't be difficult when it comes to pain medication. I know it [pain medication] is available, I just want to try and see how far I can go without it (P3)."

Situational context

Midwives mentioned that factors such as time constraints, discontinuity of care, the role of the partner and cultural influences were relevant and influenced their perception of their professional role in helping women with labour pain.

Time constraints

A major constraint to provide continuous support for women in labour seemed to be the limited time availability of midwives. Midwives believed that having more time to provide continuous support in labour would give increase their fulfilment in their work and would be more beneficial to the women they support and care for. They suggested that women might need less pain medication or epidural analgesia if midwives provided continuous support of women in labour pain.

"…What I have to offer to women in labour, how I might empower women to embrace the birth experience, but I would like to give more, in terms of hours, in being there with women….after all you know this will give you more energy (P9)."

Most midwives expressed the importance of providing information and antepartum counselling about the labour process itself, as well as the importance of managing labour pain. They wanted to spend more time having full and frank discussions with women about labour, the different possible outcomes, and the fact that labour will always be unpredictable.

"It is important to provide a good explanation [ante partum], to give more details about the nature of an epidural and to describe remifentanil, as well as the pros and cons. However, you also need to tell them that things often do not turn out the way you might expect. Now you [women] might think: 'no epidural for me, but when it comes right down to it you might want one ……Discussing all these issues takes time' (P1)."

Discontinuity of care

Most of the midwives in our study felt dissatisfied about not being able to provide continuity of care when women with labour pain were transferred to secondary obstetric care to receive pain medication or epidural analgesia. They stated that they would like to provide continuous support for women in labour, regardless of whether or not the woman under their care needed to be transferred to

obstetrician-led care; they did not want to relinquish their advocacy role for such women.

"When we arrived at the hospital, they [hospital staff] thought she was not in active labour [subsequently, the midwife went home and left the woman and her partner to her colleagues in hospital] Two hours later, she was eight centimetres' dilated, and it was too late for pain medication….. For the woman in question, those two lonely hours [as there was nobody to support her] were very traumatic. I told the physician on the phone 'I think that things will go very quickly, but afterwards I felt that I should have done more. I was very dissatisfied with the way things went. There was no acknowledgement of that pain, which turned out to be very crucial. I should have stayed with them in the hospital (P5)."

Partner's role

Most midwives expressed the belief that partners play a vital role in labour pain management. A major factor in the midwives' view of their supporting role was their commitment to the partners. This involved informing them about the labour process and involving them in the process itself.

"Some partners are well aware of the contribution they can make. When a partner feels that he is being useful, that he can make a genuine contribution, then he can make all the difference. That will really help a woman in labour (P21). *I also ask them 'What is your role in this?' 'What do you think about it?'"*

Midwives stated that they aim to give partners the same information that they give expecting mothers themselves in order to strengthen the important supporting role played by partners during labour.

"I will always involve the partner; I will discuss the nature of the labour pain at that time with both of them. But sometimes, when a woman is in active labour and she is struggling with labour pain, the partner will say: 'breathe, breathe, breathe', followed by: 'this is really too much for my wife, how much pain can she take?!' It is, of course, very difficult to see your much loved wife suffering from labour pain. I then explain the nature of the labour process to him: whether what is happening is still normal or not…(P12)."

Cultural influences

Some midwives pointed out that they also have to deal with specific cultural beliefs about labour pain management. They seemed to be aware of the need for a diverse range of support skills in order to help women manage their labour pain.

"To some extent, I also believe that this is culturally determined, e.g. in other cultures women tend to make a lot of noise during labour. The idea is that the more pain they feel, the more respect they will get from their husbands. And some of these women are just very happy that we have pain relief here, because they don't have that at home (P5)."

At the same time, midwives were aware that women from other parts of the world might have quite a different approach to labour pain.

"We also have a very special group of mostly parous women from Africa. These women have given birth before, in Africa, without pain relief. They just give birth without [pain medication], they don't even question it. They do not see this as an issue, it is just something you do (P6, midwives nodded their head and smiled)."

Midwives who work in the religious region of the Netherlands told us about their experiences with women in labour pain.

"In our region, people believe what is written in the Bible: 'Thou shalt give birth in grief'. This is a belief that I share. For this reason, in our practice, many women do not want to use pain relief, and they wonder 'is it permissible to use labour pain medication?' We have many such women….. (P1)."

Discussion

Our results revealed two main themes: 1) midwives' professional role conflict, which was reflected in the approaches to labour pain used by midwives;
2) the situational context, which consisted of factors such as time constraints, discontinuity of care, the important role of the partner and various cultural influences.

Midwives in our study felt compelled to redefine their professional identity, in line with the societal shift towards the pain relief approach. As a result, most midwives were worried about the prevailing attitude in society and among health care professionals that women need pain relief rather than adequate

continuous support during labour. Midwives seemed to think that the issue of non-pharmacological or pharmacological pain relief is not a simple dichotomous choice. These choices appeared to be ranged along a spectrum spanning the two approaches to the management of labour pain, “working with pain” and “pain relief”. Midwives expressed reservations about finding the right balance between these two approaches: helping women to work with pain versus arranging for pain relief. They highlighted the fact that it is difficult for midwives to identify the exact point in time when women in labour might benefit from pain medication or epidural analgesia. At the same time, most of the midwives in our study thought that they were more prepared to arrange for pain relief nowadays compared with 10 years ago [1, 2]. However, most midwives had been trained to promote natural childbirth [11, 12], and they firmly believed in this approach. A number of them were experiencing something of a professional identity crisis, stating that some women are no longer prepared to accept professional midwifery care during labour.

Pain medication or use of epidural analgesia during labour are only provided in hospital maternity units following transfer to obstetrician-led care. Accordingly, requests for pain medication or an epidural results in a discontinuity of care in the Netherlands. This discontinuity of care was cause of frustration and dissatisfaction for the midwives. Because of time constraints within the maternity care model in which Dutch community midwives work, midwives seemed unable to provide adequate continuity of care. They believed this leads to a situation in which some of the women requesting pain medication or epidural analgesia do not really want it, or those who want it do not really obtain it. Compared with other countries where midwives work autonomously, Dutch midwives have a relatively high caseload, which makes it difficult for them to stay with women in early labour after referral to obstetrician-led care [13]. Research showed that continuity of care in labour with a known midwife, who has built a trusting relationship during pregnancy, can reduce interventions and the use of epidurals, thereby leading to an increased number of spontaneous vaginal births and maternal satisfaction [14, 15]. Dutch women experience a relatively low intervention rate during labour [1, 3, 16]. This may have been attributed to the high degree of continuity of care when women received midwife-led care at home, in maternity care units in hospitals, or birth centres. With the increasing numbers of Dutch woman who are transferred to obstetrician-led care during labour [1, 16], it is likely that interventions will increase and maternal satisfaction will decrease. Paradoxically, this is in contrast with the legislation on access to pain medication (or epidural

analgesia), that was hoping to increase satisfaction of women in labour [6]. Other study results confirm that midwives obtain genuine job satisfaction from providing continuity of care and from the relationships that they establish with the women under their care [17;18]. These findings also show that midwives feel frustrated when they are unable to practice midwifery care in a way that conforms to their view of normal birth [19]. Midwives experienced this role conflict in the context of the change in maternity care approach towards one that is increasingly obstetrically dominated and that is reflected in a technocratic paradigm that emphasises mind-body separation [20]. Midwives' approaches to maternity care are more embedded in a humanistic and holistic approach. These two approaches emphasise the mind-body connection and coherence of body, mind and soul [19, 20, 21)]. Although the Netherlands has had the reputation of upholding physiological birth through a strong midwifery approach, there appears to be a shift towards an obstetrically dominated system [16]. This is apparent in the findings of midwives' approaches towards labour pain in our study. One could argue that in combining components of all three paradigms, mind, body and soul, one could attain the most effective maternity care system for mothers and their infants [20]. One should bear in mind in our analyses regarding the role of pain in labour that the approaches of health care professionals towards labour pain are always a creation of their individual 'bodies, minds and cultures' [23, 24)]. Some literature reviews have suggested that having 'continuity of carer' during pregnancy and labour was less important for women in labour than it was for their supporting midwives [25, 26]. It seemed more important for women to receive consistent care from health care professionals whom they trusted. Another study published after 2000 reported the opposite findings: continuity of carer was important to women and increases maternal satisfaction with their childbirth experience [14, 27]. Midwives in our study expressed their frustration of having to transfer their patients to obstetrician-led care for pain medication or epidural analgesia. Hyde and Roche-Reid (2004) concluded that modernity has implications for the role of the midwife [28]. They found that midwives believe their role is to empower women and to facilitate choices for women through dialogue. Midwives in our study also believed in the value of maintaining a dialogue with their clients and with their clients' partners.

We found that pain medication or use of epidural analgesia during labour was not really an issue for those midwives who worked in a particularly religious region of the Netherlands and those who attended women from African countries. Our findings are consistent with those of Callister et al. (2003), who found that

women's perception of pain and their pain behaviour are culturally determined [29]. This research described the cross-cultural appreciation of empowerment of women by the challenge of labour. Women might feel empowered by dealing with labour pain, which results in creating new life [30]. Culturally diverse women who have support from an unknown birth attendant and give birth in a technologic environment with routine interventions are more likely to experience anxiety and labour pain [31]. We are not aware of any recently related studies in women of diverse religious backgrounds.

Midwives in our study were aware that the ability to work with labour pain is more important, in terms of a woman's satisfaction with her childbirth experience, than actual avoidance of labour pain [32] or receiving pain medication or epidural analgesia [33]. However, midwives felt there was a shift in terms of women wanting better access to pain medication or epidural analgesia, even though a systematic review showed that the use of pharmacological pain relief and epidurals was not associated with a positive experience of childbirth [33].
In most cases, midwives viewed themselves as being sufficiently experienced and well equipped to support women in labour. They suggested that most women feel reassurance in knowing that pain medication or epidural analgesia is available if they need it, but that they prefer to experience childbirth without it if possible.
Midwives in this study wanted to spend time providing balanced information and counselling in the antepartum period, as well as sufficient time to support women in labour pain. They felt that most women were prepared to rely on their midwife's expertise to support them through labour pain. This finding is consistent with other studies about shared decision making [34, 35] that underline the importance of respectful listening and open communication in building good relationships between women and the health care professionals that tend to them. At the same time, midwives complained about having too little time to carry out their full range of duties effectively.
Midwives in our study believed that most partners played a crucial role in the management of women's labour pain. This is supported by other studies who found that, when the birthing partner of women provided them with support and encouragement in the use of pain control techniques (breathing, massage, distraction), women were less likely to ask for epidural analgesia [36, 37].
Midwives also pointed out that, during the labour process in which they are unable to encourage women's partners, some partners might react with expressions of helplessness. It is for this reason that midwives informed women in labour and

their partners about the process itself, and about how they might best manage the process and pain together [38]. A study in Italy showed that men might be affected by a dominant culture of pain medication. In this study men's experience of childbirth was improved when their partners used epidurals [39]. These men experienced less anxiety and stress and felt more involvement, participation and satisfaction with the experience of childbirth. Dutch men might also be influenced by this phenomenon, but further research is needed to explore experiences of partners of women in labour regarding management of labour pain.

Limitations

This study had several limitations. Our sample size of four focus groups was relatively small. However, the use of a robust sampling frame made it possible to capture a wide range of perceptions from midwives with varying amounts of experience, practising in a variety of clinical settings. In this study, we achieved data saturation with four focus groups. The fact that the interviewer was a former midwife might be another limitation, as the peers involved may have given the answers that they thought the interviewer wanted to hear. However, given the wide variety of perceptions captured, we believe that this had no significant influence in the results of this study.

Strengths

Our study had several strengths. To our knowledge, this is the first study to evaluate the perceptions of primary care midwives in the Netherlands regarding the management of labour pain, and to determine whether midwives think their perceptions have changed in response to the changing attitudes in society towards labour pain.

Conclusions

Midwives felt challenged by the need to balance their professional attitude towards normal birth and working with labour pain with the shift in society towards a wider acceptance of pain medication and use of epidural analgesia during labour. Most midwives in our study believed that the issue of pain relief is not a simple dichotomous choice, but rather that it should be seen as a spectrum of labour pain management. At the same time, their perceptions seem to have shifted: now midwives are more prepared to offer pain relief compared with 10 years ago. Therefore, midwives felt compelled to redefine their professional identity.

Competing interests
We do not have any conflicts of interest to disclose.

Authors' contributions
TK, AdJ, SH and AvR helped to recruit the midwifery practices, TK monitored and supervised data collection together with researcher SH. TK and SH conducted data analyses and were also primarily responsible for data interpretation. TL, EH and AdJ assisted with data interpretation. All authors read and corrected the draft version of the manuscript and approved the final manuscript.

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Chapter 8

Inhaled analgesia for pain management in labour

Klomp T, van Poppel M, Jones L, Lazet J, Di Nisio M, Lagro-Janssen ALM.

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Abstract

Background

Many women would like to have a choice in pain relief during labour and also would like to avoid invasive methods of pain management in labour. Inhaled analgesia during labour involves the self-administered inhalation of sub-anaesthetic concentrations of agents while the mother remains awake and her protective laryngeal reflexes remain intact.

Objectives

To examine the effects of all modalities of inhaled analgesia on the mother and the newborn for mothers who planned to have a vaginal delivery.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 January 2012), ClinicalTrials.gov, and Current Controlled Trials (2 June 2012), handsearched conference proceedings from the American Society of Clinical Anesthesia (from 1990 to 2011) and contacted content experts and trialists.

Selection criteria

Randomised controlled trials comparing inhaled analgesia with other inhaled analgesia or placebo or no treatment or other methods of non-pharmacological pain management in labour.

Data collection and analysis

Review authors independently assessed trials for eligibility, methodological quality and extracted all data. Data were double checked for accuracy.

Main results

Twenty-six studies, randomising 2959 women, were included in this review.

Inhaled analgesia versus a different type of inhaled analgesia

Flurane derivatives were found to offer better pain relief than nitrous oxide in first stage of labour as measured by a lower pain intensity score (average mean difference (MD) 14.39, 95% confidence interval (CI) 4.41 to 24.37, three studies, 70 women), also a higher pain relief score for flurane derivatives compared with nitrous oxide (average MD -16.32, 95% CI -26.85 to -5.79, two studies, 70 women).

Substantial heterogeneity was found in the analyses of pain intensity (P = 0.003) and in the analysis of pain relief (P = 0.002).These findings should be considered with caution because of the questionable design of the included cross-over trials. More nausea was found in the nitrous oxide group compared with the flurane derivatives group (risk ratio (RR) 6.60 95% CI 1.85 to 23.52, two studies, 98 women).

Inhaled analgesia versus placebo or no treatment

Placebo or no treatment was found to offer less pain relief compared to nitrous oxide (average RR 0.06, 95% CI 0.01 to 0.34, two studies, 310 women; MD -3.50, 95% CI -3.75 to -3.25, one study, 509 women). However, nitrous oxide resulted in more side effects for women such as nausea (RR 43.10, 95% CI 2.63 to 706.74, one study, 509 women), vomiting (RR 9.05, 95% CI 1.18 to 69.32, two studies, 619 women), dizziness (RR 113.98, 95% CI 7.09 to 1833.69, one study, 509 women) and drowsiness (RR 77.59, 95% CI 4.80 to 1254.96, one study, 509 women) when compared with placebo or no treatment.

There were no significant differences found for any of the outcomes in the studies comparing one strength versus a different strength of inhaled analgesia, in studies comparing different delivery systems or in the study comparing inhaled analgesia with TENS.

Due to lack of data, the following outcomes were not analysed within the review: sense of control; satisfaction with childbirth experience; effect on mother/ baby interaction; breastfeeding; admission to special care baby unit; poor infant outcomes at long-term follow-up; or costs.

Authors' conclusions

Inhaled analgesia appears to be effective in reducing pain intensity and in giving pain relief in labour. However, substantial heterogeneity was detected for pain intensity. Furthermore, nitrous oxide appears to result in more side effects compared with flurane derivatives. Flurane derivatives result in more drowsiness when compared with nitrous oxide. When inhaled analgesia is compared with no treatment or placebo, nitrous oxide appears to result in even more side effects such as nausea, vomiting, dizziness and drowsiness. There is no evidence for differences for any of the outcomes comparing one strength verus a different strength of inhaled analgesia, comparing different delivery systems or comparing inhaled analgesia with TENS.

Background

Description of the condition

Labour pain and methods to relieve it are major concerns for women, healthcare workers and the general public (1). These concerns have implications for the course of labour, for the quality of maternal and infant obstetric outcomes as well as for the costs of obstetric health care. In our modern society, pain has a negative connotation for the general public. Fear of labour pain is strongly associated with the fear of pain in general (2; 3). Different views about the importance of pain during labour are reflected in great differences between countries worldwide with regard to the numbers of women who receive pain relief during labour, as well as the type of pharmacological analgesia that is used. Culture plays a significant role in attitudes towards childbirth pain, the definition of the meaning of childbirth pain, perceptions of pain and coping mechanisms used to manage pain in childbirth.

Description of the intervention

Inhaled analgesia during labour involves the inhalation of sub-anaesthetic concentrations of agents while the mother remains awake and her protective laryngeal reflexes remain intact. The use of inhaled analgesics for pain relief during labour dates back to 1847, when James Simpson used it for the first time for vaginal delivery (4). Nitrous oxide was first used in 1881 by Stanislaw Klikovich, who studied the effects of pre-mixed nitrous oxide 80% in oxygen on women in labour (5). In 1934, Minnitt introduced an apparatus for the self-administration of nitrous oxide (6). Other possibilities for inhaled analgesia for pain relief in labour are isoflurane, sevoflurane, trichloroethylene in air, methoxyflurane and cyclopropane. Trichloroethylene cannot be administered through a CO_2 absorber and is flammable, while cyclopropane is explosive even in sub-anaesthetic concentrations. Both drugs are no longer used in the developed world and therefore must be seen as of historical interest only. Sevoflurane is not recommended as analgesia because it has no analgesic activity at sub-anaesthetic concentrations. Sub-anaesthetic concentrations of nitrous oxide, enflurane, isoflurane and methoxyflurane do not significantly decrease uterine contractions and are preferable for this reason. However, only the use of nitrous oxide is widespread in modern obstetric practice. The reason why is not clear but probably due to ease of administration, lack of flammability, lack of pungent odour, lack of effect on uterine contractions, lack of relation with pathologic

temperature, minimal toxicity and minimal depression of the cardio-vascular system (7; 3). The evidence on the use of nitrous oxide for relief of labour pain has been summarised in a systematic review (3). Nitrous oxide mixed with oxygen as labour pain management in labour is self-administered by labouring women by inhalation through a mouthpiece or facemask. Entonox is a trade marked name for a mix of 50% nitrous oxide and 50% oxygen in liquid state in a single pressured container. Alternatively, Entonox can be used by blending a fixed concentration of 50% nitrous oxide and 50% oxide by two separate cylinders or hospital pipeline supply; the distribution of Entonox is carried out through a small regulator apparatus (Nitronox™). The Midogas device is another way to inhale Entonox which allows adjustment of the nitrous oxide concentration within a narrow range. The cylinders are connected to a facemask or mouthpiece. The demand valve opens only when the user applies a negative pressure by inspiring through the mouthpiece or well-sealed mask covering the parturient's mouth and nose In countries such as Canada, Denmark, Finland, New Zealand, the United Kingdom and the United States of America, midwives are allowed to 1) set up the equipment for nitrous oxide, 2) instruct the woman how to use it and 3) monitor her use of it. The woman can self-administer it after initial supervision. Inhaled analgesia can be used by the woman either intermittently with discontinuation of use as the contraction pain eases or disappears, or continuously, by inhaling both during and between contractions. There is a rapid uptake/washout rate for most of the inhaled analgesia, which means a low blood/gas solubility ratio. Maximal effect for nitrous oxide is observed in 30 to 60 seconds and wash-out effect can be obtained in three or four exhalations (8).

However, there is controversy about the use of nitrous oxide because of concerns about the safety of nitrous oxide for the sub fecundability (reduction in the ability to conceive) of female maternity care professionals and an increased incidence of spontaneous abortions of the pregnant maternity care professionals (9; 10; 11; 12;13; 14). The underlying cause is thought to be inactivation of methionine synthase by nitrous oxide (15). Cellular-level damage can begin during a maternity-care worker's shift in a poorly ventilated hospital where nitrous oxide is used without scavenging.

