UNIVERSITY OF TROMSØ UIT

FACULTY OF HEALTH SCIENCES
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Differentiated birth care for low-risk women

Medical and economic perspectives

Stine Bernitz

A dissertation for the degree of
Philosophiae Doctor

XX XX 2013

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Medical and economic perspectives

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ACKNOWLEDGEMENTS

This research project was made possible by generous funding of The Eastern Norway Regional Health Authority, The National Advisory Committee for Obstetrics in Norway and The Østfold Hospital Trust through the Womens' Clinic.

In my work with this thesis I have had the pleasure of being guided and inspired by knowledgeable professionals.

Firstly, I would like to express my sincere gratitude to Professor Pål Øian, my skilled principal supervisor who had the idea for and initiated this trial. Thank you for introducing me to the fascinating world of research. Ever-present and positive you encouraged me, believed in me and guided me through this work with your impressive wealth of knowledge and your sincere interest in birth care.

Professor Leiv Sandvik, my supervisor and super-support in statistics, thank you for backing me up, sharing your knowledge and guiding me through the jungle of methods and analyses.

Midwife and Dr.Philos Ellen Blix, my supervisor; you inspire me. Thank you for sharing your sound knowledge in fields of midwifery, statistical methods and epidemiology. I am very grateful for your countless hours on the phone, your interest in this work and constructive feedback. Thank you for being the most generous Tromsø-host and thank you for being my friend.

I am thankful to Professor Rune Rolland who co-initiated this trial and who has been encouraging and inspiring. It is a privilege to communicate with a person so respectful to others, so full of knowledge and with the most beautiful and sophisticated language.

Eline Aas, thank you for introducing me to the field of health-economics and thank you for contributing to the analyses and text. Thank you for the many hours you offered in Oslo, York and on the phone. It is a privilege being around your positive energy.

I would like to thank my co-author Katrine Sjøborg for support and advice throughout this process on a professional as well as a personal level.

I am grateful to the Department of Surgery at the Østfold Hospital Trust and especially the leader of the Women's Clinic, Hilde Hoel who supported this project and made this thesis possible. The University of Tromsø and the University Hospital of North Norway have been most generous by including me in the research group " Women's Health and Perinatology" and providing me with supervisor resources. I would like to thank Turid Bakkevoll, secretary at the Institute for Clinical Medicine for her kind help in organising the paper work.

I owe many thanks to the Department of Economics at the Østfold Hospital Trust and Karine Løllke who provided us with "numbers and knowledge" for the economic evaluation.

Arne Uleberg at the ITC unit has had the task of extracting all data from the electronic journals. He has been available for questions at all times and handled emergency requests with his ever-present positive attitude, thank you very much.

I would like to express my gratitude to the skilled librarians at the library of Østfold Hospital Trust, Anne Katrine Gullvåg, Stig Johansson and Aase Krogh for invaluable help in tracing articles and texts and for being unfailingly friendly doing so.

I would like to thank the department of Quality and Research for providing office facilities and my good colleagues and fellow PhD students for our fruitful discussions and support throughout this educational period. A special thank to Marit Flåskjer for invaluable and friendly support.

This trial could not have been conducted without the effort and work contributed by all the midwives at the Department of Obstetrics and Gynaecology. Thank you for your commitment and enthusiasm. I would specially like to thank Tone Larsen who recruited women to the trial and Ann Morris, Erika Olofsson, Hilde Ostad, Anne Sønsterud, Anne Guren, and Elin Reinholtsen for conscientious and professional contribution to this trial.

I would also like to express my gratitude to all the women who consented to participate in this trial and made this project possible.

I want to thank my friends and my family for their encouragement, for giving me room when needed and not least for providing a social life for me during this period. I'm very grateful to my brother in law, Ashley who proofread my texts whenever I asked.

Fredrik and Manisha, I am so proud, happy and grateful that it was I, that got the most lovely, caring and supportive children possible. Spending time with you is my favourite thing to do.

Mathias, my very best friend and wonderful husband, thank you for your support, your wise advice and for our trips and laughs along the way. “To the moon and back”.