Subfecundability in the form of maternal absorption of malformed conceptions has been found in animal studies of the reproductive effects of very prolonged exposures to very high doses of nitrous oxide (15). Nitrous oxide-induced fertility problems occur in rats at 1000 parts per million (ppm) but not at 500 ppm or lower. Rats are known to be particularly sensitive to damage from nitrous oxide.

Current standards in the Netherlands and United States call for limiting occupational exposure to nitrous oxide to not more than an eight-hour time-weighted average (TWA) concentration of 25 ppm (7).
The risk of reproductive failure related to occupational exposure to nitrous oxide is essentially eliminated when nitrous oxide labour analgesia is used in well-ventilated modern hospitals and 'scavenging' is used. The Boivin (1997) meta-analysis reached the same conclusion as the Rosen (2002) review: scavenging solves the problem (12;3). Other side effects are maternal drowsiness, nausea and vomiting when inhaled analgesia is used too long or extensively, especially if the rule of self-administration is violated.

How the intervention might work

The precise mechanism of action of pain relief by inhaled analgesia remains uncertain. Maze and Fuginaga hypothesised that nitrous oxide induces the release of endogenous opioid peptides in the peri-aqueductual grey area of the midbrain (16). The release of this substance in the midbrain could modulate pain stimuli through the descending spinal cord nerve pathways.

Why it is important to do this review

It is important to do this review because all women should have access to some form of relatively effective and safe analgesia during labour and to provide this analgesia when women need some form of pharmacological pain relief during labour (17). Even in hospitals with full-time obstetric anaesthesia coverage, no one may be available to place an epidural, provide another highly effective method of labour analgesia, or provide a labour-intensive non-pharmacological method to help the woman in pain.
More invasive options such as epidural analgesia are associated with significant side effects. Approximately 20% of women who had a vaginal delivery in the UK (18; 19), 59% to 61% of women in the USA (20; 21) and 10% of women in the Netherlands (22) used an epidural injection as pain relief in labour. The use of an epidural injection in labour has steadily increased until the last decade in modern highly developed countries (23). In some countries these figures are expected to rise even more in the coming years, for example, in the Netherlands. The use of epidural analgesia, especially within primary obstetric care, determines a higher rate of deliveries in secondary or tertiary obstetric care hospitals, which increases medicalisation as well as healthcare costs. In conclusion, it is important to have other options for pain relief during labour in view of the side effects of the invasive options.

Inhaled pain relief during labour, especially by nitrous oxide, is relatively easy to administer, can be started in less than a minute and becomes effective within a minute. Since it does not affect the physiology of labour, it can be started whenever it is needed. However, the effectiveness and efficacy of nitrous oxide use for management of labour pain is hard to ascertain because of the few available data. The available data are out of date (3); thus a systematic assessment of the evidence regarding the safety and efficacy of inhaled analgesia for pain relief in labour is urgently needed as well as for anaesthesiologists, obstetricians, hospital administrators, midwives, nurses, women as for the general public.
This review is one in a series of Cochrane reviews examining pain management in labour. These reviews contribute to an overview of systematic reviews of pain management for women in labour (24), and share a generic protocol (25).

Objectives
The main objective was to explore the efficacy and safety of inhaled analgesia as pain relief for women in labour planning a vaginal delivery. Although important to look at, the effects of occupational exposure and toxic effects on reproduction for maternity healthcare workers can only be found in large-scale epidemiological studies. Since we only included intervention studies (see Types of studies), we did not include these outcomes in this review.

Methods

Criteria for considering studies for this review

Types of studies
Randomised controlled trials (RCTs) and studies with a cross-over design were included. We did not include quasi-RCTs.

Types of participants
Women in labour including women in high-risk groups, e.g. preterm labour or following induction of labour.

Types of interventions
This review is one in a series of Cochrane reviews examining pain management in labour. These reviews contribute to an overview of systematic reviews of interventions for pain management in labour (24), and share a generic

protocol (25). To avoid duplication, the different methods of pain management have been listed in a specific order, from one to 15. Individual reviews focusing on particular interventions include comparisons with only the interventions above it in the list. Methods of pain management identified in the future will be added to the end of the list. The current list is as follows.

1. Placebo/no treatment
2. Hypnosis (26)
3. Biofeedback (27)
4. Intracutaneous or subcutaneous sterile water injection (28)
5. Immersion in water (29)
6. Aromatherapy (30)
7. Relaxation techniques (yoga, music, audio)* (31)
8. Acupuncture or acupressure (32)
9. Manual healing methods including massage and reflexology* (33)
10. TENS (transcutaneous electrical nerve stimulation) (34)
11. Inhaled analgesia (this review)
12. Opioids (35)
13. Non-opioid drugs (36)
14. Local anaesthetic nerve blocks (37)
15. Epidural (including combined spinal epidural) (38; 39).

Accordingly, this review only includes comparisons of inhaled analgesia with other inhaled analgesia or with: 1. placebo/no treatment; 2. hypnosis; 3. biofeedback; 4. sterile water injection; 5. immersion in water; 6. aromatherapy; 7. relaxation techniques (yoga, music, audio); 8. acupuncture or acupressure; 9. manual methods (massage, reflexology); or 10. TENS.
Interventions were any inhaled analgesia during labour such as isoflurane, enflurane methoxyflurane and nitrous oxide. We included any frequency or duration of administration, any dosage/intensity, any combinations of inhaled analgesia and any timing of labour (first, second or third stage).

Types of outcome measures
Primary outcomes

Effects of interventions

- Pain intensity (as defined by trialists) 40)
- Satisfaction with pain relief (as defined by trialists) collected within 48 hours after birth
- Sense of control in labour (as defined by trialists)
- Satisfaction with childbirth experience (as defined by trialists)

Safety of interventions

- Effect on mother/baby interaction (skin-to-skin contact of mother and baby within the first hour of birth)
- Breastfeeding (at specified time points; within the first hour of birth, at discharge of the hospital)
- Assisted vaginal birth
- Caesarean section
- Side effects (nausea, vomiting, drowsiness, renal and hepatic toxicity, uterine relaxation)
- Admission to special care baby unit/neonatal intensive care unit (as defined by trialists)
- Apgar score less than seven at five minutes
- Need for rescue analgesia (mother or baby)
- Poor infant outcomes at long-term follow-up (as defined by trialists)

Other outcomes

- Cost (as defined by trialists)

Secondary outcomes

For the baby

- Differences in the one, two, five or 10 minute Apgar scores
- Neurological integrity scale of the newborn

For the professional

- Occupational exposure
- Toxic effects on reproduction

Search methods for identification of studies

Electronic searches

The Trials Search Co-ordinator was contacted to search the Cochrane Pregnancy and Childbirth Group's Trials Register (31 January 2012).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Coordinator searches the register for each review using the topic list rather than keywords.

In addition, we searched ClinicalTrials.gov, and Current Controlled Trials to identify ongoing trials (2 June 2012).

Searching other resources

We searched reference lists of identified studies and handsearched the conference proceedings from the American Society of Clinical Anesthesia (from 1990 to 2011). We also contacted content experts and trialists.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Two review authors independently assessed for inclusion all the potential studies identified through the search strategy. Any disagreement was resolved through

discussion and, if there could not be achieved consensus, a third author was consulted.

Data extraction and management

A form was designed to extract data. For eligible studies, two review authors extracted the data using the agreed form. Discrepancies were resolved through discussion or, if required, by consulting a third author. Data were entered into Review Manager software (41) and checked for accuracy.
When information regarding any of the above was unclear, we contacted the authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (42). Any disagreement was resolved by discussion or by involving a third assessor. To assess the risk of bias, the following items were evaluated:

(1) Random sequence generation (checking for possible selection bias)

The methods used to generate the allocation sequence were described for each included study in sufficient detail to allow an assessment of whether it should produce comparable groups.
The method were assessed as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

The methods used to conceal the allocation sequence were described for each included study and determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.
The methods were assessed as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);

- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3) Blinding (checking for possible performance bias)
The methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received were described for each included study. Studies were considered at low risk of bias if they were blinded, or if was judged that the lack of blinding could not have affected the results. Blinding was assessed separately for different outcomes or classes of outcomes.
The methods were assessed as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel;
- low, high or unclear risk of bias for outcome assessors.

Partial blinding was used as an option because many of the administered inhaled analgesia cannot be completely blinded because of their odour. Partial blinding was also used for self-reported efficacy outcomes and when these outcomes are recorded by blinded personnel.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)
The completeness of data including attrition and exclusions from the analysis were described for each included study and for each outcome or class of outcomes. Where attrition and exclusions were stated it was reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we planned to re-include the missing data in the analyses which we undertook. Methods were assessed as:

- low risk of bias (20% or less missing data);
- high risk of bias;
- unclear risk of bias.

(5) Selective reporting bias

How the possibility of selective outcome reporting bias was investigated and what was found was described for each included study (43).
The methods were assessed as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other sources of bias

Concurrent or prior use of analgesia was identified in the selected studies because the concurrent or prior use of analgesia can give some bias of the effects of the studied analgesia. Furthermore, any other important concerns about other possible sources of bias was described for each included study.
Each study was assessed whether the study was free of other problems that could put it at risk of bias (low-, high-, of unclear risk of bias).

(7) Overall risk of bias

Explicit judgements were made about whether studies were at high risk of bias, according to the criteria given in the Handbook (42). The likely magnitude and direction of the bias was assessed with reference to (1) to (6) above and whether it was considered as likely to impact on the findings. We planned to explore the impact of the level of bias through undertaking sensitivity analyses.
The following questions were considered for assessing risk of bias for cross-over trials.

- Was use of a cross-over design appropriate (44)?
- Is it clear that the order of receiving treatments was randomised?
- Can it be assumed that the trial was not biased from carry-over effects? Inhaled analgesia has a relatively rapid uptake/washout effect. We take four exhalations as the safe cut-off point for no residual effect.

- Are unbiased data available (period effects)? Pain of uterine contractions are not consistent over time. The pain becomes more intense as the labour progresses until the start of delivery. Pain of the contractions change during the delivery of the baby. We looked for any control for labour progress at the start of the inhaled analgesia. If the start of the analgesia was not in the same stage of labour (in the active first stage after 3 cm dilatation) and second stage after 10 cm dilation until birth of the baby), we reported this risk of bias.

Measures of treatment effect

For dichotomous date, we presented results as summary risk ratio with 95% confidence intervals and, where relevant, as risk difference and number needed to treat either to benefit or to harm.

Results of ordinal data were transformed to dichotomous data for analysis and described in the section on data analysis.

For continuous data, we used mean difference if outcomes were measured in the same way between trials. The standardised mean difference was used to combine trials that measured the same outcome, but used different methods. Where appropriate, we used standard inverse-variance random-effects meta-analysis to combine the trials (45).The method of Hozo (2005) was used to estimate the mean and variance from the median, range, and the size of the sample when the published reports of the included trials only reported the median, range and the size of trial (46).

Unit of analysis issues

Cross-over trials

Other unit of analysis issues

The appropriate analysis for continuous data from a two-period, two-intervention cross-over trial, a paired T-test was planned if neither carry-over, (a minimum of four exhalations with room air), nor period effects were thought to be a problem. This evaluates the value of 'measurement on experimental intervention (E)' minus 'measurement on control intervention (C)' separately for each participant. The mean and standard error of these different measures are the building blocks of an effect estimate and a statistical test. The effect estimate may be included in a meta-analysis using the generic inverse-variance method in RevMan 2011 (41). The simple formula of Hozo (2005) was used for small sample sizes below 25 participants to estimate the mean using the values of the median, low and high

end of the range (46). The best estimator for sample sizes which exceeds 25 is the median itself. The known estimator Range/4 was used to estimate the standard variation for small sample sizes between 15 and 70 participants.

Dealing with missing data

Levels of attrition were noted for included studies. We planned to explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

Analyses were carried out for all outcomes, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

Heterogeneity of treatment effects was measured between trials using the Chi^2 test and the I^2statistic (47;42), which describe the percentage of total variation across trials that is attributable to heterogeneity rather than to chance. We assessed statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if T^2 was greater than zero and either I^2 was greater than 30% or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If 10 or more studies had contributed data to meta-analysis for any particular outcome, we planned to investigate reporting biases (such as publication bias) using funnel plots. We would have assessed possible asymmetry visually, and used formal tests for funnel plot asymmetry. For continuous outcomes, we would have used the test proposed by Egger (1997), and for dichotomous outcomes, we would have used the test proposed by Harbord (2006) (48;49). If asymmetry was detected in any of these tests or was suggested by a visual assessment, we planned to perform exploratory analyses to investigate it.

Data synthesis

Statistical analysis were carried out using the Review Manager software (41). Fixed-effect meta-analysis was used for combining data where it was reasonable

to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, random-effects meta-analysis was used to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. Results were presented as the average treatment effect with its 95% confidence interval, and the estimates of T^2 and I^2 where random-effects analysis was used.

Subgroup analysis and investigation of heterogeneity

If substantial heterogeneity was identified, for the primary outcomes, where data were available, we planned to carry out the following subgroup analyses.

1. Spontaneous labour versus induced labour.
2. Primiparous versus multiparous.
3. Term versus preterm birth.
4. Continuous support in labour versus no continuous support.
5. Mode of delivery: spontaneous vaginal, operative vaginal, mode of delivery mixed or unclear.
6. Different methods and doses of inhaled pain relief (inhalation agent regimen and doses).
7. Obese versus non obese women.

   We also planned to look separately at results of studies in which a 50%/50% blend of N_2O and O_2 was self-administered by labouring women and distinguish the results of those studies from the results of studies in which:

   a. the ratio of N_2O to O_2 was higher than 50%,
   b. the ratio of N_2O to O_2 was lower than 50%,
   c. the ratio of the gases could be changed by a professional,
   d. the ratio could be changed by the labouring woman,
   e. the ratio was 50%/50% but someone other than the woman who was inhaling it administered it to her.

We planned to assess differences between subgroups by interaction tests as described in the *Handbook* (42).

Sensitivity analysis

We planned to carry out sensitivity analyses to explore the effect of trial quality assessed by concealment of allocation, and for the cross-over trials as assessed by 'correct analyses for cross-over design used', with poor quality studies with high risk of bias being excluded from the analyses in order to assess whether this made any difference to the overall results. We planned to carry out sensitivity analyse for primary outcomes only.

Results

Description of studies

Results of the search

A total of 54 reports of studies were identified from the search strategy. A total of 26 studies reporting data on 2959 women (31 reports) were included in this review (see Characteristics of included studies) and 21 studies (23 reports) were excluded.

Included studies

Study design

Eighteen of the studies were parallel design (8;50-66) and eight cross-over design (68-75). One study had two parts (70); the second part was a randomised cross-over study. For this study, we used only the data from the cross-over study (part II), and data were only available for the first period (before first cross-over). Two studies had three arms (54; 63) and all the remaining studies had two comparison arms. We did not include the third arm of these two studies which were the control arms (no treatment). The main comparison groups included:

1. studies comparing one type of inhaled analgesia with another type of inhaled analgesia (50;51;53;54;57;58;63;64;67;68;71-74);
2. studies comparing the same types of inhaled analgesia of different strengths (55;60);
3. studies comparing the same types of inhaled analgesia using different delivery systems (52;56);
4. studies comparing inhaled analgesia with placebo control/no treatment (8;54;57;61-63;65;66;69);
5. and one study comparing inhaled analgesia with TENS (70).

Sample sizes
Sample size in the included studies ranged from 18 (73) to 509 patients (8).
For further details of the included studies, see the table Characteristics of included studies.

Risk of bias in included studies
See Figure 1; Figure 2, for further details regarding 'Risk of bias' assessment.

Random sequence generation
Seven of the trials (27%) were rated as low risk of bias for sequence generation and in the remaining trials the method of sequence generation was unclear.

Allocation concealment
In only three studies (11%) was allocation concealment rated as low risk of bias and unclear in the remaining trials.

Blinding
Blinding of participants and personnel was at low risk of bias three studies (11%), high risk in four studies and unclear in the remaining studies.
Blinding of outcome assessment was at low risk of bias in three studies (9%), high risk in four studies and unclear in the remaining studies.

Incomplete outcome data
Thirteen (50%) of the trials were rated as low risk of bias for incomplete outcome data and at high risk of bias in. In the remaining studies risk of bias for incomplete outcome data was unclear.

Selective outcome reporting
Sixteen (62%) of the trials were rated as low risk of bias for selective outcome and at high risk of bias in five. In the remaining studies risk of bias for was unclear.

Other bias
Six (23%) of the trials were rated as being at low risk of bias for 'other bias' and at high risk of bias in three studies (baseline imbalance including no information of prior or concurrent use of other analgesia; delivery systems for interventions not comparable. In the remaining 17 studies (65%), risk of bias for was unclear.

Cross-over trials

All eight cross-over trials randomised the order of interventions. Three studies were at low risk of bias for method of randomisation due to well described randomisation and five studies are with unclear risk of bias due to unclear description of randomisation.

In one study, the study was divided into two parts: the first part was not randomised and the second part was a randomised cross-over trial (70). The data from the first period of the cross-over trial were used and analysed as a parallel trial. One study (72) had an adequate wash-out period of two contractions. Two studies (67;68) used one contraction with air breathing between the two different agents, long enough to ensure an adequate four wash-out exhalation period. Three cross-over trials (69;71;73) reported no information on a wash-out period, but the inhaled analgesia were self-administered during contractions. This means that an adequate wash-out period of a minimum of four exhalations was met in the pause between two contractions. In one study, the wash-out period is unclear, due to the fact that participants were given the option, if they wished, to omit the wash-out period of breathing room air over one contraction between the different agents (74). No information was given on how many participants took this option. However, the minimum wash-out period of four exhalations was probably met, due to the method of self-administering the inhaled analgesia in this study. It is very likely that the women will have rested for a moment between the contractions, probably without inhaling the agent.

Two double cross-over design included compensation for the progressive nature of labour and therefore are evaluated as a good and appropriate design (73;74). Five cross-over studies were all single cross-over studies but are believed to have an appropriate design due to the short duration of the intervention and comparison period, from three to five contractions in active part of labour (67-69;71;72). In these single cross-over studies progression of labour is not thought to be of influence.

All the eight cross-over studies were carried out during the first stage in active (established) labour until 10 cm dilation or when women felt the urge to push (end of the first stage and start second stage) (67-74). We were only able to obtain individual patient data from one study which appeared to be incomplete (73). We decided to use only the data of the first part of this study as a parallel group trial. The appropriate data necessary to include from a paired analysis were only available for the incidence of side effects from one study (74). However, because of concern over carry-over effects, outcome data for side effects for cross-over studies were not included in any analyses.

In two studies, the Wilcoxon paired T-sample test was performed for the effect estimate of pain relief and pain intensity (71;72). No data were available on individual patients for the meta-analysis. It was not possible to extract the paired data from these two studies. In five cross-over studies, continuous data on pain intensity or pain relief were reported (67;71-74), and data were represented as mean/SD (67) or median/range (71;74) or mean/range (72) or individual VAS after one hour (73) before the first cross-over. These data were available only for the whole experimental and comparison group periods separately and analysed as if the trials were a parallel group trial of experimental versus comparison. This statistical method is of high risk due to the conservative way that studies are under weighted, rather than over weighted (44).

Correct analysis for cross-over design used

Five of the cross-over studies (63%) were rated as high risk of bias for 'correct analysis for cross-over design used'.

Effects of interventions

We included data from 23 trials (2599 women) using different modalities of inhaled analgesia for pain management in labour for our meta-analyses. In three studies (62;65;69), data could not be included in the meta-analyses. In one study, data were not reported in a form that could be included in the meta-analyses (only in figures) (69). In two studies, the data are limited in the translation of the papers, which were not published in English (62;65). We included only the data of the first period before the first cross over for one cross-over trial, because the data from the second and third periods were incomplete (73). This study was analysed as if the trial was a parallel group study design. We used the data from the whole of each intervention period for four cross-over studies (67;71;73;74) and analysed the data as if it were from a parallel study. We did not combine results from parallel and cross-over studies in the analyses, but analysed these separately.