Fredrikstad, October 2012
Stine Bernitz

SUMMARY

Background There has been an increasing trend toward centralisation of childbirth in larger clinics in developed countries over the last few decades. Simultaneously as availability of medical technology increases in birth care surveillance, the use of this technology increases as well, leaving researchers to question whether low-risk women may receive excess interventions. As a counterbalance towards the trend of increased intervention rates, low-risk birth care units have been established. These units can be either freestanding i.e. localized away from a hospital, or alongside i.e. localized inside a hospital, adjacent to the labour ward. The low-risk birth care units are most often led by midwives who have the responsibility for the mother and baby throughout a normal birth, whilst the medical liability lies with the responsible physician at the labour ward, in the hospital or referral hospital. Low-risk birth care units offer birth care to women assessed to be at low-risk and with expected normal births. A woman is transferred to a labour ward if medical services are required. At the Department of Obstetrics and Gynaecology at Østfold Hospital Trust, with 3000 births per year a midwife-led unit (MU) was established in 2004. The obstetric department is divided into three separate birth care units placed on separate floors: the MU, the normal unit (NU) and the special unit (SU). The MU is organised for low-risk women who prefer as little intervention as possible during labour. In order to qualify for the unit, all women have to fulfil the unit's selection criteria. Women attending the MU are transferred to either the NU or the SU if extended surveillance is needed or if the birth needs to be taken over by an obstetrician. The NU suits the needs of women with expected normal births. The unit has access to extended surveillance, epidural analgesia and operative vaginal delivery; hence transfer to the SU is not required if extended care is necessary throughout labour. The SU caters for women who are in need of extended care in the antenatal period, during labour and after birth.

Aims The main aim of the trial was to investigate if there were differences in medical outcomes between the MU compared to a standard obstetric unit represented by the NU and the SU with operative delivery rate as the primary outcome. We also wanted to evaluate if organisation of birth care for low-risk women could be favourable in a cost-effective manner by establishing a separate midwife-led low-risk birth unit within the same hospital. The realisation that the rate of augmentation with oxytocin in low-risk nulliparous women was unexpectedly high at all three units, and that oxytocin, to some extent, was given without apparent indication, triggered us to investigate this further. We wanted to describe the use of oxytocin and to study associations between labour dystocia and adverse birth outcome, and associations between the use of oxytocin and adverse birth outcomes.

Material and methods The analyses presented in the three papers included in this thesis are based on the material and findings of the randomised controlled trial (RCT) carried out at the Østfold Hospital Trust between September 2006 and February 2010. All women giving birth at our hospital during the trial period were given written information about the trial and those eligible and willing to participate were recruited, and signed a written consent at the ultrasound screening at approximately 18 weeks of gestation. The 1111 low-risk women still eligible and willing to participate at onset of spontaneous labour were included and randomised to one of the three birth care units, MU (n=412), NU (n=417) and SU (n=282). A comparison between the three units on medical outcomes is presented in paper I. Paper II investigates the cost-effectiveness of the MU compared to the NU and SU combined. The combination of NU and SU is named standard obstetric unit (SCU). If the outcomes are improved at the same time as the costs are reduced in the alternative setting investigated, the alternative setting is cost-effective. Costs were calculated using the hospital's activity-based costing system CPP. The use of oxytocin in all 747 nulliparous women at all three units are described and analysed in a cohort study presented in paper III.

Results We found no difference in operative delivery rates between the three units, 16 %, 18 % and 18.8 % at the MU, NU and SU respectively. The use of oxytocin for augmentation of birth and the use of epidural analgesia were lower at the MU compared to the NU and SU. Women randomised to the MU were more likely to have acupuncture for pain relief compared with the other two units. No other significant differences were found in medical outcome comparisons between the units. The cost-effectiveness analysis showed that delivering at the MU resulted in a reduction in costs compared to the SCU, provided equal capacity at the units, without jeopardising the outcomes. Total costs per stay were € 1,672 and € 1,950 at the MU and SCU respectively. Of all 747 nulliparous participants 43.8 % were augmented with oxytocin of which 42.5 % did not fulfil the criteria for dystocia at onset of oxytocin infusion. We found a higher risk of operative vaginal delivery $p<0.001$ and episiotomy $p=0.002$ for participants without dystocia if augmented with oxytocin.

Conclusions and relevance to clinical practice For low-risk women without an outspoken preference of birth place, the operative delivery rate is not dependent on the level of birth

care. The rates of medical interventions like epidural analgesia and augmentation with oxytocin are higher at the NU and SU compared with the MU without improving the outcomes. The findings of the cost-effectiveness analysis support the organising of birth care for low-risk women in a separate midwife-led unit. Careful attention should be paid to criteria for labour progression and guidelines for augmentation with oxytocin to avoid unnecessary use, as this may prevent excess instrumental vaginal deliveries.

OPPSUMMERING (SUMMARY IN NORWEGIAN)

Bakgrunn Det har vært en økende trend mot sentralisering av fødselsomsorgen til større klinikker i industrialiserte land i løpet av de siste tiårene. Samtidig med at tilgangen på medisinsk teknologi har økt, har også bruken av denne økt, hvilket har fått forskere til å spørre seg om lavrisikokvinner utsettes for overflødige intervensjoner. Som en motvekt til den stadig økende sentraliseringen og medikaliseringen av fødselsomsorgen, har lavrisiko-enheter blitt etablert. Disse enhetene kan være frittstående utenfor sykehus eller etablert som en fysisk adskilt enhet inne i sykehuset. Lavrisikoenheter er som oftest ledet av jordmødre som har ansvar for mor og barn gjennom det normale fødselsforløpet, mens det medisinske ansvaret ligger hos obstetrikere ved fødeavdelingen i sykehuset eller referanse-sykehuset. Enhetene tilbyr omsorg til lavrisikokvinner med forventet normal fødsel. En kvinne blir overflyttet til fødeavdeling dersom medisinsk overvåking eller inngripen er nødvendig. Ved føde-barselavdelingen ved Sykehuset Østfold med ca 3000 fødsler per år, ble det etablert en jordmorstyrt enhet (MU) i 2004. Føde-barselavdelingen er delt inn i tre separate enheter plassert i hver sin etasje i samme bygg: MU, normalenheten (NU) og spesialenheten (SU). MU er organisert for lavrisikokvinner som foretrekker minst mulig intervensjon under fødselen. For å kunne føde ved MU må kvinnene fylle seleksjons-kriteriene for enheten. Kvinnene blir flyttet til en av de andre enhetene dersom utvidet overvåking er nødvendig, eller dersom ansvaret for fødselen bør overføres til en obstetriker. NU etterkommer behovene for kvinner med forventet normal fødsel. Enheten har tilgang på utvidet overvåkingsutstyr, epiduralbedøvelse og operativ vaginal forløsning, det vil si at det ikke er behov for overflytting til SU dersom utvidet omsorg er påkrevd i løpet av fødselen. SU tar hånd om kvinner med utvidet behov for omsorg i graviditeten, under fødselen og i barsel-perioden.

Hensikt Hovedhensikten med denne studien var å undersøke om det var forskjeller i medisinske utkomme mellom MU sammenlignet med en standard obstetrisk enhet presentert ved NU og SU, med operativ forløsningsfrekvens som primært endemål. Vi ville også undersøke om organisering av fødselsomsorgen for lavrisikokvinner kunne være gunstig på en kosteffektiv måte ved å etablere en separat jordmorstyrt enhet for lavrisikokvinner i sykehuset. Da vi så at andelen av førstegangsfødende lavrisikokvinner som ble stimulert med oksytocin var uventet høy ved alle de tre enhetene, og at oksytocin til en viss grad ble gitt uten skikkelig indikasjon, ønsket vi å undersøke dette videre. Vi ønsket å beskrive bruken av oksytocin og undersøke assosiasjoner mellom langsom fremgang og uønskede fødselsutfall, og assosiasjoner mellom bruken av oksytocin og uønskede fødselsutfall.

Materiale og metoder Analysene presentert i de tre artiklene inkludert i denne avhandlingen baserer seg på materiale og funn fra den randomiserte kontrollerte studien som ble gjennomført ved Sykehuset Østfold mellom september 2006 og februar 2010. Alle kvinner som fødte ved sykehuset i studieperioden fikk skriftlig informasjon om studien, og de som fylte inklusjonskriteriene og sa seg villig til å delta signerte en samtykkeerklæring ved rutineultralyd ved ca 18 ukers graviditetsvarighet. De 1111 lavrisikokvinnene som fremdeles fylte kriteriene og var villige til å delta ved spontan fødselsstart, ble inkludert og randomisert til en av de tre enhetene MU (412), NU (417) og SU (282). En sammenligning av de medisinske resultatene mellom de tre enhetene er presentert i artikkel I. Artikkel II undersøker om MU er kostnadseffektiv sammenlignet med NU og SU kombinert. Kombinasjonen av NU og SU benevnes standard obstetrisk enhet (SCU). Dersom utkomme er bedret samtidig med at kostnadene er redusert ved den alternative settingen som blir undersøkt, er den alternative settingen kostnadseffektiv. Kostnadene ble hentet ut i fra sykehusets eget aktivitetsbaserte kostnadssystem (CPP). Bruken av oksytocin hos alle 747 førstegangsfødende kvinner ble beskrevet og analysert i en kohortstudie, presentert i artikkel III.