1) Inhaled analgesia nitrous oxide versus a different type of inhaled analgesia (flurane derivatives)

Primary outcomes

Effects of interventions

1.1) Pain intensity

Pain intensity was measured using a VAS from 0 to 100 mm, where 0 corresponds to no pain at all and 100 corresponds to the worst pain. Measurements were taken during the first stage of labour (until pushing occurred) and the data were reported as continuous data. Three studies with 123 measurements of 70 women (Analysis 1.1) reported on this outcome. The three studies were all cross-over trials with an adequate wash-out period of minimum of four exhalations. No period effect was present, because the trials started in active labour with regular contractions to 4 cm dilatation, during a period of three to five consecutive contractions (71;72) to one hour (73). We could not analyse the outcomes for the first period, before the first cross-over took place, because only one study gave the individual patient data after correspondence with the trialist (73). The other two studies did not report on this first period and we did not succeed in contacting the trialist for the original data (71;72). The data for a paired analysis were not available. We decided to analyse the studies conservatively, as if the trials had a parallel group design, thereby under-estimating rather than over-estimating any differences between interventions.

There was substantial heterogeneity indicated by the I^2 statistics ($Tau^2 = 32.85$, $I^2 = 42\%$) and therefore we applied a random-effects model. The flurane derivatives group reported a lower intensity of pain compared with the nitrous oxide group (average mean difference (MD) 14.39, 95% confidence interval (CI) 4.41 to 24.37), Analysis 1.1.

1.2) Pain relief

Pain relief was measured using a VAS from 0 to 100 mm in the first stage of labour where 100 means the most relief. The highest score is the most positive contrary to 'pain intensity' in which the higher scores is more negative. Continuous data on pain relief of women in the first stage of labour were reported from two cross-over trials with 158 measurements of 70 women (Analysis 1.2). The two studies were both cross-over trials with no data available to use for paired analysis. We also decided to analyse these studies

in the conservative way. There was substantial heterogeneity indicated by the I^2 statistics (Tau^2 = 24.42, I^2 = 40%) and therefore, we applied a random-effects model. The Flurane derivatives group reported better pain relief compared with the nitrous oxide group (average MD -16.32, 95% CI -26.85 to -5.79).

1.3) Satisfaction with pain relief

Satisfaction with pain relief scores assesses to what extent women are satisfied with the form of pain relief, rather than scoring the extent of pain itself. Satisfaction of pain relief was measured during the first and second stages of labour as considerable to complete and reported as dichotomous data. A considerable to complete score means the women were satisfied with the amount of pain relief. It was reported in two studies with 98 women (Analysis 1.3). There was no difference in satisfaction with pain relief for women receiving methoxyflurane (continuous (mean 0.22%) or intermittent (0.35%)) compared with women receiving nitrous oxide (continuous (41.2%) or intermittent (50%)) (risk ratio (RR) 0.97, 95% CI 0.80 to 1.18).

1.4) Satisfaction with pain relief

This was measured during the second stage of labour as good to excellent and was reported in four studies with 323 women (Analysis 1.4). A good to excellent score means the women were satisfied with the amount of pain relief.There was no difference in satisfaction with pain relief for women receiving nitrous oxide (self-administered, intermittent or continuous) compared with women receiving an agent from the flurane derivatives group (self-administered or continuous) (RR 0.89, 95% CI 0.78 to 1.01).

No trials reported on the following outcomes: sense of control in labour and satisfaction with childbirth experience.

Safety of interventions

1.5) Assisted vaginal birth (vacuum extraction or forceps)

There were no differences in assisted vaginal births between women receiving nitrous oxide and those receiving a flurane derivative (average RR 0.71, 95% CI 0.44 to 1.15). All the trials were conducted in the second stage of labour.

1.9) Nausea

Nausea in women, which was scored as a dichotomous outcome, was reported in two trials with 98 women (Analysis 1.9). The nitrous oxide group reported

more nausea compared with the flurane derivatives group (RR 6.60, 95% CI 1.85 to 23.52).

For the professional
No trials reported on differences in occupational exposure and toxic effects on reproduction for the professional.

4) Inhaled analgesia versus placebo control/no treatment
Primary outcomes

Effects of interventions
4.1) Pain intensity (dichotomous)
Pain intensity during the first stage of labour reported as clear or severe to intense or extreme was reported in two studies with 310 women (Analysis 4.1). There was substantial heterogeneity indicated by the I^2 statistics (I^2 = 51%, Tau^2 = 1.08) and therefore we applied a random-effects model. The inhaled analgesia group of nitrous oxide 30% to 50% reported less pain compared with the control (O2 100%) or no treatment group (average RR 0.06, 95% CI 0.01 to 0.34).

4.2) Pain intensity (continuous)
Pain intensity in the first stage of labour reported with the VAS (VAS, 0-10) after one hour was reported in one study with 509 women (Analysis 4.2). The study compared nitrous oxide 50% versus oxide 50%. The nitrous oxide group reported less pain compared with the oxide group (MD -3.50, 95% CI -3.75 to -3.25).

Safety of interventions
4.5) Vomiting
Vomiting, which was scored as a dichotomous outcome, was reported in two studies with 619 women (Analysis 4.5). The studies compared nitrous oxide 30% to 50% versus oxide 50% to 100%. The nitrous oxide group reported more vomiting compared with the oxide group (RR 9.05, 95% CI 1.18 to 69.32).

4.6 - 4.7 - 4.8) Nausea, dizziness and drowsiness
Dichotomous data on nausea, dizziness and drowsiness were reported in one study with 509 women (Analysis 4.6, Analysis 4.7, Analysis 4.8).The study compared nitrous oxide 50% versus oxygen 50%. The nitrous oxide group reported significantly more nausea (RR 43.10, 95% CI 2.63 to 706.74), dizziness

(RR 113.98, 95% CI 7.09 to 1833.69) and drowsiness (RR 77.59, 95% CI 4.80 to 1254.96) compared with the oxygen group.

Discussion

Summary of main results

This review demonstrated that women in labour using flurane derivatives as inhaled analgesia during the first stage of labour reported better pain relief and less intense pain than nitrous oxide, and reported less nausea. However, these findings should be considered with caution because of the way we analysed the data from the cross-over studies. The cross-over studies did not provide data in the form of a correct paired analysis. We were therefore only able to include data in meta-analyses from the whole of each intervention period for four of the studies (67;71;72;74) and from the first period before cross-over for one study (73). We therefore analysed the data from the cross-over studies as if they were parallel group trials. The results for flurane derivatives are based on data from 13 studies. However, there was a high level of heterogeneity for the analyses of pain relief and for intensity of pain, and so these results should also be examined with caution. Although we reported on drowsiness with regards to safety of the intervention, we also know that drowsiness is often seen as a beneficial side effect.

This review also demonstrated that women reported less pain intensity for intermittent (self-administered) nitrous oxide 50% when compared to no analgesia, during the first stage of labour and less intense pain intensity for intermittent (self-administered) nitrous oxide 50% when compared to oxygen 50% in the first stage of labour. More vomiting was observed with intermittent (self-administered) nitrous oxide 30% to 50% when compared to oxygen 50% to 100%, and more nausea, dizziness and drowsiness was observed with intermittent (self-administered) nitrous oxide 50% when compared to oxygen 50%. These results are based on data from three studies. There was a high level of heterogeneity for the analysis of pain intensity for nitrous oxide 50% versus no analgesia. Therefore, this result should also be examined with caution.

There were no significant differences found for any of the outcomes in the studies comparing one strength versus a different strength of inhaled analgesia, in studies comparing different delivery systems or in the study comparing inhaled analgesia with TENS.

All these conclusions need to be considered in the context of small sample sizes (range 27 to 320); only three trials achieved a sample size of more than 200; blinding to the intervention was hardly possible in many studies, due to the smell of the agent; and many outcomes were only considered in one or two trials in specific groups of comparison. These factors limit the interpretation of the results. A sensitivity analysis was planned in order to explore the impact of excluding the cross-over trials, assessed as being at a high risk of bias for the item 'correct analysis for cross-over design used', to see if this would make a difference to the overall results. We could not perform this analysis for 'pain intensity' or 'pain relief' because these analyses only included cross-over trials and all of these were at high risk of bias for 'correct analysis for cross-over design used.' The majority of cross-over trials were analysed as if they were parallel group trials, using the data from the overall outcome of the intervention versus the overall outcome of the comparison agent. This statistical method is at high risk of bias due to the conservative way, that studies are under weighted rather than over weighted (44).

Overall completeness and applicability of evidence

The completeness and applicability of the evidence is limited from the 26 included trials, with no trial at a low risk of bias on all domains. A weakness of a number of the trials is the inclusion of relatively few outcomes and for all trials omission of clinical safety outcomes for the professional. Although almost all participants across the included trials were considered at low risk of complications because of the following exclusion criteria within the individual trials: major uterine abnormalities, multiple gestation, cardiovascular or respiratory instability and acute or chronic obstetric pathologies such as pre-eclampsia and mostly participants in spontaneous labour, one trial explicitly included nulliparous with induced labour in the second part of the study, which was randomized (70). This trial is the only trial in the comparison group 'Inhaled analgesia versus TENS' and therefore, it was not possible to assess for subgroup differences. There were also no significant differences found between inhaled analgesia of nitrous oxide 50% and TENS for the two outcomes analysed. In 19% of the trials prior or additional use of other analgesia was an exclusion criteria (8;61;69;70;72). In 50% of the trials additional or prior use of other analgesia was unclear (50;51;54;55;57;60;62;64; 65-67;73;74). In 31% of the trials prior or additional use of other analgesia was available and used by the participants but not controlled for in the analysis of the effect estimate. Due to the fact that use of other analgesia can influence women's perception of the use of inhaled analgesia, results must be taken with caution.

The findings of this review may not be applicable to current practice due to the differences in obstetric care in different countries worldwide, especially for low-risk women. Nitrous oxide is relatively inexpensive, has no pungent smell and is easy to administer by the women themselves with the right equipment and circumstances. It can also be used in primary care which means labouring women under supervision of primary care midwives or general practitioners. These births can take place either in a hospital, in a birthing centre or at home.

Inhaled analgesia from the flurane derivatives are also relatively inexpensive depending on which agent is used. They may be more expensive if the agent still has a patent. However, administration of these agents needs to be controlled by a well-trained anaesthesia professional in order to ensure the right concentration of the agent and thus prevent unconsciousness or other administration problems. This is probably the main reason why use of flurane derivatives is not widespread and also why little research is done on this form of inhaled analgesia for the management of labour pain.

Quality of the evidence

The 'Risk of bias' tables (Figure 1; Figure 2) demonstrate that inhaled analgesia has not been consistently subjected to consistent rigorous study. The quality of reporting was poor in over 50% of trials. The risk of bias was low in respect of randomisation (27% and 11%). In all the other trials randomisation was unclear. Not one trial was rated at a low risk of bias on all domains.

Potential biases in the review process

We attempted to minimise publication bias. The search was comprehensive and there were no language restrictions. However, some of the articles were in Chinese and Iranian, and although these were translated, it is not possible to rule out the possibility of missed data.

Agreements and disagreements with other studies or reviews

There is no other systematic review with meta-analysis of inhaled analgesia. Nevertheless, there is one other systematic review without meta-analysis of nitrous oxide as inhaled analgesia for relief of labour pain (3). This study of Rosen (2002) suggests that inhaled analgesia offers safe, reasonably effective pain relief for many women. However, our review also highlights some of the adverse effects

(such as nausea and drowsiness) associated with some types of inhaled analgesia such as nitrous oxide with our meta-analysis.

Authors' conclusions

Implications for practice

Despite limitations in the 'Risk of bias' assessment of the randomised clinical trials with regards to trial design and representation of the results in the papers, the statistically significant results for reduction in pain intensity and increase in pain relief indicates that inhaled analgesia may be a useful form of pain management for some women in labour. Inhaled analgesia may be beneficial for those women in labour who want to have some form of pharmacological pain relief, without invasive methods. It was not possible to draw any conclusions in relation to poorer outcomes for the newborns or the mothers due to a paucity of evidence.

Implications for research

Further randomised controlled trials should be adequately powered and include relevant clinical outcomes as described in this review especially for three primary outcomes: 1) sense of control in labour and 2) satisfaction with childbirth and 3) breastfeeding experience of women. Particularly studies without the confounding factor of co-administration of other analgesia, would be very helpful.

Characteristics of included studies

Abboud 1981

Methods	Randomised control trial conducted in Department of Obstetrical Anesthesia, University of Southern California, Los Angeles, California, USA.
Participants	105 participants, 50 in the experimental group and 55 in the controls. Inclusion criteria: healthy parturients undergoing normal delivery.
Interventions	Experimental group received continuous 30% to 60% N2O titrated by an anaesthesiologist, while control group received continuous Enflurane 0.25% to 1.25% based on anaesthesiologist titration, mean 0.5%, both during second stage of labour.
Outcomes	Satisfactory pain relief and use again for future delivery, Total blood loss, fluoride levels serum and urine, Apgar score, cord blood gases, values for biochemical findings in maternal blood and urine and in neonatal urine.
Notes	Not controlled for concurrent or prior use other analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly assigned.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias)	Low risk	Participant and clinician are both unaware of which drug is administered.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias)	Low risk	None.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Unclear risk	Both groups comparable but not controlled for prior or concurrent use of other analgesia.
Correct analyses for cross-over design used	Low risk	Not cross-over design.

Abboud 1995

Methods	Randomised control trial conducted in Department of Anesthesiology, Los Angeles County and University of Southern California Medical Center, Los Angeles, California, USA.
Participants	80 participants, 40 in each group. Inclusion criteria: healthy parturients undergoing normal vaginal delivery. Exclusion criteria: any clinical significant history of gastrointestinal hepatic, renal, endocrine or respiratory disease, convulsive or neurological disorder, fetal distress, any history of chronic alcohol or drug use.
Interventions	Experimental group received Desflurane 1% to 4.5% and oxygen during second stage of labour, while control group received nitrous oxide, 30% to 60% oxygen during second stage of labour.
Outcomes	Patient, anaesthesiologist and obstetrician assessment of quality of pain relief. Patient willingness to receive again the same agent. Blood loss estimated the obstetrician, Apgar score at 1 and 5 minutes, cord acid base status and NASC at 2 and 24 hours of age of the baby, Hb, Ht, before use of analgesia and after 12 and 24 hours postpartum, osmolality and sodium ion concentrations of urine of the mother at the same time postpartum.
Notes	No information regarding concurrent or prior use of analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly assigned using computer generated randomisation table
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias)	Low risk	Patient, obstetrician and paediatrician unaware of drug.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias)	Low risk	None.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Unclear risk	Both groups comparable but not controlled for prior or concurrent use of other analgesia.
Correct analyses for cross-over design used	Low risk	Not cross-over design.

Arora 1992

Methods	Single cross-over study conducted in Department of Anaesthetics, Aberdeen Royal Infirmary, Foresterhill, Aberdeen, UK.
Participants	39 participants, 20 in the experiment group and 19 in the controls. Inclusion criteria: patients in normal labour with regular painful uterine contractions who required inhalation analgesia.
Interventions	Experimental group received Entonox-isoflurane 0.25%, while control group received Entonox (50% nitrous oxide premixed in oxygen) in first stage of labour during 5 consecutive contractions.
Outcomes	Pain relief, patient's responsiveness, patient's cooperation, reaction to odour and any adverse effects.
Notes	6th contraction wash-out period with room air (supposed to be minimal 4 exhalation). Afterwards trial there was use of other anaesthetics during labour. No information regarding concurrent or prior use of analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number sequence.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias)	Unclear risk	The Oxford Miniature Vaporizer (OMV) was concealed in a box from the view of both investigator and mother but 1 agent has a particular smell (blinding not possible), unclea
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias)	Low risk	2 women, unable to come to any decision on a linear analogue scale scores for pain relief.
Selective reporting (reporting bias)	High risk	Baby outcomes not clear.
Other bias	Unclear risk	None apparent but not controlled for prior or concurrent use of other analgesia.
Correct analyses for cross-over design used	High risk	Paired samples using Wilcoxon Rank Sum Test but mean/SD for experimental intervention alone and control (intervention) alone, not possible to extract paired data

Arthurs 1979

Methods	This trial was conducted in Maelor General Hospital, Wrexham, UK. 3 studies were conducted in this trial: Kinetic studies: observational study, the expired concentration of nitrous oxide was measured and recorded continuously with a mass spectrometer to measure the maximum concentrations and the end-tidal nitrous oxide concentration and its effects on mothers and babies. Within patient studies: observational study to measure patient preference. Between patient studies: randomised trial, comparing self-administration of Entonox with a nasal supplement of Entonox with self-administration of Entonox with no nasal supplement for the evaluation of pain, mothers opinion, midwives opinion, acceptability of nasal catheter and maximum tolerable flow.
Participants	49 participants 24 in the study group and 25 in the control group.
Interventions	Experiment group received self-administered Entonox and continuous nasal supplement of Entonox and controls received self-administered Entonox and no continuous nasal inhalation, probably during first and second stage of labour ("recording until delivery").
Outcomes	Pain on linear analogue after 2, 4, 6 contractions, pain rated immediately after delivery and between 24 and 48 hours later, how much inhalation helped, satisfaction with pain relief (memory of pain in labour), nausea and vomiting, caesarean section, Apgar score – mean at 1 and 5 minutes, pain relief as assessed by midwives.
Notes	Only data from between patient studies used in this review. Opiods also available.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly allocated
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported.
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported.
Selective reporting (reporting bias)	High risk	Pain data after 6 contractions and immediately after delivery not reported.
Other bias	Unclear risk	Baseline characteristics seems comparable but other opioids also available and no information of the use of these other analgesia.
Correct analyses for cross-over design used	Low risk	Not cross-over design.

Belfrage 1974

Methods	Randomised trial conducted in Karolinska Sjukhuset Hospital, Stockholm, Sweden.
Participants	98 participants, 47 in the experiment group and 51 in the control group.
Interventions	Experiment group received 0.3% to 0.8% of Methoxyflurane and controls received nitrous oxide 70% with 30% oxygen in second stage of labour.
Outcomes	Pain scores, assisted vaginal birth, caesarean section.
Notes	Concurrent or prior use of pethidine.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Women were randomly divided into 2 groups.
Allocation concealment (selection bias)	Unclear risk	Women were randomly divided into 2 groups
Blinding of participants and personnel (performance bias)	High risk	Not blinded.
Blinding of outcome assessment (detection bias)	High risk	Not blinded.
Incomplete outcome data (attrition bias)	Unclear risk	Unclear from translation.
Selective reporting (reporting bias)	Unclear risk	Unclear from translation
Other bias	Unclear risk	No baseline characteristics and concurrent use of pethidine in both groups.
Correct analyses for cross-over design used	Low risk	Not cross-over design.

Bergsjo 1971

Methods	Randomised single cross-over trial conducted in Aker Hospital Oslo, Norway.
Participants	63 participants, 26 in the experiment group and 37 in the control group. Inclusion criteria: women in established labour with obvious pain and expected labour to be normal. Exclusion criteria: history of liver and kidney disease
Interventions	Experimental group received Nitrous oxide mixed with oxygen in 50% concentration inhaled intermittent, followed by methoxyflurane, while control group received first 0.5% to 0.8% methoxyflurane, inhaled intermittent, followed by nitrous oxide/oxygen 50% in first stage of labour during 3 consecutive contractions
Outcomes	Drug of preference, degree of analgesic effect, unpleasant subjective side effects, other side effects scored by observer, Apgar scores, total labour time and additional drugs needed after the trial stopped
Notes	A wash-out period of 1 contraction with air breathing. Concurrent or prior use of opioids or diazepam

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A list of random numbers
Allocation concealment (selection bias)	Low risk	List of random numbers to decide in which order the drugs are given owned by office personnel, not seen by the doctors.
Blinding of participants and personnel (performance bias)	High risk	Entonox is inhaled through anaesthetic face masks working by inhaled flow, and methoxyflurane is inhaled by a specially made Analgizer which is a cylindrical tube with a mouthpiece.
Blinding of outcome assessment (detection bias)	High risk	Entonox is inhaled through anaesthetic face masks working by inhaled flow, and methoxyflurane is inhaled by a specially made Analgizer which is a cylindrical tube with a mouthpiece
Incomplete outcome data (attrition bias)	Low risk	3 participants did not scored their preference
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon
Other bias	Unclear risk	1 group older, but should have no impact on results, prior or concurrent use of opioids or diazepam.
Correct analyses for cross-over design used	Unclear risk	Single cross-over design.