Resultater Vi fant ingen forskjell i operative forløsningsrate mellom enhetene, respektive 16 %, 18 % og 18,8 % på MU, NU og SU. Bruken av oksytocin og epiduralbedøvelse var lavere ved MU sammenlignet med NU og SU. Kvinner som ble randomisert til MU fikk akupunktur som smertelindring i større grad enn ved de to andre enhetene. Ingen andre signifikante forskjeller i medisinske utkomme ble funnet mellom de tre enhetene. Kosteffektanalysen viste at det å føde ved MU førte til en reduksjon i kostnadene sammenlignet med SCU, sett at det var likt belegg ved enhetene, uten å svekke de medisinske resultatene. Totalkostnader per opphold var respektive 1,672 € og 1,950 € ved MU og SCU. Av alle 747 førstegangsfødende studiedeltagere ble 43,8 % stimulert med oksytocin hvorav 42,5 % ikke fylte kriteriene for langsom fremgang da oksytocindryppet ble startet. Vi fant en økt risiko for operativ vaginal forløsning (p<0.001) og episiotomi (p=0.002) hos studiedeltagere uten langsom fremgang dersom de ble stimulert med oksytocin.

Konklusjoner og relevans for klinisk praksis For lavrisikokvinner uten uttrykt ønske om fødested er ikke den operative forløsningsfrekvensen avhengig av omsorgsnivå. Andelen medisinske intervensjoner som epidural og stimulering med oksytocin er høyere ved NU og SU sammenlignet med MU uten å bedre utkomme. Resultatene i kosteffektanalysen støtter organisering av fødselsomsorgen for lavrisikokvinner i en separat jordmorstyrt enhet. Fokus bør holdes på kriterier for fremgang i fødsel og på retningslinjer for stimulering med oksytocin for å unngå unødig bruk, da dette kan bidra til å forhindre unødige instrumentelle vaginale forløsninger.

ABBREVIATIONS

BE	Base Excess
BMI	Body Mass Index
CI	Confidence Interval
CPP	Cost Per Patient
DRG	Diagnose Related Groups
ICER	Incremental Cost-Effectiveness Ratio
LD	Labour Dystocia
MBRN	Medical Birth Registry of Norway
MMR	Maternal Mortality Rate
MU	Midwife-led Unit
NICU	Neonatal Intensive Care Unit
NPR	Norwegian Patient Register
NU	Normal Unit
OR	Odds Ratio
SCU	Standard Care Unit
SU	Special Unit

LIST OF INCLUDED PAPERS

PAPER I

Stine Bernitz, Rune Rolland, Ellen Blix, Morten Jacobsen, Katrine Sjøborg, Pål Øian

Is the operative delivery rate dependent on the level of birth care? A randomised controlled trial. BJOG An International Journal of Obstetrics and Gynaecology 2011;118:1357-1364

PAPER II

Stine Bernitz, Eline Aas, Pål Øian

Economic evaluation of birth care in low-risk women. A comparison between a midwife-led birth unit and a standard obstetric unit within the same hospital in Norway. A randomised controlled trial. Midwifery 2012; epub ahead of print

PAPER III

Stine Bernitz, Pål Øian, Rune Rolland, Leiv Sandvik, Ellen Blix

Dystocia and augmentation with oxytocin as risk factors for adverse birth outcomes in low-risk nulliparous women. Submitted

INTRODUCTION

Birth care in a global perspective

There are major challenges in decreasing maternal, neonatal and perinatal mortality, and to improve safety for both mother and child when viewing birth care in a global perspective today. WHO defines maternal mortality as " The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes" (1). For the last 50 years the term "perinatal mortality" has been used to include deaths that might somehow be attributed to obstetric events after 20 weeks of gestation, such as stillbirths and neonatal deaths in the first week of life (2).

Birth care in developing countries

Developing countries accounted for 99 % of all maternal deaths worldwide in 2005 (3) and 98 % of all perinatal deaths in 2000 (2). Just over 40 % of deliveries occur in health facilities and a little more than half of these with the assistance of a doctor, midwife or qualified nurse in developing countries (2).