Carstoniu 1994

Methods	Single cross-over randomised trial conducted in Toronto Hospital, Toronto, Ontario, Canada.
Participants	26 participants, 14 in the experimental group and 12 controls. Exclusion criteria: age < 18 years, maternal cardiorespiratory disease, fetal distress, any condition affecting the accuracy of pulse oximetry or the use of opioids or regional anaesthesia
Interventions	Experimental group received self-administered 50% nitrous oxide and oxygen for 5 consecutive contractions. For the next 5 contractions compressed air was self-administered. Control group received same gases in reverse order. Used in first stage of labour.
Outcomes	VAS pain scores, the lowest Spo2 (maternal haemoglobin oxygen saturation) observed after a contraction, ability correctly to identify the order of the gases in the 2 groups, only reported in figures.
Notes	No wash-out period (comparison with compressed air). No concurrent or prior use of other analgesia

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Low risk	Numbered sealed envelopes.
Blinding of participants and personnel (performance bias)	Unclear risk	Valves hidden from participants but nurses are the ones hiding it and who open randomisation envelope.
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias)	High risk	3 participants excluded for not completing the trial
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Other bias	Low risk	Both groups comparable.
Correct analyses for cross-over design used	Unclear risk	Data for paired groups only in figures, not possible to extract paired data

Cheng 2001

Methods	Randomised controlled trial conducted in Third Affiliated Hospital, Henan Medical University, Zhengzhou, China.
Participants	75 participants, 25 in each group. Inclusion criteria: healthy full term 22-30 years old singleton vertex presentation primipara.
Interventions	Group 1 received isoflurane 0.2% to 0.75% and oxygen. Group 2 received nitrous oxide 30% to 50% and oxygen. Group 3 – controls – received air.
Outcomes	Pain intensity – effectiveness of inhalation analgesia, duration of each stage of labour, mode of delivery, postpartum haemorrhage, gas analysis of neonatal umbilical artery and vein, Apgar score and NACS.
Notes	Concurrent or prior use of other analgesia not known.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomly.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	Semi-closed anaesthetic method.
Blinding of outcome assessment (detection bias)	Unclear risk	Semi-closed anaesthetic method.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported.
Selective reporting (reporting bias)	High risk	Data on pain intensity and mode of delivery reported upon in another article which was not referenced.
Other bias	Unclear risk	No baseline characteristics and prior or concurrent use of other analgesia unknown
Correct analyses for cross-over design used	Low risk	Not cross-over design.

Chia 1990

Methods	This study was conducted in National University Hospital, Singapore in 2 parts. Part I is a quasi-randomised trial and part II is a cross-over trial, first period data available.
Participants	20 participants, 10 in each group. Inclusion criteria were nulliparous who were to have surgical induction of labour and exclusion criteria included desire for epidural analgesia, in advanced labour or given any other form of analgesia.
Interventions	Group C received TENS and group D received Entonox (a switch over of the modes of pain relief was made when labour pain was no longer tolerable; patient using TENS was commenced on Entonox and vice versa). Any use of wash-out time or time indication of switch-over period not reported.
Outcomes	Pain intensity, satisfaction with pain relief (nil, partial, complete), birthweight admission to NICU and Apgar score.
Notes	Only data from part II trial used in this review. Any information of wash-out period is not reported. No prior or concurrent use of other analgesia (excluded)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised.
Allocation concealment (selection bias)	Low risk	randomly allocated by use of sealed envelopes.
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported.
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported.
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Other bias	Low risk	Both groups are comparable, no use of other analgesia.
Correct analyses for cross-over design used	Low risk	Only use of part II, this part is a randomised controlled trial (parallel groups).

Einarsson 1996

Methods	Randomised controlled trial conducted in Dept Obstetrics and Gynaecology, Sahlgrenska University Hospital, Sweden.
Participants	24 participants, 12 in each group. Inclusion criteria: women undergoing vaginal delivery. Exclusion criteria: maternal cardiorespiratory disease, pre-eclampsia, any evidence of fetal distress or used opioid or regional analgesia.
Interventions	Experimental group received 50% nitrous oxide and control group received 70% nitrous oxide.
Outcomes	Inspiratory and end-tidal (E') concentrations of carbon dioxide (CO_2), oxygen and nitrous oxide, pulse oximetry (Spo_2) respiratory rate, tidal volume and expiratory minute ventilation volume (V_E).
Notes	No information regarding use of prior or concurrent other analgesia, but presumably not because intervention started when women first requested analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Allocated randomly.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported.
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias)	Low risk	No loss.
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Other bias	Unclear risk	Both groups comparable but no information of use of other analgesia.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Enrile 1973

Methods	Randomised controlled trial conducted in Cleveland Metropolitan General Hospital, Cleveland, Ohio, USA.
Participants	26 participants, 14 in the experiment group and 12 in the controls. Inclusion criteria: American Society of Anaesthesiologists classification of physical status (ASA) Class 1 or 2.
Interventions	Both groups received Methoxyflurane but the experiment group used Analgizer while controls used Cyprane Inhaler.
Outcomes	Cord blood PH, Methoxyflurane concentration in maternal blood, Apgar score (2 missing in Cyprane group), orientation, motor co-ordination, level of analgesia, level of amnesia, caesarean section, satisfaction with analgesia, nausea and vomiting.
Notes	Inhaler and pudendal block possible (7p in Cyprane, 7p in Penthrane), and spinal (3p in Cyprane, 5p in Penthrane).

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation table.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias)	High risk	Not reported but both delivery systems completely different from each other.
Blinding of outcome assessment (detection bias)	High risk	Not reported but both delivery systems completely different from each other.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported. 2 missing in Cyprane group for Apgar score is less than 20% (low risk of bias).
Selective reporting (reporting bias)	High risk	Some of outcomes incompletely reported upon –results reported for only 1 of the groups, e.g. evaluation of pain, satisfaction pain relief, nausea and vomiting.
Other bias	High risk	The patients utilising a mask attached to the analgizer obtained better pain relief than those using the analgizer without a mask because the diluter hole in the analgizer was left open during administration resulting in a lower concentration of Methoxyflurane available for inhalation.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Ji 2002

Methods	Randomised controlled trial conducted in Qingdao Municipal Hospital, Qingdao, China. From January 2001 to November 2001.
Participants	300 participants, 100 in each arm. Inclusion criteria: primiparous with single fetus, no significant cephalopelvic disproportion, with no contraindications to anaesthesia.
Interventions	Group 1 received combined spinal epidural analgesia. Group 2 received 50% nitrous oxide and 50% oxygen, at a rate of 0-15 L every minute. Controls received no treatment.
Outcomes	Analgesic effect, duration of labour, method of delivery, postpartum bleeding, rate of newborn anoxia, maternal radial artery blood for blood gas analysis and fetal umbilical blood for blood gas analysis.
Notes	Only data from group 2 (nitrous oxide) versus control included in this review. Control group did not receive any analgesia, no information regarding prior or concurrent use of other analgesia in nitrous oxide group.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated as per translation.
Allocation concealment (selection bias)	Unclear risk	Not stated as per translation.
Blinding of participants and personnel (performance bias)	Unclear risk	Not stated as per translation.
Blinding of outcome assessment (detection bias)	Unclear risk	Not stated as per translation
Incomplete outcome data (attrition bias)	Unclear risk	Not stated as per translation.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	High risk	No baseline characteristics, no information of use of other analgesia in nitrous oxide group.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Jones 1969

Methods	Randomised control trial conducted in Department of Anaesthetics, Royal Infirmary, Cardiff, UK.
Participants	48 participants, 24 in each group. Inclusion criteria: normal labour. Exclusion criteria: received instruction in psychoprophylaxis or hypnosis.
Interventions	Experimental group received methoxyflurane continuous, while control group received nitrous oxide continuous.
Outcomes	Efficacy assessment by 4-point scale just after delivery, nausea during labour (intrapartum or first 24 hours), vomiting, dreams and Apgar score 1 minute.
Notes	Prior use of pethidine in the 4 hours preceding the beginning of inhalation (11p N2O-group, 14p meth.-group),

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random basis.
Allocation concealment (selection bias)	Unclear risk	Random basis.
Blinding of participants and personnel (performance bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias)	High risk	2 mothers not questioned after birth because of stress (abnormal child and severe nausea and vomiting.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Unclear risk	Both groups comparable but use of pethidine as analgesia prior.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Jones 1969a

Methods	Randomised control trial conducted in Department of Anaesthetics, Royal Infirmary, Cardiff, UK.
Participants	50 participants, 25 in each group. Inclusion criteria: normal labour. Exclusion criteria: received instruction in psychoprophylaxis or hypnosis.
Interventions	Experimental group received self-administered intermittent N2O 50%, while control group received self-administered intermittent methoxyflurane 0.35%.
Outcomes	Assessment of efficacy by 4-point scale just after delivery, nausea, vomiting, hazy memory, noted the smell of the gas, dreams, numbness or buzzing in the ears or 'pins and needles', Apgar score 1, 2, 5 and 10 minutes.
Notes	Concurrent or prior use of pethidine (64% meth. group, 68% N2O group).

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random basis.
Allocation concealment (selection bias)	Unclear risk	Random basis.
Blinding of participants and personnel (performance bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias)	Low risk	None.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Low risk	Both groups comparable (also comparable in prior use of pethidine).
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

McGuinness 1984

Methods	Randomised cross-over trial conducted in Department of Anaesthetics, University Hospital of Wales, Heath Park, Cardiff, UK.
Participants	20 participants, 20 measurements for each intervention, total 40 measurements. Inclusion criteria: fit women who were in early normal labour
Interventions	Experimental group received enflurane during 3 consecutive contractions (no wash-out time used), while control group received Entonox (50% N2O and 50% O2) during 3 consecutive contractions.
Outcomes	Pain assessment with linear analogue scale, drowsiness and nausea by linear analogue scale.
Notes	No wash-out time between agents. Concurrent or prior use of opioids before or during use of N2O

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Randomly given 1 of the analgesic agents. Not described how.
Blinding of participants and personnel (performance bias)	Unclear risk	The orientation of the tap (agents delivered via the same tubing and mouthpiece) was concealed from the operator. Different odour of agents, not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias)	Low risk	None.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Unclear risk	Both groups comparable, prior or concurrent use of pethidine in 1 group.
Correct analyses for cross-over design used	High risk	Linear analogues scales were compared with the Wilcoxon matched-pairs signed-rank test, but no data of individual patients. Overall median/range of experimental group and comparison group separately, not possible to extract paired data.

McLeod 1985

Methods	Randomised cross-over trial conducted in Department of Anaesthetics, Aberdeen Royal Infirmary, Foresterhill, Aberdeen, UK.
Participants	32 participants with 31 measurements of entonox and 31 measurements of isoflurane. Inclusion criteria: in ASA 1 group (completely healthy patient), in normal established labour, requiring analgesia. Exclusion criteria: receiving any other analgesic or sedative agent during labour.
Interventions	Experimental group received Isoflurane 0.75% during 5 consecutive contractions in first stage of labour (with a break of 2 contractions to allow of elimination of the first agent), while control group received nitrous oxide during 5 consecutive contractions in first stage of labour.
Outcomes	Linear analogue scores for pain measured before starting the trial (0 point) and after each contraction, drowsiness measured after the 5 contractions of each agent, comment of both analgesics and patients preference after delivery.
Notes	Wash-out period of 2 contractions. No concurrent or prior use of opioids (were excluded). Total 31 measurements of Entonox and total 31 measurements of Isoflurane, in total 62 measurements, unknown why not 64 measurements, probably one women did not completed the study.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Randomized', not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias)	Low risk	1 because of smell of isoflurane.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Low risk	Both groups comparable.
Correct analyses for cross-over design used	High risk	Pain scores were compared using the Wilcoxon rank sum test for paired samples but no data of individual patients. Overall mean/range of experimental and comparison group separately, not possible to extract paired data.

MRC 1970

Methods	Randomised trial conducted in 7 hospitals: Aberdeen Maternity Hospital, Cardiff Royal Infirmary and Maternity Hospital, Simpson Memorial Maternity Pavilion (Edinburgh), Hammersmith Hospital, Kingsbury Maternity Hospital, Kingston Hospital and Westminster Hospital.
Participants	601 participants, 259 in the experiment group and 242 in the control group. Exclusion criteria: multiple birth expected or if special delivery procedures were likely to be needed.
Interventions	Experimental group received intermittent 50% nitrous oxide, while control group received intermittent 70 % nitrous oxide.
Outcomes	Pain assessment, drowsiness and nausea, dreams, side effects.
Notes	No information regarding concurrent or prior use of other analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias)	High risk	21 were excluded from the initial analysis, 12 because they had given birth to twins and 9 because the information on the forms was incomplete. Also 277 cases were excluded from the main analysis, some being rejected for more than 1 reason.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Unclear risk	Both groups comparable but no information of prior or concurrent use of other analgesia.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Rezaeipour 2008

Methods	Randomised controlled trial conducted in Orumieh Hospital, Tehran, Iran.
Participants	155 participants, 78 in the experiment group and 77 in the control group. Inclusion criteria: primipara, 18-35 years of age, not have used any anaesthesia, not for inducing labour. With no restrictions in using Entonox (due to respiratory problems, pneumothorax, and trauma to the head in the past) and have dilated 4 cm. Exclusion criteria: any complications during labour and delivery and the need to induce labour.
Interventions	Experiment group received Entonox while control group inhaled oxygen.
Outcomes	Pain as measured by VAS, mothers vital signs, fetal heart rate, Apgar score at 1 and 5 minutes, postpartum haemorrhage, mode of delivery, side effects for mother (drowsiness and mouth stiffness) and satisfaction with delivery.
Notes	No use of prior or concurrent other analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias)	Unclear risk	Single blinding.
Blinding of outcome assessment (detection bias)	Low risk	Single blinding.
Incomplete outcome data (attrition bias)	Low risk	2 women from the intervention (Entonox) group and 3 from the control group had to be excluded from the study due to the need for emergency caesarean sections.
Selective reporting (reporting bias)	Unclear risk	Not clear from translation.
Other bias	Unclear risk	No baseline characteristics.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Shao 2000

Methods	Randomised parallel study conducted from 20th May to 9th December 1998 in Zhejiang Yuyao People's Hospital, Yuyao, China.
Participants	250 participants, 125 in each group.
Interventions	Experiment group inhaled the laughing gas and control group no treatment.
Outcomes	Pain intensity (degree of labour pains), method of delivery, Apgar scores, intrapartum haemorrhage, postpartum haemorrhage, other side effects (mild dizziness, fatigue and sleepiness).
Notes	No information regarding other used analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated.
Allocation concealment (selection bias)	Unclear risk	No information as per translation.
Blinding of participants and personnel (performance bias)	Unclear risk	No information as per translation.
Blinding of outcome assessment (detection bias)	Unclear risk	No information as per translation.
Incomplete outcome data (attrition bias)	Unclear risk	No information as per translation.
Selective reporting (reporting bias)	Unclear risk	Can not tell completely from the translation.
Other bias	Unclear risk	No information as per translation, no information of use of other analgesia.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Stefani 1982

Methods	Randomised control trial conducted in University Hospital Southern California, USA.
Participants	61 participants, 22 in the experiment group1, 18 in the experiment group 2 and 21 in the controls. Inclusion criteria: healthy full-term parturients.
Interventions	Experimental group 1 received enflurane 0.3% to 0.8%, experimental group 2 received nitrous oxide (30% to 50%), while control group received no treatment.
Outcomes	NACS using the Early Neurobehavioral Scale, satisfactory pain relief.
Notes	Concurrent or prior use of other analgesia: 50% to 41% received no narcotics, the other group received small doses of opioids, 66% pudendal block.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Assigned randomly.
Allocation concealment (selection bias)	Unclear risk	Assigned randomly.
Blinding of participants and personnel (performance bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Low risk	"Two examiners, blind to both the nature and duration of analgesia simultaneously evaluated and scored the neuro behavioural status of infants."
Incomplete outcome data (attrition bias)	Low risk	None.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Low risk	Both groups comparable and use of other analgesia in both groups seems similar.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Swart 1991

Methods	Randomised trial conducted in Department of Anesthesiology, Los Angeles County - University of southern California Medical Centre, Los Angeles, California, USA.
Participants	60 participants, 30 in each group
Interventions	Experimental group received desflurane 1% to 4.5% and oxygen while control group received nitrous oxide 30% to 60% and oxygen.
Outcomes	Analgesia assessment, blood loss, Apgar score, blood acidity and NACS.
Notes	Abstract (poster session) only - data limited. No information regarding concurrent or prior use of other analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly assigned.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias)	Low risk	Both patient and obstetrician did not know the gas.
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported.
Selective reporting (reporting bias)	Unclear risk	There is insufficient information about the numerical results in the abstract.
Other bias	Unclear risk	Groups characteristics not reported in the abstract.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Talebi 2009

Methods	Randomised control trial conducted from September 2004 to 2006 in Department of Anaesthesiology, Arak University Hospital, Arak, Iran.
Participants	534 ASA I and II parturients, 260 in experimental group and 249 in control group. Inclusion criteria: scheduled for elective labour, term (38-42 weeks) in active stage of labour (dilation more then 4 cm). Exclusion criteria: any evidence of fetal distress, or abnormal fetal heart pattern, maternal cardiorespiratory disease or any condition effecting the accuracy of pulse oximetry, history of taking opioids, administrations of sedation or regional analgesia (pudendal block, local infiltration), intolerance of Entonox, during trial when birth ended in caesarean section or forceps.
Interventions	Experimental group received self-administration of pre-prepared mixture of 50% nitrous oxide and oxygen started as early as the onset of pain with each contraction (when patient first requested analgesia), while control group received self-administration of 50% oxygen as early as the onset of pain with each contraction.
Outcomes	Pain scores of contractions by VAS (time at the start of inhaled analgesia and every hour from time 1 to 5), the lowest spO2 (by pulse oxymeter) and mean arterial blood pressure of the mother, Apgar scores of 1 and 5 minutes postpartum. Side effect as nausea, vomiting dizziness, dry mouth from gas, pins and needles or numbness and drowsiness measured at the end of the study.
Notes	No concurrent or prior use of other analgesia (excluded).

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation with a coin.
Allocation concealment (selection bias)	Unclear risk	Randomisation with a coin.
Blinding of participants and personnel (performance bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Low risk	Participants rating of pain was recorded by someone blind to allocation, plus arterial pressure and Apgar score.
Incomplete outcome data (attrition bias)	Low risk	4 of 523 loss to follow-up. No patient excluded after randomisation. Intention to treat not known.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	High risk	More primipara in nitrous oxide group. This would be in favour of control group regarding pain.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Wang 1994

Methods	Randomised study conducted in The Third Affiliated Hospital of Henan Medical School, China.
Participants	84 participants, 34 in the experiment group and 50 controls.
Interventions	Experiment group received nitrous oxide and control group received no treatment.
Outcomes	Analgesic effects, respiratory and circulatory functions, uterine contractions, progress of labour, Apgar score and postpartum bleeding.
Notes	No information of prior or concurrent use of other analgesia.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported.
Selective reporting (reporting bias)	Unclear risk	Only the abstract translated.
Other bias	Unclear risk	Only the abstract translated.
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Wee 1993

Methods	Randomised cross-over trial conducted in St Michael's Hospital, Bristol, UK.
Participants	18 participants with 17 measurements of drowsiness and 18 measurements of pain intensity after 1 hour in first period before the first cross-over ended. Inclusion criteria: between 16 and 38 years old, in ASA grade 1, in normal labour and requesting inhalation analgesia (mothers were allowed to opt out if inhalational analgesia subsequently proved to be unsatisfactory).
Interventions	Experimental group received E-I-E sequence, mothers inhaled Entonox alone at the first hour, Entonox and 0.2% Isoflurane for the second and Entonox alone for the third hour, while control group received I-E-I sequence, mother inhaled Entonox and 0.2% isoflurane at the first hour, Entonox alone for the second and Entonox and 0.2% isoflurane for the third hour.
Outcomes	Pain and drowsiness assessment measured with VAS, baseline score before any inhalation, subsequently scores recorded at 20 minutes intervals, obtained as soon as possible after each contraction during the hour of 1 agent (intervention and comparison group), baby Apgar score 1 and 5 minutes. The differences in median scores in both groups between baseline and the first hour, the first and the second hour, the second and the third hour were calculated.
Notes	No information on wash-out period between agents but inhalation agent was used for 1 complete hour and efficacy was scored after 20 minutes. Moreover the inhalation gases were self-administered during contractions. This means that the minimal wash-out period of 4 exhalations must have passed during the pauses between contractions. Probably no prior or concurrent use of other analgesia because women were allowed to drop out if analgesia was not satisfactory. We used only data of the first period (measurements after 1 hour) with 18 participants and 11 measurements of Entonox use and 8 measurements of Isoflurane/Entonox use.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.

Incomplete outcome data (attrition bias)	Low risk	1 woman did not complete the study.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported upon.
Other bias	Unclear risk	Baseline not reported for the 2 groups, no information about other additional drugs.
Correct analyses for cross-over design used	High risk	Probably paired t-test in this trial (no information). Overall mean/SD for experimental and comparison groups separately calculated by individual data for first period after one hour, analysed as parallel group data.

Yeo 2007

Methods	Randomised, open label, double cross-over trial conducted in Anaesthetic Department, The County Hospital, Union Walk, Hereford, UK.
Participants	31 participants, 15 in the experiment group and 16 in the controls with 37 measurements of Entonox and 43 measurements of enflurane. Inclusion criteria: active labour (≥ 3 cm cervical dilatation) with contractions occurring at least 1 every 3 minutes, spontaneous or induced, ≥ 37 weeks' gestation with prior consent. Exclusion criteria: women who had no knowledge of the study before, major uterine abnormalities, multiple gestation, cardiovascular or respiratory instability, acute or chronic obstetric pathology and women who received any analgesia before recruited.
Interventions	Experimental group received Entonox/Sevoflurane 0.7%/Entonox (ESE), each agent during 10 contractions, while control group received Sevoflurane 0.7%/Entonox/Suvoflurane 0.7% (SES), each agent during 10 contractions. Between each agent a wash-over period of breathing room air during 1 contraction, participant could omit this wash-over period if they wished.
Outcomes	VAS of overall pain relief with each contraction, pain intensity, sedation, mood and coping before and after each of 10 contractions with a specific agent, inspired and expired gas concentration, maternal ventilator frequency, intermittent non invasive arterial pressure, heart rate and maternal arterial oxygen saturation, fetal heart rate and maternal contractions on cardiotocograph, type of analgesia used after trial, mode of delivery, and preferred agent scored within 48hours after delivery.
Notes	Between agent a wash-out period during 1 contraction, participant could omit this wash-over period if they wished (no information on numbers) but the agents were self-administered so probably there was a minimum of 4 exhalations between the 2 agents. No prior use of other analgesia before treatment (excluded), no information on concurrent use. We extracted 43 measurements with Enflurane and 37 measurements with Entonox.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'randomised.'
Allocation concealment (selection bias)	Unclear risk	'randomised.'
Blinding of participants and personnel (performance bias)	High risk	'open label.'
Blinding of outcome assessment (detection bias)	High risk	'open label.'

Incomplete outcome data (attrition bias)	High risk	2 women withdrew after the first contraction because of unpleasant odour of sevoflurane (preferred Entonox), 1 woman withdrew before inhalation of any administration (requested an epidural), these 3 women were not followed up because of the early withdrawal (before first cross-over). 5 withdrew because of requested epidural analgesia whilst in the Entonox phase of the study, 4 in the ESE group in the last phase using Entonox and 1 in the SES group, 2 withdrawals because of starting the second stage of labour before ending the trial
Selective reporting (reporting bias)	Low risk	Aall prespecified outcomes reported upon.
Other bias	Low risk	Both groups comparable and no use of other analgesia.
Correct analyses for cross-over design used	High risk	Overall pain relief scores of experimental and comparison groups separately.

Zhang 2001

Methods	Randomised study conducted in The Third Affiliated Hospital of Henan Medical School, China.
Participants	110 participants, 60 in the experimental group and 50 in the control group.
Interventions	Experiment group received 30% to 50% nitrous oxide and oxygen 5L/min while controls received only oxygen 5L/min.
Outcomes	Labour pain, mode of delivery, Apgar score, postpartum haemorrhage, vomiting and neonatal asphyxia.
Notes	Concurrent or prior use of other analgesia not reported.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly chosen.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported.
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	No loss.
Selective reporting (reporting bias)	High risk	Apgar score mentioned in abstract of study, but no results were reported within the results section of the paper.
Other bias	Unclear risk	Not clear
Correct analyses for cross-over design used	Low risk	Not cross-over trial.

Footnotes
ASA: American Society of Anaesthesiologists; NACS: neurologic and adaptive capacity score; NICU: neonatal intensive care unit, OMV; Oxford Miniature. Vaporizer
SD; standard deviation, VAS: visual analogue scale

Data and analyses

1 Nitrous oxide versus flurane derivatives

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Pain intensity (VAS 0-100 first stage)	3	70	Mean Difference(IV, Random, 95% CI)	14.39 [4.41, 24.37]
1.2 Pain relief (VAS 0-100 as 100 is the most pain relief, first stage)	2	70	Mean Difference(IV, Random, 95% CI)	-16.32 [-26.85, -5.79]
1.3 Satisfaction with pain relief (first and second stage, considerable to complete)	2	98	Risk Ratio(M-H, Fixed, 95% CI)	0.98 [0.80, 1.18]
1.4 Satisfaction with pain relief (second stage, good to excellent)	4	323	Risk Ratio(M-H, Fixed, 95% CI)	0.89 [0.78, 1.01]
1.5 Assisted vaginal birth	5	371	Risk Ratio(M-H, Random, 95% CI)	0.71 [0.44, 1.15]
1.6 Caesarean section	1	98	Risk Ratio(M-H, Fixed, 95% CI)	Not estimable
1.7 Amnesia	3	245	Risk Ratio(M-H, Random, 95% CI)	0.26 [0.03, 2.38]
1.8 Drowsiness (VAS 0-100 mm)	1	18	Mean Difference(IV, Fixed, 95% CI)	11.64 [-16.04, 39.32]
1.9 Nausea	2	98	Risk Ratio(M-H, Fixed, 95% CI)	6.60 [1.85, 23.52]
1.10 Vomiting	3	203	Risk Ratio(M-H, Fixed, 95% CI)	2.02 [0.75, 5.46]
1.11 Blood loss in mL	2	185	Mean Difference(IV, Fixed, 95% CI)	6.00 [-32.91, 44.91]
1.12 Apgar score less than seven at five minutes	5	373	Risk Ratio(M-H, Fixed, 95% CI)	0.22 [0.01, 4.47]
1.13 NACS < 35 at 2 hours after delivery	3	170	Risk Ratio(M-H, Fixed, 95% CI)	1.45 [0.91, 2.33]

2 Inhaled analgesia of one strength versus inhaled analgesia of different strength

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Satisfaction with pain relief (first stage, good to complete)	1	501	Risk Ratio(M-H, Fixed, 95% CI)	1.05 [0.94, 1.17]
2.2 Satisfaction with pain relief (second stage, good to complete)	1	501	Risk Ratio(M-H, Fixed, 95% CI)	0.97 [0.87, 1.08]
2.3 Caesarean section	1	501	Risk Ratio(M-H, Fixed, 95% CI)	0.31 [0.06, 1.53]
2.4 Assisted vaginal birth	1	501	Risk Ratio(M-H, Fixed, 95% CI)	0.83 [0.61, 1.14]
2.5 Vomiting	1	501	Risk Ratio(M-H, Fixed, 95% CI)	1.29 [0.86, 1.94]
2.6 Postpartum haemorrhage	1	501	Risk Ratio(M-H, Fixed, 95% CI)	0.80 [0.38, 1.70]
2.7 Hypoxaemia mother	1	24	Risk Ratio(M-H, Fixed, 95% CI)	1.00 [0.07, 14.21]

3 Inhaled analgesia using one type of delivery system versus a different delivery system

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
3.1 Satisfaction with pain relief (first stage, considerable to complete)	1	42	Risk Ratio(M-H, Fixed, 95% CI)	1.18 [0.94, 1.48]
3.2 Caesarean section	1	26	Risk Ratio(M-H, Fixed, 95% CI)	2.60 [0.12, 58.48]
3.3 Vomiting (N2O + nasal)	1	49	Risk Ratio(M-H, Fixed, 95% CI)	1.76 [0.77, 4.00]
3.4 Vomiting dichotomous Penthr./Cypr.	1	26	Risk Ratio(M-H, Fixed, 95% CI)	Not estimable
3.5 Postpartum haemorrhage	1	26	Risk Ratio(M-H, Fixed, 95% CI)	0.29 [0.01, 6.50]
3.6 Mild pre-eclampsia	1	26	Risk Ratio(M-H, Fixed, 95% CI)	0.86 [0.06, 12.28]
3.7 Apgar score (continuous, at 5 min. Penthr/Cypr)	1	24	Mean Difference(IV, Fixed, 95% CI)	0.00 [-0.37, 0.37]
3.8 Apgar score (continuous N2O/N2O with nasal suppl.)	1	49	Mean Difference(IV, Fixed, 95% CI)	-0.30 [-0.81, 0.21]

4 Inhaled analgesia versus placebo control/no treatment

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
4.1 Pain intensity (first stage, clear/severe to intense/extreme)	2	310	Risk Ratio(M-H, Random, 95% CI)	0.06 [0.01, 0.34]
4.2 Pain intensity (first stage, VAS 0-10 after 1 hour)	1	509	Mean Difference(IV, Fixed, 95% CI)	-3.50 [-3.75, -3.25]
4.3 Assisted vaginal birth	1	200	Risk Ratio(M-H, Fixed, 95% CI)	1.50 [0.44, 5.15]
4.4 Caesarean section	3	465	Risk Ratio(M-H, Fixed, 95% CI)	1.20 [0.75, 1.91]
4.5 Vomiting	2	619	Risk Ratio(M-H, Fixed, 95% CI)	9.05 [1.18, 69.32]
4.6 Nausea	1	509	Risk Ratio(M-H, Fixed, 95% CI)	43.10 [2.63, 706.74]
4.7 Dizziness	1	509	Risk Ratio(M-H, Fixed, 95% CI)	113.98 [7.09, 1833.69]
4.8 Drowsiness	1	509	Risk Ratio(M-H, Fixed, 95% CI)	77.59 [4.80, 1254.96]
4.9 Neonatal asphyxia	1	110	Risk Ratio(M-H, Fixed, 95% CI)	1.11[0.26, 4.73]
4.10 Apgar score 5 min. ⩽ 7 dich.	1	200	Risk Ratio(M-H, Fixed, 95% CI)	9.00 [0.49, 165.00]
4.11 Apgar score 5 min. cont.	1	509	Mean Difference (IV, Fixed, 95% CI)	0.00 [-0.13, 0.13]

5 Inhaled analgesia versus TENS

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
5.1 Satisfaction pain relief first period ordinal partial to complete	1	20	Risk Ratio(M-H, Fixed, 95% CI)	0.56 [0.29, 1.07]
5.2 Pain intensity first period ordinal moderate to severe	1	19	Risk Ratio(M-H, Fixed, 95% CI)	1.10 [0.84, 1.45]

Analysis 1.1. Comparison 1 Nitrous oxide versus flurane derivatives, Outcome 1 Pain intensity (VAS 0-100 first stage).

Analysis 1.1. Comparison 1 Nitrous oxide versus flurane derivatives, Outcome 1 Pain intensity (VAS 0-100 first stage).

Review: Inhaled analgesia for pain management in labour

Comparison: 1 Nitrous oxide versus flurane derivatives

Outcome: 1 Pain intensity (VAS 0-100 first stage)

Study or subgroup	Nitrous oxide N	Mean(SD)	-Fluranegroup N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
McGuinness 1984	10	53 (12.5)	10	48 (16.5)		34.2 %	5.00 [-7.83, 17.83]
McLeod 1985	16	63 (17)	16	46.6 (16.75)		37.9 %	16.40 [4.71, 28.09]
Wee 1993	11	74.6 (17.8)	7	51.4 (14.8)		27.9 %	23.20 [8.01, 38.39]
Total (95% CI)	**37**		**33**			**100.0 %**	**14.39 [4.41, 24.37]**

Heterogeneity: Tau² = 32.85; Chi² = 3.46, df = 2 (P = 0.18); I² =42%

Test for overall effect: Z = 2.83 (P = 0.0047)

Test for subgroup differences: Not applicable

Analysis 1.2. Comparison 1 Nitrous oxide versus flurane derivatives, Outcome 2 Pain relief (VAS 0-100 as 100 is the most pain relief, first stage).

Analysis 1.2. Comparison 1 Nitrous oxide versus flurane derivatives, Outcome 2 Pain relief (VAS 0-100 as 100 is the most pain relief, first stage).

Review: Inhaled analgesia for pain management in labour

Comparison: 1 Nitrous oxide versus flurane derivatives

Outcome: 2 Pain relief (VAS 0-100 as 100 is the most pain relief, first stage)

Study or subgroup	Nitrous oxide N	Mean(SD)	-Fluranegroup N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Arora 1992	19	58 (15)	20	70 (15)		60.7 %	-12.00 [-21.42, -2.58]
Yeo 2007	15	51 (21.75)	16	74 (16.75)		39.3 %	-23.00 [-36.73, -9.27]
Total (95% CI)	**34**		**36**			**100.0 %**	**-16.32 [-26.85, -5.79]**

Heterogeneity: Tau² = 24.42; Chi² = 1.68, df = 1 (P = 0.20); I² =40%

Test for overall effect: Z = 3.04 (P = 0.0024)

Test for subgroup differences: Not applicable

Analysis 1.9. Comparison 1 Nitrous oxide versus flurane derivatives, Outcome 9 Nausea.

Analysis 1.9. Comparison 1 Nitrous oxide versus flurane derivatives, Outcome 9 Nausea.

Review: Inhaled analgesia for pain management in labour

Comparison: 1 Nitrous oxide versus flurane derivatives

Outcome: 9 Nausea

Study or subgroup	Nitrous oxide n/N	-Fluranegroup n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Jones 1969	8/24	2/24		80.0 %	4.00 [0.95, 16.92]
Jones 1969a	8/25	0/25		20.0 %	17.00 [1.03, 279.53]
Total (95% CI)	**49**	**49**		**100.0 %**	**6.60 [1.85, 23.52]**

Total events: 16 (Nitrous oxide), 2 (-Fluranegroup)
Heterogeneity: Chi^2 = 0.90, df = 1 (P = 0.34); I^2 =0.0%
Test for overall effect: Z = 2.91 (P = 0.0036)
Test for subgroup differences: Not applicable

Analysis 4.1. Comparison 4 Inhaled analgesia versus placebo control/no treatment, Outcome 1 Pain intensity (first stage, clear/severe to intense/extreme).

Analysis 4.1. Comparison 4 Inhaled analgesia versus placebo control/no treatment, Outcome 1 Pain intensity (first stage, clear/severe to intense/extreme).

Review: Inhaled analgesia for pain management in labour

Comparison: 4 Inhaled analgesia versus placebo control/no treatment

Outcome: 1 Pain intensity (first stage, clear/severe to intense/extreme)

Study or subgroup	nitrous oxide 50% n/N	no analgesia n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Ji 2002	9/100	100/100		72.4 %	0.09 [0.05, 0.17]
Zhang 2001	0/60	30/50		27.6 %	0.01 [0.00, 0.22]
Total (95% CI)	**160**	**150**		**100.0 %**	**0.06 [0.01, 0.34]**

Total events: 9 (nitrous oxide 50%), 130 (no analgesia)
Heterogeneity: Tau^2 = 1.08; Chi^2 = 2.03, df = 1 (P = 0.15); I^2 =51%
Test for overall effect: Z = 3.14 (P = 0.0017)
Test for subgroup differences: Not applicable

Analysis 4.2. Comparison 4 Inhaled analgesia versus placebo control/no treatment, Outcome 2 Pain intensity (first stage, VAS 0-10 after 1 hour).

Analysis 4.2. Comparison 4 Inhaled analgesia versus placebo control/no treatment, Outcome 2 Pain intensity (first stage, VAS 0-10 after 1 hour).

Review: Inhaled analgesia for pain management in labour

Comparison: 4 Inhaled analgesia versus placebo control/no treatment

Outcome: 2 Pain intensity (first stage, VAS 0-10 after 1 hour)

Study or subgroup	nitrous oxide 50% N	Mean(SD)	O2 50% N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Talebi 2009	260	4.8 (1.6)	249	8.3 (1.3)		100.0 %	-3.50 [-3.75, -3.25]
Total (95% CI)	**260**		**249**			**100.0 %**	**-3.50 [-3.75, -3.25]**

Heterogeneity: not applicable

Test for overall effect: Z = 27.14 (P < 0.00001)

Test for subgroup differences: Not applicable

Analysis 4.5. Comparison 4 Inhaled analgesia versus placebo control/no treatment, Outcome 5 Vomiting.

Analysis 4.5. Comparison 4 Inhaled analgesia versus placebo control/no treatment, Outcome 5 Vomiting.

Review: Inhaled analgesia for pain management in labour

Comparison: 4 Inhaled analgesia versus placebo control/no treatment

Outcome: 5 Vomiting

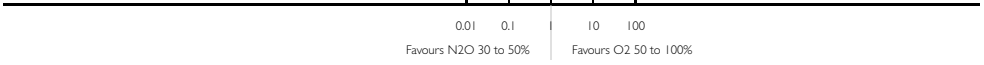
Study or subgroup	N2O 30-50% n/N	O2 50-100% n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Talebi 2009	6/260	0/249		48.4 %	12.45 [0.71, 219.88]
Zhang 2001	3/60	0/50		51.6 %	5.85 [0.31, 110.68]
Total (95% CI)	**320**	**299**		**100.0 %**	**9.05 [1.18, 69.32]**

Total events: 9 (N2O 30-50%), 0 (O2 50-100%)

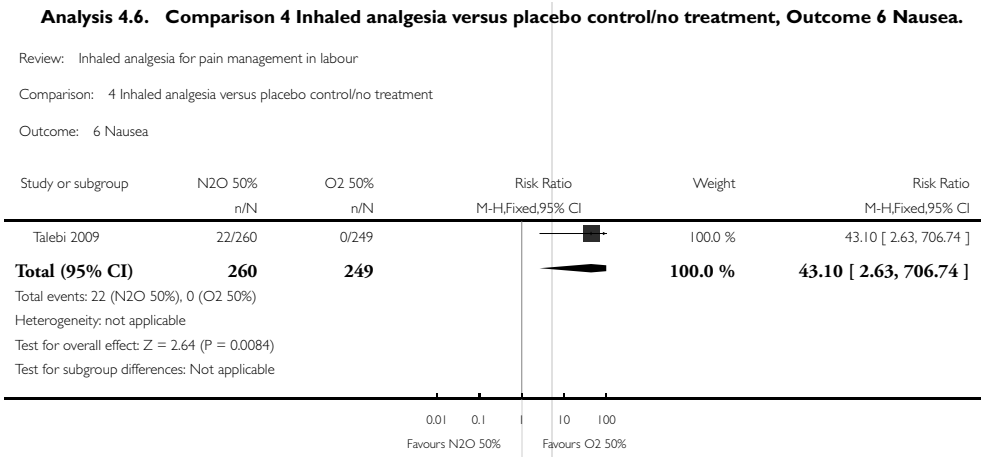
Heterogeneity: $Chi^2 = 0.13$, df = 1 (P = 0.72); $I^2 = 0.0\%$

Test for overall effect: Z = 2.12 (P = 0.034)

Test for subgroup differences: Not applicable



Analysis 4.6. Comparison 4 Inhaled analgesia versus placebo control/no treatment, Outcome 6 Nausea.



For complete overview of the study results, see www.thecochranelibrary.com, 2012, Issue 9.

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Chapter 9

General discussion

General discussion

Overview of this study

In the previous chapters, results were presented of our study on dealing with labour pain. In this last chapter our main findings will be discussed and the separate studies will be connected to each other. The methodological limitations and strengths of our study will also be discussed, the implications for practice and suggestions for further research will be offered. Next the final conclusions will be formulated.

The study aimed:

- to describe the design of the DELIVER study, the first nationwide multicenter cohort study of primary midwife-led care in the Netherlands that provided data for two of the other papers included in this thesis.
- to improve our understanding of women's expectations, preferences and experiences regarding dealing with labour pain and the use of pain medication
- to evaluate the association between planned place of birth and sense of control and to control for the effect of receiving medicinal pain relief as one of the potential confounding factors
- to improve our understanding of midwives' perception of working with women who experienced labour pain and to explore whether this perception has changed in response to changing societal attitudes.
- to evaluate the efficacy and safety of inhaled analgesia for management of pain relief in labour

Main findings

DELIVER study, design article

The DELIVER study paper describes the research design and methodology of the multicenter multidisciplinary prospective DELIVER study which is the first large-scale study evaluating the quality and provision of primary midwifery care (Chapter 2). Clients from twenty midwifery practices throughout the country received up to three questionnaires to assess the expectations and experiences of clients (e.g. quality of care, prenatal screening, emotions, health, and lifestyle). These client data were linked to data from the Netherlands Perinatal Register and electronic client records kept by midwives. The study provided insight into labour pain through questions in questionnaire two (after 35 weeks until the onset of labour) and questionnaire three (on average one week until six weeks after birth)

about women's intended place of birth, women's prenatal and postnatal sense of control, women's prenatal preferences of pain medication and what women used to manage labour pain. It is the first large-scale study evaluating the quality and provision of primary midwifery care in the Netherlands. The study was very important to evaluate primary midwifery care from the point of view of women, partners and midwives at this time of changing attitudes in society toward dealing with labour pain which results in changes in the maternity care system (1).