In the year 2000, 189 world leaders signed onto the Millennium Declaration (4) and agreed to meet the Millennium Development Goals (MDGs) (5) at the United Nations Millennium Summit. The MDGs are an eight-point road map with measurable targets and clear deadlines for improving the lives of the world's poorest people by 2015. Goal 4 is targeted to reduce child mortality by two thirds, between 1990 and 2015, and by 2009 child mortality for children under five was reduced by a third. The target of Goal 5 is to improve maternal health by reducing maternal mortality by three quarters during the same period and to achieve universal access to reproductive health care (5). The maternal mortality rate (MMR) has dropped from 440 maternal deaths per 100.000 live births in 1990 to 290 maternal deaths in 2008, which is a 34 % decrease. More pregnant women are offered at least minimal care during pregnancy and major gains have been made in increasing skilled attendance at birth, but MDG targets are still far off, especially in sub-Saharan Africa and Southern Asia (5). The MMR varies greatly throughout the world with 4 in Italy and 1575 in Afghanistan (6). In 2010 the United Nations Secretary-General launched the Global Strategy for Women's and Children's health to catalyse action for renewed and enhanced commitments to improve women's and children's health. Four out of five elements in the commitments include plans, strategies and systems for strengthening health services and access to the services (7) to secure adequate birth care.

Birth care in developed countries

In developed countries, the challenges in care for the pregnant woman, the labouring woman and the child, are at a complete different level. The term "birth care" leads us to think about institutional settings, surveillance, doctors and midwives as birth care has become a public and medical matter in these countries today. Looking back in the Norwegian history of child birth, care in labour was initially a domestic matter where the labouring mother was supervised by an untrained birth attendant and later by a trained midwife (8,9). Along with the industrialisation and modernisation of society in the last part of the 19th century and first part of the 20th century, the welfare system improved. Care for the birthing woman moved into birthing homes and institutions, and deliveries were attended by doctors and midwives (8). At the same time there was a growing interest for the welfare of child and the development of the fetus (10).

Today most women in developed countries give birth in high technological hospitals regardless of being assessed as a low- or a high-risk patient (11). Birth care has over time developed from being a women's affair to becoming a medical science characterised by medical and technological innovations and obstetric management (9,12). In the development of modern birth care there has been a momentous improvement on the safety of childbirth over the last 50 years (13). Neonatal and perinatal mortality has decreased to a level of 10/1000 overall (2) and in Norway the perinatal death rate was 3.8/1000 in 2010 (14). Maternal mortality has decreased to a level of 0.017 % in developed regions in 2008 (5) and in Norway the rate was 0.007 % in 2011 (15). Whether it is technology and medical science that have the greatest impact on the increased safety of child birth, or if safety is most influenced by an overall improvement on hygiene, health and environment, is questioned (13). At the same time, obstetrician involvement and medical interventions in normal childbirths have become routine without evidence of effectiveness which triggers the question whether medicalisation of birth care have gone too far (16)?

It is a paradox that the major challenges in developing countries mostly depend on the lack of qualified care during pregnancy and delivery (5), whilst medicalisation and over-treatment in birth care are challenges in developed countries (11,16). Following the WHO's principals of perinatal care, effort should be made to accomplish evidence based birth care by minimizing medical interventions and technological procedures whenever possible (17).

Differentiated birth care

As a counterbalance to the increasing institutional and technological birth care system, low-risk birth care units or birth centres have been established (12,18,19). The intention of low-risk birth care units is to provide care at a suitable care-level for low-risk women, and aims at avoiding unnecessary interventions. Differentiated birth care entails means-tested care and requires careful monitoring throughout pregnancy and a thorough selection of birth place depending on each individual's condition and criteria for the low-risk birth care units. Alternative settings for low-risk births may either be a free standing low-risk birth care unit geographically separated from a hospital or a low-risk birth care unit adjacent to a standard obstetric unit within a hospital (18) often referred to as an alongside unit. Low-risk birth care units are most often midwife-led and the midwives are responsible for all normal births. Most often the medical liability lies with the obstetricians at the adjacent obstetric unit or at the obstetric unit at the referral hospital, implying that all parturients need to be carefully monitored throughout labour and transferred to the obstetric unit if the case no longer is considered to be normal and needs to be taken over by an obstetrician.

Differentiated birth care is more prevalent in some countries like in England, New Zealand and the Netherlands, and studies have been conducted to evaluate the organisation in these countries (20-23). Even though differentiated birth care is not that common worldwide, studies on birth care organisation for low-risk women have been conducted in Canada (24), Scotland (25), Hong Kong (26), USA (27,28), Ireland (29), Denmark (30), Sweden (31,32) and Norway (33-35) indicating a worldwide interest in different models of organising birth care for low-risk women.