Women's views on management of labour pain ante- and postpartum
In face to face interviews, the majority of pregnant and postpartum women in midwife-led care – at the onset of labour – said that they hoped to have a natural birth but were happy to accept pain medication if this proved necessary. The women in our study who used a deliberately uninformed approach protected themselves from disappointment by having no specific expectations. A few women planned to have pain medication in advance in order to prevent the pain from getting too unbearable. In order to adapt care to the individual women, midwives need to recognise that women have different approaches to, or strategies around, pain management in labour (Chapter 2). Interestingly, a few women who were interviewed in the postpartum period expressed disappointed with the Dutch approach to labour pain when they faced difficulty in accessing pain medication in hospital despite the advice given in the recent guideline that maternal request is sufficient as an indication for pain medication (Chapter 4) (2). Women appreciated a communicative, supportive and pro-active attitude of the midwife. Some women even expected that the midwife who cared for them would recognise their need for pain medication even if they did not ask for it (Chapter 3). An important finding was that some women switched their approach early in labour from planned pain relief to pragmatic natural indicating the need for midwives to reassess women's wishes during labour and remain flexible with regard to the desired approach to labour pain. A few women were disappointed about the discontinuity of care-giver associated with accessing medical pain relief because they had to be transferred from midwife-led care to obstetrician-led care. Additionally, the post-partum interviews showed that midwives might be unable to discriminate between women who need support through labor without pain medication and those who genuinely desire pain medication at a certain point in labor, and who will be dissatisfied after birth if this need goes unheeded and unfulfilled (Chapter 3).

Preferences and use of pain medication in labour
In the cohort study using data from the DELIVER study, only a small minority of women expressed a preference for intra-partum pain medication before labour and most women did not receive pain medication during labour, even if they had expressed a preference for it during pregnancy. The results suggest that women expressed a preference for pain medication during pregnancy in case they would require some in labour. These results also showed that nulliparous women who indicated a preference to use medicinal pain relief were more likely to use it than parous women who had indicated a preference to use pain relief. Women with a planned hospital birth who indicated a preference to use pain medication were more likely to use it than women with a planned home birth.Care providers therefore should discuss the variability of the labour process and the fact that actual use of pain medication often does not match with women's preference prenatally (Chapter 5).

Women's sense of control in relation to their planned place of birth and transfer during birth from midwife-led care at home to obstetrician-led care in hospital
In the cohort study using data from the DELIVER study there was found a difference in sense of control between women who planned their birth at home versus hospital, but these difference seemed not to be clinically relevant. Transfer of care during labour lowered sense of control, but sense of control was similar for transferred women who planned a home or hospital birth. The explanatory analysis showed that for nulliparous women, the negative association between planned place of birth and sense of control during the first stage of labour was partly explained by pain medication. This could suggest that medicinal pain relief is in the causal pathway: women who planned a hospital birth more often received medicinal pain relief (our results) and the use of medicinal pain relief has been associated with a lower sense of control. As far as their expected sense of control is concerned, low risk women should be encouraged to give birth at the location of their preference (Chapter 6).

Midwives perceptions of labour pain
A focus group interview study revealed two main themes: 1] 'midwives' professional role conflict' which is reflected in the approaches to labour pain used by midwives, 2] the 'situational context' which consists of 'time constraints'; 'discontinuity of care'; importance of 'role of partner' and various 'cultural influences'.

The midwives in our study felt compelled to redefine their professional identity, in line with the societal shift towards the 'pain medication approach'. Most midwives were worried about the prevailing attitude in society and among health care professionals that women need pain medication rather than adequate continuous support in labour. Midwives believed that the issue of pain medication is not a simple dichotomous choice for women. Choices are made along a spectrum spanning the two approaches to the management of labour pain, 'working with pain' and 'pain medication'. At the same time, most of the midwives in our study were more prepared to arrange for pain medication than was the case ten years ago. However, most midwives have been trained in natural childbirth, and they firmly believed in this approach. A number of them were experiencing some kind of an identity crisis, as some women were no longer prepared to accept professional traditional midwifery care during labour which is based on 'the working with pain' approach (Chapter 7).

Inhaled analgesia for pain management in labour
Inhaled pain relief appeared to be effective in reducing pain intensity and in giving pain relief in the first stage of labour. These conclusions came from a systematic review that drew data from twenty-six separate studies that involved a total of 2,959 women, and are published in The Cochrane Library (Chapter 8). However, substantial heterogeneity was detected for the measurement of pain intensity. Furthermore, nitrous oxide appeared to result in more side effects compared with flurane derivatives. Flurane derivatives resulted in more drowsiness when compared with nitrous oxide. When inhaled analgesia was compared with no treatment or placebo, nitrous oxide appeared to result in even more side effects such as nausea, vomiting, dizziness and drowsiness. No differences were found for any of the outcomes comparing one of the inhaled analgesia strengths (percentage of effective agent) versus another, comparing different delivery systems or comparing inhaled analgesia with TENS.

Reflections on the findings
Perceptions of women and midwives – working with pain during labour –
In the Dutch culture, working with pain during labour is the principal focus of most women planning and experiencing a vaginal birth. Additionally, working with labour pain is the main focus of midwives who support women who experience labour pain. Giving birth without pain medication is still the norm despite the growing numbers of women using pain medication during labour (3). Midwives are

the main health professionals to help women to work with their labour pain; and to experience natural labour with as little interventions as possible (4;5). This can be argued specifically for the majority of women who choose a 'pragmatic natural' or 'deliberately uninformed' approach to labour pain. At the same time, access to pain medication has become easier (2). Where in the past only women with a difficult birth could have pain medication and sometimes after hard negotiations with the care provider, nowadays women are given the choice to have medication or not. Most midwives are aware of the changing attitude of dealing with labour pain in society. Consequently in the last decade, because of this changing societal attitude more and more women request to have pain medication (3;6;7). Because more women requested pain relief during labour, perceptions of Dutch midwives about dealing with labour pain changed as well. Facilitating women to make choices in dealing with labour pain is challenging for midwives. Shared decision making might be a useful method to invite women to participate in decision making during pregnancy and labour about management of labour pain (8;9).

Shared decision making

Most women prefer to have control over management of labour pain which means that they want to feel free to decide if they need pain medication. On the other hand, women are not always explicit about their needs during labour (Chapter 4). Women expect midwives to know what they need during labour to achieve a satisfying birth experience. The challenge is that what women think they prefer antenatally may not be what they want in labour, and that midwives need to respect women's antenatal preferences towards pain relief, but at the same time remain flexible and assess the woman's needs in the moment of labour pain. In order to achieve this, midwives might be provided with tools such as a shared-decision making approach to help midwives and women in this process.
Shared decision making – as a process of mutual understanding and making optimal joint decisions – may help to clarify women's needs (10). This approach can give women the option to be actively involved in decision making regarding pain management during labour (11). Midwives should help women with the interpretation and ordering of all the information involved around management of labour pain. Part of this process of shared decision making is informing women about their options in dealing with labour pain and making these choices available for women (8). Women need information about options that are available to them and to prevent them from believing in options that are not accessible (12). In 2010, epidural analgesia was 24/7 accessible in 65% of the Dutch hospitals (3;6).

In addition, midwives can help women understand the variability of childbirth by discussing with pregnant women different scenarios that may happen during labour and by clarifying that women may change their approach of dealing with labour pain because of changed circumstances. To allow women to make genuine choices in dealing with labour pain, it is important that midwives are open to women's active participation in decision making during labour. This includes the willingness and competence of the care professionals in this process (13;14). Midwives should invite women to express their feelings, needs and uncertainties during the labour process and explain to women that they will help them in working with labour pain if they prefer this but at the same time that they will support women if they need pain medication.
In the Netherlands, pain medication is only provided in secondary, obstetrician-led care. Women's request for medicinal pain relief results in discontinuity of care (15;16). As a consequence of this Dutch system, some women expressed dissatisfaction with the discontinuity of caregiver (Chapter 4). Another system of maternity care in which primary and secondary care are more integrated may overcome this discontinuity of care.

Integrated care
Integrating primary midwife-led care and secondary obstetrician-led care during labour may be a way to enhance continuity of care (1;17), if midwives continue to look after women who request pain medication. In the Netherlands, in most situations, hospital midwives take over the care for women if they are referred from midwife-led care to obstetrician-led care for the need of pain medication (18). Community midwives can take over some of this care from hospital staff but they need to be educated in additional skills, for example interpretation of electric foetal monitoring. Continuous support by community midwives would give women confidence in their capability to deal with labour pain (4;5). Recent developments in the Netherlands with regard to inhaled analgesia of nitrous oxide facilitate offering continuous support during labour (19).

Nitrous oxide as inhaled analgesia
Since September 2014, midwives are authorised by law to supervise women who use nitrous oxide as a method of inhaled analgesia during labour. Midwives are entitled to prescribe and supervise the use of this method if they have received a training in this method (19;20). Midwives should be supported by policy makers and insurance companies to have access to nitrous oxide as inhaled analgesia

for women who want to use this method of pain relief in all maternity care units in the Netherlands. With nitrous oxide, midwives can offer women another effective and safe method to deal with labour pain in addition to the use of non-medicinal methods. This is especially useful for women who desire a method of pain medication that is not invasive with less severe side-effects compared to an epidural or remiphentanil infusion (21). Non-medicinal pain relief methods like immersion in warm water, relaxation, acupuncture or hypnosis are other safe and relatively effective methods that midwives can offer (22).

Besides access to nitrous oxide, midwives should be authorized to prescribe remiphentanil and epidural analgesia as labour pain relief for women who request this method of pain relief. In an integrated maternity care system, primary care midwives can offer women continuity of care and continuity of caregiver. In this system, primary care midwives can support women continuously even if women want to use pain medication. In these situations, midwives can consult an obstetrician or anaesthesiologists if pain medication, other than nitrous oxide, is needed.

This study into management of labour pain provided insights into Dutch midwife-led care concerning management of labour pain that might be important for countries that are currently encouraging midwife-led care in order to support physiological birth (23-25). The Lancet series on midwifery developed a framework for quality maternal and newborn care in which components of maternal and newborn health were included. Access to midwifery care worldwide was one of the main recommendations. Homer et al. concluded that midwifery can deliver most (cost)effective maternity care, and can enable access to medium and high care if necessary (26). Although several health professionals may provide aspects of midwifery care, care led by midwives compared with care led by other professionals is associated with more positive outcomes as they can provide continuity of care (27). Enabling midwives to continue caring for women who need medical pain relief would be consistent with the recommendations of the Lancet series. This thesis ads new findings to the limited understanding of factors that are important to women's perceptions of dealing with labour pain and midwives' perceptions of working with women who experience labour pain. This thesis also added new findings on women's preferences and use of pain medication. In addition, this thesis found evidence for the efficacy and safety of inhaled analgesia as a method of pain relief that was able to inform policy which now enables

women in the Netherlands to access nitrous oxide during labour while in primary midwife-led care.

Limitations and strengths

There are some limitations on the generalizability of the findings. In most studies of this thesis, women with lower levels of education and women of non-Dutch ethnic background were underrepresented. These limitations should be kept in mind when relating the results to women and maternity care professionals from other social and cultural backgrounds.

Another limitation is the possibility of selection bias. In the ante-partum, post-partum interview studies and in the focus group study of midwives, midwifery practices and women participating in the studies were self-selected. Women and midwives who participated could have been more interested in the topic of labour pain than most women or midwives. However, the fact that we searched for disconfirming cases and reached data saturation suggests that such bias may not have been a significant problem. Finally, recall bias may exist in the quantitative study of medicinal pain relief (Chapter 5) because the women of the DELIVER study filled in the post-partum questionnaire at different points in time from two weeks post-partum until three months post-partum. This study, therefore, does not take into account that some women may have altered their memories of the used method of pain relief in labour.

A major strength of this thesis is the use of a variety of research methods to explore different factors of the concept of pain management during labour. We used quantitative and qualitative research methods to illuminate views of women and midwives as well as preferences, experienced pain relief with inhaled analgesia, safety of this pain relief and use of women's medicinal pain relief. Combining these two methods might give a broader understanding of a complicated concept (28) such as management of labour pain.

This thesis focussed on the concept of labour pain management of women in midwife-led care and of midwives who cared for these women, gaining an understanding of how dealing with labour pain works for women and midwives and how some aspects can be improved to gain greater satisfaction with the childbirth experience.

To our knowledge, this is the first comprehensive study in the Netherlands of women's and midwives' perceptions, women's preferences and use of methods of labour pain management.
The Dutch system has inspired maternity care professionals in many countries around the world (29;30). It is therefore crucial that the quality and characteristics of this system are described and that this information is made public to inform care providers, women, and policy makers internationally about its benefits and shortcomings.

Implementations for practice
A number of recommendations can be made for midwifery practice, health care policy and midwifery education, based on the findings of this thesis.
With regard to midwifery practice, professionals should individualise counselling and information around labour pain management to adapt to the different approaches women adopt in order to achieve woman-centred care. Midwives need to make women aware of their options of non-medicinal and medicinal pain relief during labour. Additionally, midwives should take the time to explore with women what options are available, what coping techniques women might want to use, what the pros and cons are of the different options and how women expect to be involved in decision making around labour pain management during labour. Midwives should also talk about the variability of birth, that birth can be more or less painful than anticipated and that women's preferences for pain relief often do not match with what women use during labour in order to deal with labour pain. During labour, maternity care professionals should stay in contact with women, talk with women about their needs and invite women to share their feelings of fear, uncertainty and wishes concerning labour pain management. After birth, women's experiences of dealing with labour pain need to be evaluated. This should include reflecting and explaining why sometimes expectations and wishes regarding pain relief are unmet.
To meet the expectations of women regarding continuity of care-giver, substitution of care from obstetrician-led care to midwife-led care would highly improve continuity of care. This would be consistent with recommendations given in the Lancet series on midwifery (23). To realise this, midwives should be authorized to prescribe remiphentanil and epidural analgesia to achieve integrated care for all women in midwife-led care who require medicinal pain relief. Midwives can consult an obstetrician or anaesthesiologist to discuss the care that is needed.

In addition, women in midwife-led care should be informed that concerning their sense of control during labour, choosing for home birth or hospital birth does not make a difference.
Policy makers and insurance companies need to invest in implementation of nitrous oxide equipment in all maternity care units to give all women the option to choose nitrous oxide as pain relief in labour. This is especially useful for women who want to use a method of medicinal pain relief but would rather not use an invasive method.
Aspects of cost-effectiveness can be brought into the discussion of availability of medicinal pain relief for all women and expand the choice of relatively inexpensive, effective and safe methods such as nitrous oxide in midwife-led care.
Furthermore, all education programs for maternity care professionals need to incorporate aspects of integrated care as part of the organisation of care, working in close partnership with other care providers to achieve understanding and mutual respect for each other's competencies. Education programs similarly need to incorporate the concept of shared decision making as professional skill for student midwives and offer these students the opportunity to practice this attitude in simulations in schools and in midwifery practices during student placements. Finally, education programs need to embed the working with pain approach for student midwives. This means, that student midwives should not only learn in theory all methods of non-medicinal and medicinal pain relief but also how to offer continuity of care and support to women in labour. These future midwives need to understand that most women expect continuous support of the midwife during labour in order to help them through labour pain and that women expect them to know when pain relief is needed.

Recommendations for further research

The results of this thesis give us a better understanding in management of labour pain for women in midwife-led care and recommendations to improve this care, but more research is needed.
Partners of women play an important role in decision making in maternity care but were not subjects in this thesis (31). More research is needed about the role of the partner of the (pregnant) women and how this role might influence the management of labour pain process. This research needs to focus on which aspects of the partner's role might perform as a positive or negative factor for women's satisfaction of childbirth. Additionally, more research is needed among women with lower levels of education and women of different cultural

backgrounds to improve the generalizability of our findings. One could similarly argue that further research is needed among women with experiences of sexual abuse or family violence because our research did not take into account these characteristics of women (32;33).
Furthermore, future research is needed to identify areas for improvement in working with labour pain: to identify which specific coping techniques are helpful for women, and how midwives can balance supporting women to give birth without pain medication versus arranging medication in time, when necessary.

To assess the efficacy and safety of inhaled analgesia, in particular the use of nitrous oxide because of the option to use this method in midwife-led care, further randomised controlled trials should be adequately powered and include relevant clinical outcomes as described in this review (Chapter 8) especially for the three primary outcomes: sense of control in labour; satisfaction with childbirth; and breastfeeding experience of women. Particularly studies without the confounding factor of co-administration of other analgesia, would be very helpful. Integrated maternity care for women in the Netherlands might overcome women's dissatisfaction of discontinuity of care when care has to be taken over by obstetrician-led care for request of medicinal pain relief. However, although many maternity care professionals are positive about more integration between midwife-led and obstetrician-led care to improve continuity of care, there is no consensus on the model of organization of care (17). Further research should be done to identify the factors that promote and hinder the implementation of integrated care in the Dutch health care system.

Final conclusion
Active involvement in management of labour pain is important for women as it promotes their sense of control. Women prefer continuous support from their maternity care professional both at home and in hospital. To realize continuous support for all women in primary care who request medicinal pain relief, substitution of providing medical pain relief from obstetrician-led to midwife-led care should be realized. Most women in our study adopted a 'Pragmatic Natural approach', i.e. they preferred to go through labour without pain medication but were happy that medication would be available if needed. However, midwives need to discuss the variability of birth with women and invite them to openly express their needs, wishes and expectations throughout their pregnancy and labour. To offer women broad choices in pain management methods, nationwide

access to nitrous oxide as inhaled analgesia for pain relief in labour has to be realized for all women. Midwives face the difficult challenge of supporting women to go through labour without pain medication if possible and desired. If required, they have to provide woman of pain medication as well. Ultimately, midwives have to provide all women continuous support during labour, independently of how women choose to deal with labour pain.

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Chapter 10

Summary & Samenvatting

Summary

Chapter 1

Introduction

This chapter describes the rationale and aims of this thesis and introduces the research questions.

Labour pain is a major concern for women, their partners and maternity health care professionals. In 2008, a new Dutch guideline was implemented on the use of medicinal pain relief. This guideline advices that women's request on its own is sufficient as an indication for pain medication or an epidural during labour. An epidural is the mode of choice for the elimination of labour pain. Despite the Dutch culture of natural childbirth, in the Netherlands the number of women having a vaginal birth who use pain medication in labour has risen from 5.4% in 2003 to 17.6% in 2012 since the introduction of this guideline.

Most research on labour pain has been conducted in countries where women have limited choice regarding their place of birth and a medical model with routine pain medication or an epidural is the dominant approach to intra-partum care. Little is known about women's expectations and experiences of dealing with labour pain and the use of pain medication or an epidural in the Dutch midwife-led care system.

The aim of this thesis was to examine management of labour pain from the point of view of women and midwives and to synthesize evidence on the effectiveness and safety of inhaled analgesia for mother and child. The research conducted consists of seven studies.

Chapter 2

Evaluation of primary care midwifery in the Netherlands: design and rationale of a dynamic cohort study (DELIVER).

In this chapter, the research design and methodology of this multicentre multidisciplinary prospective study was described. Research to support evidence based midwifery care in the Netherlands has been limited. Therefore, it was important to set out a nationwide multi-center research project to evaluate the maternity care system and practice in order to get an understanding of the Dutch midwifery care and to provide knowledge for improvement. The DELIVER study provided data for two of the other papers included in this thesis: Chapter 5 and Chapter 6. Clients from 20 midwifery practices throughout the country volunteered to participate in this study. These clients were invited

to fill in up to three questionnaires (Q1 until 34 weeks of pregnancy, Q2 from 34 weeks of pregnancy up to birth, Q3 around six weeks post-partum), to assess the expectations and experiences. In total, 7685 clients completed at least one questionnaire.
Conclusion: the DELIVER study provides an extensive database with national representative data on the quality of primary care midwifery in the Netherlands. This study will support evidence-based practice in primary care midwifery in the Netherlands and contribute to a better understanding of the maternity care system.