The "Care in Normal birth: a practical guide" published by the WHO points at the high levels of interventions in normal births in developed countries and questions the value of general use of medication to initiate, augment and accelerate the physiological process of labour. The guide recommends useful practices which should be encouraged throughout normal birth irrespective of the setting or the level of care, but also recommends that a women should give birth in a place she feels safe and at the most peripheral level at which appropriate care is feasible and safe with access to a properly-staffed referral centre (36).

Organisation of birth care in Norway

There has been an increasing trend towards centralisation of maternity care and childbirth to large hospitals over the last decades in developed countries (37). In Norway, the number of maternity units have decreased from more than 150 at the beginning of the seventies (38) to 51 in 2010 (39) Figure I.

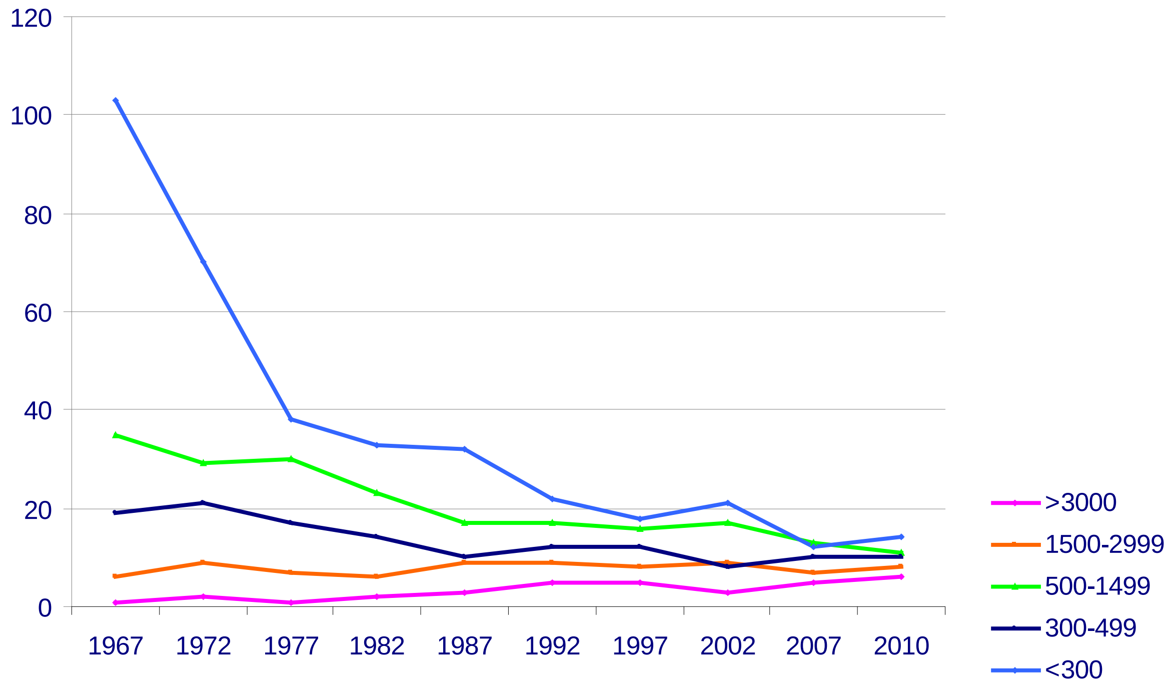

Figure I. Numbers and size of birth places in Norway 1967-2010, numbers obtained from the Medical Birth Registry of Norway April 2012.

Based on the Parliamentary report (White Paper) number 43, 1999-2000 concerning the emergency care policy, the Norwegian Parliament decided in 2001 to organise national birth care into three levels of institutions (40).

1. Departments of obstetrics and gynaecology with more than 1500 births per year providing all birth care services with obstetricians, paediatricians and anaesthesiologists on duty at all times, and neonatal care.
2. Smaller obstetrical departments with 400-1500 births per year providing selected births, with obstetricians and anaesthesiologist on call.
3. Free standing midwife-led maternity homes with 40-400 births per year providing birth care for healthy women with expected normal births.

The Norwegian Parliament also advised obstetric departments to have low-risk birth care units within hospitals. The prior Eastern Norway Regional Health Authority's Project no. 12, ”Utredning av fødsel- og nyfødtomsorgen i Helse Øst” (Evaluation of birth and neonatal care in the Eastern Norway Regional Health Authority) stated in June 2003, that all level 1 and 2 departments in the Eastern Norway health region should organise the activity in units for high- and low-risk birth care. It was not predetermined in what way the organisation should be conducted and the foundation of knowledge of which the statement was based upon was not presented (personal correspondence with the Regional Health Authority).

In 2009 it was suggested that the birth number limits for the three levels of birth institutions be replaced by quality criteria for mother and child (41). The fact that it is stated that it is safe for low-risk women to give birth at any of the three levels leads organisation of birth care for low-risk women to being a political as well as medical matter. In Norway there were 59,810 births in 2011, 73 % took place in departments of more than 1500 births per year. Five of the largest departments have alongside midwife-led low-risk birth care units, Østfold Hospital Trust, Oslo University Hospital, Stavanger University Hospital and Haukeland University Hospital. Between 7 and 29 % of the population in each region deliver at the units and the intrapartum transfer rate differ between 20 and 30 %. All units welcome primiparous and multiparous low-risk women, although there is some discrepancy between selection criteria and organisation models between the units.

Organisation of birth care at Østfold Hospital Trust

Based on the decision of the Regional Health Authority to organise the activity into units for high- and low-risk women, the Department of Obstetrics and Gynaecology at Østfold Hospital Trust, with approximately 3000 births per year, was divided into three separate birth care units in 2004. The Midwife-led Unit (MU), the Normal Unit (NU) and the Special Unit (SU), the three units are located on separate floors within the same building in the hospital. Low-risk women, expecting normal births, may attend any of the three units provided capacity. Each unit has it's own separate staff of midwives who are responsible for all normal deliveries. The MU has approximately 600 births annually, the NU 1200 and the SU 1200 as well, all units provide both birth- and postpartum care.

The MU is organised for low-risk women with expected normal births who are prepared to deliver without medical interventions surrounded by midwives supporting their attitude. To attend the MU, restrictive selection criteria have to be fulfilled. Neither epidural analgesia nor augmentation with oxytocin is offered, unless for the second phase of the second stage. If extended surveillance is needed or if the birth needs to be taken over by an obstetrician, the woman will be transferred to either the NU or the SU. Obstetricians are not present at the unit unless summoned, for a specific reason. The NU is organised for women, with expected normal births. The unit has access to extended surveillance, epidural analgesia and operative vaginal delivery. It also gives room for healthy women with elective caesarean sections and inductions after spontaneous rupture of membranes. If extended surveillance is necessary throughout birth at the NU, transfer to SU is not required. The SU is organised for women who are in need of extended surveillance in the antenatal period, during labour and after birth.

Care for low-risk women

The traditional view of labour care is characterised by "worst case approach" and the unpredictability of labour (42). Among Norwegian obstetricians it has been a tradition to claim that all births should be centralised into larger units due to potential risk (43). By stating that labour care was to be decentralised and differentiated, the Norwegian Parliament radically altered its earlier views on risk assessment in 2001 (43). Despite the decision of organising birth care in the three levels of institutions mentioned above, there has been a wide discussion among professionals whether low-risk women should give birth in large hospitals with medical and technological equipment available, or if it is safe to deliver at smaller departments or units. A two-year prospective study of 1275 low-risk women, planning to deliver in maternity homes in Norway, showed a low rate of transfer to obstetric unit (4.5 %), and a low operative delivery rate (2.5 %) (44). A retrospective Norwegian study compared caesarean section rates between a low-risk birth unit, located in a hospital with no obstetric unit, but with an obstetrician on call at all times, to a conventional ward. The researchers found an increased risk for caesarean section in the low-risk birth unit (OR 1.4, 95 % CI 1.2–1.6) (34). In a prospective study of low-risk primiparous women, comparing a midwife-led alongside unit to a conventional labour ward, no difference in operative delivery rate between the units were found (33).

Internationally, randomised controlled trials have been conducted with the intention to assess the quality of birth care for low—risk women in different settings. A Cochrane review including nine RCT's comparing conventional birth settings to hospital-based alternative birth settings was published in 2010. The review concluded that the alternative birth settings are associated with increased likelihood of spontaneous vaginal birth, reduced medical interventions and increased maternal satisfaction, though no difference in caesarean section rate was found (18). The National Institute for Health and Clinical Excellence concludes in their guidelines "Intrapartum care" that if a low-risk woman plans to give birth in a midwife-led unit she will have a higher likelihood of a normal birth with less intervention (45). Almost 65 000 low-risk women were included in the Birth Place in England Study comparing birth outcomes in different settings. The large cohort concluded that labouring in midwife-led units, both freestanding and alongside units, compared to standard obstetric units decreased the risk of interventions with no impact on perinatal outcome (21).