Chapter 3
What do midwives need to know about approaches of women towards labour pain management?
A qualitative interview study into expectations of management of labour pain for pregnant women receiving midwife-led care in the Netherlands.
A qualitative method was used to enable in-depth exploration of women's perception towards dealing with labour pain to understand pregnant women's expectations of labour pain. Fifteen pregnant women were selected by purposive sampling and interviewed between 36 and 40 weeks gestation. All these women were in primary midwife-led care in five midwifery practices across the Netherlands between June 2009 and July 2010. We found three major themes to be important in women's expectations for management of labour pain: preparation, support and control & decision-making. In addition, three distinct approaches to women's planning for pain management in labour were identified: the '*pragmatic natural',* the *'deliberately uninformed'* and the *'planned pain relief'* approach. These approaches clustered within women's other expectations around pain management.
Conclusion: midwives should individualise counselling and information around labour pain management to accommodate the different approaches of women towards this process in the interests of woman-centred care.

Chapter 4
A qualitative interview study into experiences of management of labour pain among women who received midwife-led care in the Netherlands
Using purposive sampling, we selected seventeen women from five midwifery practices across the Netherlands, from August 2009 to September 2010.

The semi-structured postpartum interviews were analyzed using the constant comparison method.
Women reported that control over decision-making during labour (about dealing with pain) helped them to deal with labor pain, as did continuous midwife support at home and in hospital, and effective childbirth preparation. Most women adopted a 'Pragmatic Natural' approach to labour pain, i.e. they preferred to go through labour without pain medication or an epidural but were happy that medication or an epidural would be available if needed. Women with a 'Deliberately Uninformed' approach would rather experience their labour as it occurs and 'Pro Pain Relief' women definitely planned to use pain medication. However, during labor, some women switched their approach to labour pain from 'Pro Pain relief' to 'Pragmatic Natural'. Some of these women implicitly or explicitly indicated that midwives should know which method of pain management they need during labor and arrange this in good time.
Conclusion: women in our study appreciated the option of requesting pain medication, and they expected this would be available when they request it, either explicitly or implicitly. The women wanted continuous support from their maternity care professional during labour, to enhance the communication of needs, such as switching approaches to labour pain. They also felt that this would provide real support in working with the pain, and when care switches from being midwife-led to being obstetrician-led. It may be difficult for midwives to discriminate between women who need continuous support through labour without pain medication and those who genuinely desire pain medication at a certain point in labor, and who will be dissatisfied postpartum if this need is unrecognized and unfulfilled.

Chapter 5

Dutch women in midwife-led care at the onset of labour: which pain relief do they prefer and what do they use?

The data for this study were collected between September 2009 and March 2011, from women of the DELIVER study. Inclusion criteria for women were: singleton pregnancies, in midwife–led care at the onset of labour and speaking Dutch, English, Turkish or Arabic. Our study sample consisted of 1511 women in primary care who completed both questionnaire two (from 34 weeks of pregnancy up to birth) and questionnaire three (around six week post-partum). These questionnaires were presented either online or on paper.
Prenatally, 15.9% of women preferred some method of medicinal pain relief.

During labour 15.2% of the total sample used medicinal pain relief and 25.3% of the women who indicated a preference to use medicinal pain relief during pregnancy, used pain medication. Non-Dutch ethnic background and planned hospital birth were associated with indicating a preference for medicinal pain relief during pregnancy. Primiparous and planned hospital birth were associated with actual use of the preferred method of medicinal pain relief during labour. Furthermore, we found that 85.5% of women who indicated a preference not to use pain medication prenatally, did not use any medication.
Conclusions: only a small minority of women had a preference for intrapartum pain medication prenatally. Most women did not receive medicinal pain relief during labour, even if they had indicated a preference for it.
Care providers should discuss the variability of the labour process and the fact that actual use of pain medication often does not match with women's preference prenatally.

Chapter 6
Birth setting, transfer and maternal sense of control: results from the DELIVER study.
The aim of this study was to evaluate the association between planned place of birth and sense of control and to control for the effect of receiving medicinal pain relief as one of the potential confounding factors. The data for this study were collected between 2009 and 2011 from women of the DELIVER study in the Netherlands. Sense of control during labour was assessed 6 weeks after birth, using the short version of the Labour Agentry Scale (LAS-11). A higher LAS-11 score indicates a higher feeling of control. We considered a difference of a minimum of 5.5 points as clinically relevant.
Nulliparous- and parous women who planned a home birth had a 2.8 (95% CI 1.0, 4.5) and a 3.0 (1.6, 4.4) higher LAS score during first stage of labour respectively and during second stage a higher score of 2.8 (0.9, 4.8) and 2.3 (0.6, 4.0), compared with women who planned a hospital birth. Overall, women who were transferred experienced a lower sense of control than women who were not transferred. Parous women who planned a home birth and who were transferred had a 4.3 (0.2, 8.4) higher LAS score in 2nd stage, compared to those who planned a hospital birth and who were transferred.
Conclusion: we found no clinically relevant differences in feelings of control among women who planned a home or hospital birth. Transfer of care during labour lowered feelings of control, but feelings of control were similar for transferred women who planned a home or hospital birth. As far as their expected

sense of control is concerned, low-risk women should be encouraged to give birth at the location of their preference.

Chapter 7

Management of labour pain; perceptions of labour pain by Dutch primary care midwives, a focus group interview study

Little is known about Dutch midwives' perceptions of working with women experiencing labour pain. The aim of this study was to explore midwives' perceptions of supporting women in dealing with pain during labour.

We conducted a qualitative focus group study with four focus groups, including a total of 23 midwives from 23 midwifery practices across the country. Purposive sampling was used to select the practices. The constant comparison method of Glaser and Straus (1967, ren. 1995) was used to gain an understanding of midwives' perceptions regarding labour pain management.

We found two main themes. The first theme concerned the midwives' professional role conflict, which was reflected in their approach of labour pain management along a spectrum from "working with pain" to a "pain relief" approach. The second theme revolved around how midwives saw their professional role being influenced by the situational context, including factors such as time constraints; discontinuity of care; the important role of the partner; and various cultural influences.

Conclusion: midwives felt challenged by the need to balance their professional attitude towards normal birth and labour pain management, which favours working with pain, with the shift in society towards a wider acceptance of pharmacologic pain management during labour. This shift compelled them to redefine their professional identity.

Chapter 8

Inhaled analgesia for pain management in labour (Review).

Many women would like to have a choice in pain relief during labour and also would like to avoid invasive methods of pain management in labour. Inhaled analgesia during labour involves the self-administered inhalation of sub-anaesthetic concentrations of agents while the mother remains awake and her protective laryngeal reflexes remain intact. Most of the agents are easy to administer, can be started in less than a minute and become effective within a minute. The objective of this study was to examine the effects of all modalities of inhaled analgesia on the mother and the newborn for mothers who planned to have a vaginal delivery.

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 January 2012), ClinicalTrials.gov, and Current Controlled Trials (2 June 2012), hand-searched conference proceedings from the American Society of Clinical Anesthesia (from 1990 to 2011), contacted content experts and trialists and searched reference lists of retrieved studies. We selected randomised controlled trials comparing inhaled analgesia with other inhaled analgesia or placebo or no treatment or other methods of non-pharmacological pain management in labour. Review authors independently assessed trials for eligibility, methodological quality and extracted all data. Data were double checked for accuracy. Twenty-six studies, randomising 2959 women, were included in this review.

Inhaled analgesia versus a different type of inhaled analgesia
Pain relief was measured using a Visual Analogue Scale (VAS) from 0 to 100 mm where 100 corresponds to the most relief. Pain intensity was measured using a VAS from 0 to 100 mm, where 0 corresponds to no pain at all and 100 corresponds to the worst pain. The highest score for pain relief is the most positive in contrast to 'pain intensity' in which the higher score is more negative.
Flurane derivatives were found to offer better pain relief than nitrous oxide in first stage of labour as measured by a lower pain intensity score (average mean difference (MD) 14.39, 95% confidence interval (CI) 4.41 to 24.37, three studies, 70 women), also a higher pain relief score for flurane derivatives compared with nitrous oxide (average MD -16.32, 95% CI -26.85 to -5.79, two studies, 70 women). Substantial heterogeneity was found in the analyses of pain intensity (P = 0.003) and in the analysis of pain relief (P = 0.002).These findings should be considered with caution because of the questionable design of the included cross-over trials. More nausea was found in the nitrous oxide group compared with the flurane derivatives group (risk ratio (RR) 6.60 95% CI 1.85 to 23.52, two studies, 98 women).

Inhaled analgesia versus placebo or no treatment
Placebo or no treatment was found to offer less pain relief compared to nitrous oxide (average RR 0.06, 95% CI 0.01 to 0.34, two studies, 310 women; MD -3.50, 95% CI -3.75 to -3.25, one study, 509 women). However, nitrous oxide resulted in more side effects for women such as nausea (RR 43.10, 95% CI 2.63 to 706.74, one study, 509 women), vomiting (RR 9.05, 95% CI 1.18 to 69.32, two studies, 619 women), dizziness (RR 113.98, 95% CI 7.09 to 1833.69, one study, 509 women) and drowsiness (RR 77.59, 95% CI 4.80 to 1254.96, one study, 509 women) when compared with placebo or no treatment.

There were no significant differences found for any of the outcomes in the studies comparing one strength versus a different strength of inhaled analgesia, in studies comparing different delivery systems or in the study comparing inhaled analgesia with TENS. Due to lack of data, the following outcomes were not analysed within the review: sense of control; satisfaction with childbirth experience; effect on mother/baby interaction; breastfeeding; admission to special care baby unit; poor infant outcomes at long-term follow-up; or costs.
Conclusion: inhaled analgesia appears to be effective in reducing pain intensity and in giving pain relief in labour. However, substantial heterogeneity was detected for pain intensity. Furthermore, nitrous oxide appears to result in more side effects compared with flurane derivatives. Flurane derivatives result in more drowsiness when compared with nitrous oxide. When inhaled analgesia is compared with no treatment or placebo, nitrous oxide appears to result in even more side effects such as nausea, vomiting, dizziness and drowsiness.

Chapter 9

General Discussion

Finally, the general discussion of this thesis, presents a brief overview of the main findings and addresses methodological considerations. It ends, with the implications and recommendations for further research and practice.
Active involvement in management of labour pain is important for women as it promotes their sense of control. Women prefer continuous support from their maternity care professional both at home and in hospital. To realize continuous support for all women in primary care who request medicinal pain relief, substitution of providing medical pain relief from obstetrician-led to midwife-led care should be realized. Most women in our study adopted a 'Pragmatic Natural approach', i.e. they preferred to go through labour without pain medication but were happy that medication would be available if needed. However, midwives need to discuss the variability of birth with women and invite them to openly express their needs, wishes and expectations throughout their pregnancy and labour. To offer women broad choices in pain management methods, nationwide access to nitrous oxide as inhaled analgesia for pain relief in labour has to be realized for all women. Midwives face the difficult challenge of supporting women to go through labour without pain medication if possible and desired. If required, they have to provide woman of pain medication as well. Ultimately, midwives have to provide all women continuous support during labour, independently of how women choose to deal with labour pain.

Samenvatting

Hoofdstuk 1

Introductie

Dit hoofdstuk beschrijft de rationale en het doel van deze thesis en introduceert de onderzoeksvragen.

Pijn tijdens de baring is een zorg voor vrouwen, hun partners en verloskundige beroepsbeoefenaren in de gezondheidszorg. In 2008 werd een nieuwe Nederlandse richtlijn geïmplementeerd voor het gebruik van pijnmedicatie als pijnbestrijding tijdens de baring. Deze richtlijn adviseert dat het verzoek van vrouwen op zich voldoende is als indicatie voor pijnmedicatie of een ruggenprik tijdens de baring. Een ruggenprik zou de eerste keus moeten zijn voor de eliminatie van de baringspijn. Ondanks de Nederlandse cultuur van de natuurlijke baring is in Nederland het aantal vrouwen (met een vaginale baring) dat gebruik maakt van medicinale pijnbestrijding gestegen van 5,4% in 2003 tot 17,6% in 2012, sinds de invoering van deze richtlijn.

Het meeste onderzoek over omgaan met baringspijn is uitgevoerd in landen waar vrouwen een beperkte keuze hebben voor de plaats van de baring en een medisch model met routine pijnmedicatie of een ruggenprik de dominante benadering van intra-partum zorg is. Er is weinig bekend over verwachtingen en ervaringen van vrouwen met omgaan met baringspijn en het gebruik van pijnmedicatie of een ruggenprik in het Nederlands verloskundig (eerstelijns) zorgsysteem.

Het doel van dit proefschrift was het omgaan met baringspijn te onderzoeken vanuit het oogpunt van vrouwen en verloskundigen en bewijsmateriaal over de effectiviteit en de veiligheid van geïnhaleerde analgesie voor moeder en kind te synthetiseren. Deze thesis bestaat uit zeven studies.

Hoofdstuk 2

Evaluatie van de eerstelijns verloskundige zorg in Nederland: ontwerp en rationale van een dynamische cohort studie (DELIVER)

In dit hoofdstuk werden de onderzoeksopzet en de methodologie van deze multicenter, prospectieve, multidisciplinaire studie beschreven. Onderzoek om evidence based verloskundige zorg te ondersteunen in Nederland is beperkt. Daarom was het belangrijk een landelijk multi-center studie uit te zetten naar het verloskundig zorgsysteem en -praktijk ter evaluatie - voor begripsvorming van de Nederlandse verloskundige zorg en deze te voorzien van kennis voor verbetering. Deze studie verstrekte gegevens voor twee van de andere artikelen in dit

proefschrift: Hoofdstuk 5 en Hoofdstuk 6. Cliënten uit 20 verloskundige praktijken in het hele land hebben vrijwillig meegedaan aan deze studie. Deze cliënten werden uitgenodigd voor het beantwoorden van maximaal drie vragenlijsten (Q1 tot en met 34 weken van de zwangerschap, Q2 vanaf 35 weken van de zwangerschap tot aan de geboorte, Q3 ongeveer zes weken na de bevalling), om hun verwachtingen en ervaringen te beoordelen. In totaal hebben 7685 cliënten minimaal één vragenlijst ingevuld.
Conclusie: de DELIVER-studie biedt een uitgebreide database met nationaal representatieve gegevens over de kwaliteit van de eerstelijns verloskunde in Nederland. Deze studie zal 'evidence-based practice' in de eerstelijns verloskunde in Nederland ondersteunen en bijdragen aan een beter begrip van het verloskundig systeem.

Hoofdstuk 3
Wat moeten verloskundigen weten over de wijze waarop vrouwen baringspijn benaderen?
Een kwalitatieve interview studie naar de verwachtingen van omgaan met baringspijn van zwangere vrouwen die in eerstelijns verloskundige zorg zijn in Nederland
Een kwalitatieve methode werd gebruikt om een grondige verkenning te maken van de perceptie van vrouwen over omgaan met baringspijn. Vijftien zwangere vrouwen werden geselecteerd met een doelgerichte steekproef en geïnterviewd tussen 36 en 40 weken zwangerschap. Al deze vrouwen waren in eerstelijns verloskundige zorg in vijf verloskundige praktijken in Nederland tussen juni 2009 en juli 2010. We extraheerde drie grote thema's belangrijk in de verwachtingen van vrouwen voor omgaan met baringspijn: 1] de voorbereiding, 2] ondersteuning en 3] controle & invloed op besluitvorming. Daarnaast zijn er drie verschillende benaderingen geïdentificeerd voor de planning van vrouwen voor barings-pijnbestrijding: 1] de *"pragmatisch natuurlijke*", 2] de "*doelbewust ongeïnformeerde*" en 3] de "*geplande pijnbestrijding*". Deze benaderingen clusterden binnen de andere verwachtingen van vrouwen over omgaan met baringspijn.
Conclusie: verloskundigen dienen informatie en counseling rondom omgaan met baringspijn per vrouw te individualiseren om tegemoet te komen aan de verschillende benaderingen van dit proces van vrouwen in het belang van vrouwvriendelijke zorg.

Hoofdstuk 4

Een kwalitatieve interview studie naar de ervaringen over omgaan met baringspijn bij vrouwen in eerstelijns verloskundige zorg in Nederland

Met behulp van doelgerichte steekproef werden zeventien vrouwen geselecteerd uit vijf verloskundige praktijken in Nederland, van augustus 2009 tot september 2010. De semi-gestructureerde interviews postpartum werden geanalyseerd met behulp van de constante vergelijking methode.

Vrouwen meldden dat controle op de besluitvorming tijdens de baring (over het omgaan met pijn) hen hielp om te gaan met de baringspijn, net als de verloskundige continue begeleiding thuis en in het ziekenhuis en effectieve bevallings-voorbereiding. De meeste vrouwen adopteerde een *"pragmatisch natuurlijke"* benadering van omgaan met baringspijn, dat wil zeggen dat zij voorkeur gaven aan omgaan met baringspijn zonder pijnmedicatie of een epiduraal maar gelukkig waren met pijnmedicatie of een ruggenprik die beschikbaar zou zijn als dat nodig zou zijn. Vrouwen met een *"doelbewust ongeïnformeerde"* benadering zeiden dat zij omgaan met baringspijn liever ervoeren zoals het zich voordeed en vrouwen met een "geplande pijnbestrijding" wilden zeker pijnmedicatie gebruiken. Echter, tijdens de baring waren sommige vrouwen overgestapt van pijnbenadering. Hun benadering wisselde van "geplande pijnmedicatie" naar "pragmatisch natuurlijk".

Sommige van de vrouwen gaven expliciet of impliciet aan dat verloskundigen zouden moeten kunnen inschatten welke methode van pijnbestrijding de vrouw nodig zou hebben en dit ook op tijd moeten regelen.

Conclusie: vrouwen in onze studie waardeerden de optie van het kunnen vragen naar pijnmedicatie en verwachtten dat deze beschikbaar was als ze daarom vroegen, expliciet of impliciet. De vrouwen wilden continue begeleiding van hun professionele, verloskundige hulpverlener tijdens de baring voor verbetering van communicatie van hun behoeften, zoals het schakelen tussen pijnbenadering. Vrouwen waren overtuigd dat deze continue begeleiding daadwerkelijke steun tijdens het omgaan met baringspijn zou geven en ook wanneer de zorg van eerstelijn naar tweedelijn zou overgaan. Het kan moeilijk zijn voor verloskundigen om onderscheid te maken tussen vrouwen die continue begeleiding tijdens omgaan met baringspijn nodig hebben zonder pijnmedicatie en degenen die oprecht verlangen naar pijnmedicatie op een bepaald punt tijdens de baring en die ontevreden zullen zijn als deze noodzaak niet werd waargenomen en onvervuld bleef.

Hoofdstuk 5

Nederlandse vrouwen in eerstelijns verloskundige zorg bij het begin van de baring: welke pijnstillingsvoorkeur hebben zij en wat gebruiken ze?

De data voor deze studie werden verzameld tussen september 2009 en maart 2011, van de vrouwen van de DELIVER studie. De inclusie criteria voor deze vrouwen waren: eenlingzwangerschap, in eerstelijns verloskundige zorg bij het begin van de baring en Nederlands, Engels Turks of Arabisch sprekend.
De steekproef van deze studie bestond uit 1511 vrouwen in de eerstelijns zorg die twee vragenlijsten beiden invulden (Q2 vanaf 34 weken zwangerschap tot de geboorte) en de derde vragenlijst (Q3 ongeveer zes weken na de bevalling). Deze vragenlijsten werden ofwel online of op papier aangeboden.
Prenataal gaven 15,9% van de vrouwen een voorkeur aan een methode van medicinale pijnbestrijding. Tijdens de baring gebruikten 15,2% van de totale steekproef een methode van medicinale pijnbestrijding en 25,3% van de vrouwen die een voorkeur aangaven voor een methode van medicinale pijnbestrijding gebruikten daadwerkelijk pijnmedicatie. Een niet-Nederlandse etnische achtergrond en een geplande ziekenhuis baring (poliklinisch) waren geassocieerd met een prenataal vermeldde voorkeur voor medicinale pijnbestrijding.
Primipara en geplande ziekenhuis baring waren geassocieerd met het huidige (daadwerkelijke) gebruik van de voorkeur van medicinale pijnbestrijding tijdens de baring. Verder vonden we dat 85,5% van dat vrouwen die prenataal een voorkeur aangaven voor het niet gebruik willen maken van pijnmedicatie, daadwerkelijk geen gebruik maakten van pijnmedicatie.
Conclusies: slechts een kleine minderheid van de vrouwen gaven prenataal een voorkeur aan voor medicinale pijnbestrijding tijdens de baring. De meeste vrouwen maakten geen gebruik van pijnmedicatie tijdens de baring zelfs als ze prenataal een voorkeur hiervoor aangaven.
Verloskundige zorgverleners dienen de onvoorspelbaarheid van de baring te bespreken en het feit dat het daadwerkelijke gebruik van medicinale pijnbestrijding vaak niet overeenkomt met de voorkeur van vrouwen prenataal.

Hoofdstuk 6

Plaats van de baring, overdracht en gevoel van controle: de resultaten van de DELIVER studie

Het doel van de studie was om een associatie aan te tonen tussen de geplande plaats van baring en het gevoel van controle en om te corrigeren voor het effect van gebruikte pijnmedicatie als één van de mogelijke verstorende factoren.

De data voor het deze studie werden verzameld tussen 2009 en 2011 van de vrouwen van de DELIVER studie in Nederland. Gevoel van controle tijdens de baring werd gemeten zes weken na de geboorte met de verkorte versie van de “Labour Agentry Scale” (LAS-11). Een hogere score LAS-11 geeft een hoger gevoel van controle. Een verschil van minimaal 5,5 punten beschouwden we als klinisch relevant.
Nulliparous- en parous vrouwen met een geplande thuisbaring hadden respectievelijk een 2,8 (95% CI 1,0, 4,5) en 3,0 (1.6, 4.4) hogere LAS-score tijdens de eerste fase van de baring en tijdens de tweede fase een hogere score van respectievelijk 2,8 (0,9, 4.8) en 2.3 (0.6, 4.0), in vergelijking met vrouwen die een geplande ziekenhuis baring hadden. Over het algemeen ervaren vrouwen die overgedragen werden tijdens de baring een lager gevoel van controle dan vrouwen die niet werden overgedragen. Parous vrouwen die een geplande thuisbaring hadden en waren overgedragen hadden een 4.3 (0.2, 8.4) hogere LAS score in de 2e fase, vergeleken met degenen die een geplande ziekenhuis baring hadden en waren overgedragen.
Conclusie: we vonden geen klinisch relevante verschillen in gevoelens van controle bij vrouwen die een geplande thuisbaring hadden versus een geplande ziekenhuisbaring. Overdracht van zorg tijdens de baring verlaagde het gevoel van controle, maar waren vergelijkbaar voor alle vrouwen die overgedragen werden en die ofwel een geplande thuisbaring of een geplande ziekenhuis baring hadden. Laag-risico vrouwen moeten worden aangemoedigd te bevallen op de locatie van hun voorkeur voor zover het hun gevoel van controle betreft.

Hoofdstuk 7

Omgaan met baringspijn: percepties over baringspijn van Nederlandse eerstelijns verloskundigen, een focus groep studie

Er is weinig bekend over percepties van Nederlandse verloskundigen die werken met vrouwen die baringspijn ervaren. Het doel van deze studie was om de percepties van verloskundigen te exploreren over het ondersteunen van vrouwen die baringspijn ervaren.
We voerden een kwalitatieve focusgroep studie uit met vier focusgroepen met in totaal 23 verloskundigen uit 23 verloskundige praktijken in het hele land.
Een doelgerichte steekproef werd gebruikt om de praktijken te selecteren.
De constante vergelijking methode van Glaser en Straus (1967, ren. 1995) werd gebruikt om een goed begrip te krijgen van de percepties van verloskundigen over omgaan met baringspijn.

We identificeerden twee belangrijke thema's. Het eerste was het professionele rolconflict van de verloskundigen wat tot uiting kwam in hun benadering van baringspijn langs een spectrum van "werken met pijn" naar een "pijnmedicatie" aanpak. Het tweede thema draaide om hoe verloskundigen hun professionele rol beïnvloed ervoeren door de situationele context zoals tijdsdruk; discontinuïteit van zorg; de belangrijke rol van de partner en diverse culturele invloeden. Conclusie: verloskundigen voelden zich uitgedaagd door de noodzaak om hun professionele attitude in evenwicht te brengen met de 'normale' baring en daarbij omgaan met pijn. Verloskundigen gaven een voorkeur aan voor werken met pijn terwijl zij een verschuiving ervoeren in de samenleving naar een bredere acceptatie van medicinale pijnbestrijding tijdens de baring. Deze verschuiving dwong verloskundigen hun professionele identiteit te herdefiniëren.

Hoofdstuk 8

Inhalatie analgesie voor pijnbestrijding tijdens de baring (Review)

Veel vrouwen willen graag een keuze in verlichting van de baringspijn en ook willen (sommige) vrouwen invasieve methoden van baringspijnbestrijding vermijden. Geïnhaleerde analgesie tijdens de baring betreft de in eigen beheer inademing van sub-anesthetica concentraties van analgesie stoffen terwijl de moeder wakker blijft en haar beschermende laryngeale reflexen intact blijven. Het merendeel van de inhalatie stoffen zijn eenvoudig te beheren, de methode kan gestart worden in minder dan een minuut en wordt effectief binnen een minuut. Het doel van deze studie was om de effecten van alle modaliteiten van geïnhaleerd analgesie te onderzoeken op de moeder en de pasgeborene voor moeders met een geplande vaginale baring.

We zochten in de Cochrane Zwangerschap en Bevalling Trials Group's Register (31 januari 2012), ClinicalTrials.gov, en Current Controlled Trials (2 juni 2012), doorzochten met de hand conference proceedings van de American Society of Clinical Anesthesia (1990-2011) en namen contact op met inhoud experts en Trialists. We selecteerden gerandomiseerde gecontroleerde studies die geïnhaleerde analgesie vergeleken met andere geïnhaleerde analgesie of geïnhaleerde placebo of geen behandeling of andere niet-medicinale methoden van pijnbestrijding tijdens de baring. Review auteurs beoordeelden onafhankelijk de studies voor toepasbaarheid, methodologische kwaliteit en extraheerden alle data. De gegevens werden dubbel gecontroleerd op juistheid. Zesentwintig studies met 2959 gerandomiseerde vrouwen werden opgenomen in deze review.

Geïnhaleerde analgesie versus een ander type geïnhaleerde analgesie
Pijnvermindering werd gemeten met een visuele analoge schaal (VAS) van 0 tot 100 mm waarbij 100 gelijk stond aan de meeste vermindering. Pijnintensiteit werd gemeten met een VAS van 0 tot 100 mm, waarbij 0 overeenkwam met 'geen pijn' en 100 overeen kwam met de 'ergste pijn'. De hoogste score voor pijnvermindering was de meest positieve in tegenstelling tot de 'intensiteit van de pijn', waarin de hogere score negatiever was.
Flurane derivaten bleken betere pijnbestrijding dan distikstofoxide (lachgas) te geven in de eerste fase van de baring zoals gemeten door een lagere intensiteit van de pijn score (gemiddeld verschil (MD) 14.39, 95% betrouwbaarheidsinterval (CI) 4,41-24,37, drie studies, 70 vrouwen) ook een hogere score voor pijnvermindering voor flurane derivaten in vergelijking met distikstofoxide (gemiddeld MD -16,32, 95% CI -26,85 tot -5,79, twee studies, 70 vrouwen). Aanzienlijke heterogeniteit werd gevonden in de analyses van pijnintensiteit (P = 0,003) en bij de analyse van pijnvermindering (P = 0,002). Deze bevindingen dienen met de nodige voorzichtigheid worden beschouwd vanwege de twijfelachtige opzet van de meegeleverde cross-over trials. Meer misselijkheid werd gevonden in de distikstofoxide groep tegenover de flurane derivaten groep (risicoverhouding (RR) 6.60, 95% CI 1,85-23,52 twee studies, 98 vrouwen).

Geinhaleerde analgesie versus placebo of geen behandeling
Placebo of geen behandeling bleek minder pijnverlichting te bieden in vergelijking met distikstofoxide (RR 0,06, 95% BI 0,01-0,34, twee studies, 310 vrouwen, MD -3,50, 95% BI -3,75 tot -3,25, één studie, 509 vrouwen). Echter, distikstofoxide leidde tot meer bijwerkingen voor vrouwen zoals misselijkheid (RR 43,10, 95% CI 2,63-706,74, een studie, 509 vrouwen), braken (RR 9.05, 95% BI 1,18-69,32, twee studies, 619 vrouwen), duizeligheid (RR 113,98, 95% CI 7,09-1.833,69, een studie, 509 vrouwen) en slaperigheid (RR 77,59, 95% CI 4,80-1.254,96, één studie, 509 vrouwen) vergeleken met placebo of geen behandeling.
Er zijn geen significante verschillen gevonden voor één van de uitkomsten van de studies die verschillende concentraties van inhalatie stoffen vergeleken met een andere sterkte van geïnhaleerde analgesie, tussen studies die verschillende inhalatie systemen vergeleken en niet voor de studie die inhalatie analgesie vergeleek met TENS.
Door gebrek aan gegevens werden de volgende uitkomsten niet geanalyseerd: gevoel van controle; tevredenheid met bevalervaring; effect op moeder / kind interactie; borstvoeding; toelating tot de speciale babyzorgunit (NICU); kinderlijke

morbiditeit en mortaliteit op lange termijn; kosten.
Conclusie: geïnhaleerde analgesie bleek effectief in het verminderen van pijnintensiteit en in het bieden van pijnvermindering tijdens de baring. Echter werd er aanzienlijke heterogeniteit waargenomen voor pijnintensiteit. Bovendien leek distikstofoxide te leiden tot meer bijwerkingen vergeleken met flurane derivaten. Flurane derivaten resulteerden in meer slaperigheid vergeleken met distikstofoxide. Bij inhalatie analgesie vergeleken met geen behandeling of placebo, leek distikstofoxide nog meer bijwerkingen te veroorzaken zoals misselijkheid, braken, duizeligheid en slaperigheid.

Hoofdstuk 9

Algemene Discussie

De algemene discussie van dit proefschrift presenteert een kort overzicht van de belangrijkste resultaten en adresseert methodologische overwegingen. Het hoofdstuk eindigt met de implicaties en aanbevelingen voor verder onderzoek en praktijk.
Actieve betrokkenheid bij de besluitvorming over het omgaan met baringspijn is belangrijk voor vrouwen omdat dit hun gevoel van controle bevordert. Vrouwen geven de voorkeur aan continue begeleiding van hun zorgprofessional zowel thuis als in het ziekenhuis. Om continue begeleiding te realiseren voor alle vrouwen in de eerstelijns zorg die een verzoek uiten voor medicinale pijnbestrijding is substitutie van obstetrische zorg naar verloskundige zorg voor pijnmedicatie nodig. De meeste vrouwen in onze studie adopteerden een *"pragmatische natuurlijke"* benadering. Deze vrouwen gaven de voorkeur aan omgaan met baringspijn zonder pijnmedicatie maar waren tegelijkertijd gelukkig dat pijnmedicatie beschikbaar zou zijn als dat nodig zou zijn. Verloskundigen dienen echter de onvoorspelbaarheid van de baring met de vrouw te bespreken en hen uitnodigen voor openheid over hun behoeften, wensen en verwachtingen tijdens hun zwangerschap en baring. Voor het bieden van een brede keuze aan pijnmedicatie voor vrouwen met een pijnbestrijdingswens is landelijke toegang nodig tot geïnhaleerde distikstofoxide analgesie voor alle vrouwen. Verloskundigen staan voor de uitdaging van het ondersteunen van vrouwen in omgaan met baringspijn zonder pijnmedicatie indien mogelijk en gewenst. Indien pijnmedicatie is gewenst, dienen verloskundigen deze ook aan vrouwen voor te schrijven en hen daarin te begeleiden. Uiteindelijk dienen verloskundigen continue begeleiding te bieden aan alle vrouwen tijdens de baring, onafhankelijk van hoe vrouwen kiezen om te gaan met baringspijn.

Appendices

Appendix 1, Chapter 3: *Topic list*
Interviews with pregnant women on 'Pain management during labour'
Expectations of pain and pain management during labour

Pain
What are your expectations concerning the pain during the initial stages of labour?
Probes:
- How do you expect the pain to be?
- How strong, how long, and how frequent do you think the contractions will be?

What are your expectations concerning the pain during the actual birth?
Probes:
- How strong, how long, and how frequent?

Pain management – methods
What are your expectations concerning the pain relief during labour?
Probes:
- Expected method of pain relief during labour and childbirth?
- Expected availability of methods?
- How much influence do you expect to have on the method of pain relief used?

Planning - Birth plan
What kind of plans did you make for labour and childbirth?
Probes:
- Do you have a birth plan?
- If so, what does it contain?
- If not, why not? Did you agree any plans during the discussion of your expectations concerning labour pain management, and if so what kind of plans were they?

Preparation

How are you preparing for labour and childbirth?

Probes:
- What information about labour pain management did you receive?
- How was the information presented (article from a journal, leaflet, books)?
- How are you preparing for giving birth?
- What is the role of your partner in the preparation?

Support

What are your expectations concerning the people who will help you during labour and childbirth?

Probes:
- What are you expecting from your midwife regarding management of labour pain? What can she do for you?
- What are you expecting from your maternity care assistant during labour and birth? What can she do for you?
- What are you expecting from your partner during labour and birth? Did you agree any plans with him or her?

Is there anything else you would like to tell me?

Additional questions for parous women:

Probes:
- What kind of things would you definitely do again to manage your labour pain on the basis of your previous birth experience?
- What kind of things do you definitely plan to avoid in connection with labour pain management on the basis of your previous birth experience?

Appendix 2, Chapter 4

Interview guide to women's experiences of labor pain and how they dealt with it
Postpartum interviews with women.

Opening question:

We would like to know how you dealt with labor pain, what can you tell me about it?

Pain

How did you experience pain during the initial stages of labor?
How did you experience pain during the pushing period or when actually giving birth?

Pain approach – methods

What are your experiences of labor pain relief methods?
Probes:
- How did you perceive the availability of pain relief methods?
- What influenced the method of pain relief used?

Support

What are your experiences of the support provided by maternity care professionals during labor?

Is there anything else you would like to tell me?

Appendix 3, Chapter 5

Additional file 1: DELIVER study, women's questionnaire 2 (>34 weeks – < date of birth)

1. Do you have any preference regarding labour pain management?
   - 0 No → please continue to question 3 and further
   - 0 Yes

2. What would be your preference in terms of pain medication? (if you would use pain medication during labour you have to be referred to obstetrician led care in hospital)
   - 0 Injection with medicinal pain relief (pethidine or morphine)
   - 0 Self-controlled drip with medicinal pain relief (remiphentanil)
   - 0 Low back drip with the option of self-control (epidural)
   - 0 No medication

Additional file 2: DELIVER women questionnaire 3 (around six weeks post-partum)

1. Did you use any method of medicinal pain relief during labour?
   - 0 No → please continue to question 2 and further
   - 0 Yes → What method of medicinal pain relief was used? (You may select more than one answer)
   - 0 Injection with medicinal pain relief (pethidine or morphine)
   - 0 Self-controlled drip with medicinal pain relief (remiphentanil)
   - 0 Low back drip with the option of self-control (epidural)
   - 0 General anaesthetic

Appendix 4, Chapter 6

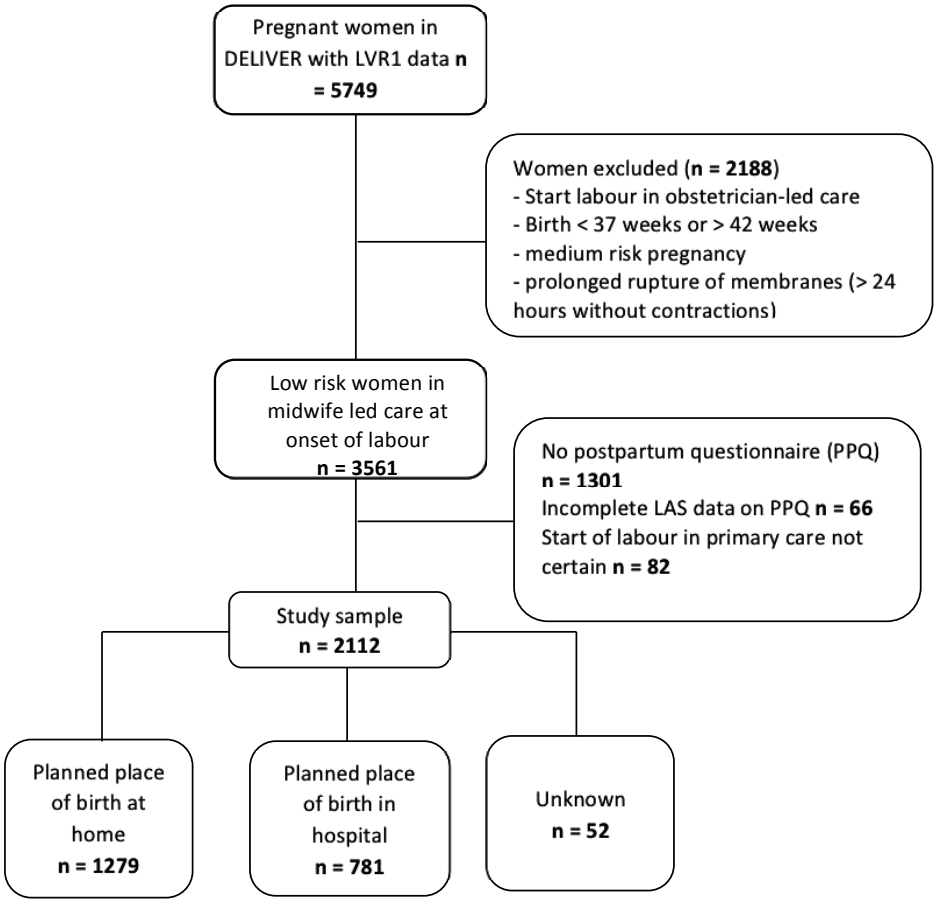

Figure 1. Selection of low risk women who started labour in midwife-led care

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Curriculum Vitae

Geertruida Maria Theodora (Trudy) Klomp is geboren op 8 maart 1959 in Vaassen, gemeente Epe op de Veluwe als het eerste kind van Berendina Hermina Maria (Dini) Klomp-Casteel en Johannes Hermanus Antonius (Joop) Klomp.
Na het behalen van het VWO diploma aan het Katholiek Veluws College te Apeldoorn in 1978 startte zij, nadat ze was uitgeloot voor de studie geneeskunde, in Rotterdam met HBO Jeugdgezondheidszorg. Na het behalen van haar propedeuse, startte zij haar verloskunde opleiding aan het Rijksopleidingscentrum voor Verloskundigen te Rotterdam. Met het behaalde diploma van verloskundige in 1983 heeft zij een jaar verspreid over het land waargenomen in verschillende praktijken en heeft zich vanaf 1 mei 1985 als zelfstandig verloskundige gevestigd in een verloskundige maatschap te Zutphen.
Na 17 jaar als zelfstandig verloskundige te hebben gewerkt en haar 1e graads docenten opleiding aan de HGZO Amsterdam te hebben gehaald is zij op projectbasis bij de Koninklijke Nederlandse Opleiding voor Verloskundigen (KNOV) te Bilthoven gaan werken. Hier is zij gestart als docent en ontwikkelaar en na een jaar als projectleider verder gegaan voor de training voor buitenlands opgeleide verloskundigen. Sinds 2004 werkt zij aan de Verloskunde Academie Amsterdam.
In 2005 heeft zij haar Master Verloskunde aan de Universiteit van Amsterdam behaald en in 2008 is zij parttime gestart aan dit promotieonderzoek aan de Radboud Universiteit Nijmegen met als werkplek de afdeling EMGO+, Midwifery Science van het Vu medisch centrum.
Trudy is lid van een service club in Haarlem, actief als vrijwilliger, lid van het Mammoni Netwerk voor verloskundigen, als Academie voor Verloskunde Amsterdam Groningen (AVAG) afgevaardigd lid van de Verloskundige Zorgstandaard werkgroep van het College Perinatale Zorg en AVAG coördinator van het Midwifery Research Network Netherlands.

Trudy woont met haar partner Niek Kruisheer in Vijfhuizen en samen hebben ze drie kinderen: Johan (1986), Suze (1988) en Liz (1992).
Januari 2015

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