Even though outcome measures differ, the majority of the studies on the topic include mode of delivery, augmentation with oxytocin, use of epidural analgesia and outcomes for the newborns. Randomised controlled trials comparing alongside midwife-led birth units to conventional labour wards conducted over the last 20 years (20,25,26,29,31,46), show no significant differences in mode of delivery or prevalence's of Apgar score <7 at 5 minutes between the units, but reveal a significant increase in the use of epidural analgesia and augmentation with oxytocin in conventional labour wards (Table 1).

Table 1. Randomised controlled trials comparing midwife-led units to standard care units in the last 20 years

	Caesarean section	Instrumental vaginal delivery	Augmentation	Epidural analgesiaOR	Apgar score < 7 at 5 min
	OR (95% CI)	OR (95% CI)	OR (95% CI)	(95% CI)	OR (95% CI)
MacVicar 1993	**0.96 (0.73-1.29)**	**0.85 (0.66-1.08)**	**0.70 (0.57-0.86)**	**0.79 (0.65-0.96)**	Median 9/9
Hundley 1994	**0.82 (0.63-1.08)**	**0.90 (0.71-1.14)**	**1.03 (0.82-1.28)**	**0.87 (0.69-1.09)**	Median 9/9
Waldenstrøm 1997	**0.78 (0.55-1.10)**	**0.88 (0.55-1.39)**	**0.44 (0.36-0.53)**	**0.78 (0.59-1.02)**	< 7 v/5 min **1.11 (0.46-2.69)**
Byrne 2000	**0.61 (0.24-1.48)**	**0.93 (0.44-1.98)**	**0.75 (0.43-1.32)**	**0.64 (0.36-1.12)**	< 7 v/5 min **2.01 (0.15-60.16)**
Begley 2011	**0.97 (0.73-1.29)**	**0.87 (0.64-1.17)**	**0.50 (0.40-0.61)**	**0.70 (0.55-0.90)**	< 8 v 5/ min **0.55 (0.22-1.42)**
Chambliss 1992	**5.49 (0.75-131.40)**	**0.01 (0.0-0.18)**	**0.16 (0.06-0.34)**		< 7 v/5 min **10.86 (0.02-7241)**
Law 1999	**1.13 (0.62-2.08)**	**0.92 (0.66-1.29)**	**0.66 (0.49-0.88)**	**0.81 (0.53-1.25)**	< 7 v/5 min **0.01 (0.0-16.44)**

When assessing the significance of birth settings for low-risk women, the time for inclusion is of importance. Studies reporting results from low-risk units often include participants during pregnancy (20,25,29,31,46). This implies that a certain number of included women do not fulfil the selection criteria for midwife-led low-risk birth care units at onset of labour, and therefore do not attend these units at all in labour. Following the important principle of "intention to treat", the participants are still analysed according to the group they were allocated to. It is important to notice that studies including participants during pregnancy will evaluate both antepartum and intrapartum care, while studies including participants at onset of labour will evaluate intrapartum care.

Defining low-risk

There is no consensus concerning the term low-risk women in obstetrics, and in studies comparing different birth settings, the inclusion criteria vary. Even though it seems to be a common understanding that a low-risk woman should be healthy with no medical conditions, physiological or mental, the term is open to interpretation. The Cochrane review comparing alternative to conventional birth setting describes the participants as “Pregnant women at low-risk of obstetric complications” (18), which leave room for diversity in inclusion criteria. Nevertheless criteria such as gestational age between 37 and 42 weeks and the requirement of a singleton in cephalic position are common and used in cohort studies as well as randomised controlled trials (22,27,35,47). When assessing perinatal and maternal outcomes by planned place of birth for healthy women with low-risk pregnancies in the Birthplace in England Research programme (21), the definition of “low-risk” was based on the National Institute for Health and Clinical Excellence (NICE) Intrapartum Care Guidelines (48). The Guideline defines a woman to be low-risk if she is giving birth to a singleton at 37-42 weeks, the baby is growing properly, she has no pre-eclampsia, diabetes, or infections such as group B streptococcus, HIV or genital herpes virus, and if she is not in need of a caesarean section (48). The majority of the RCT’s comparing alternative to conventional birth setting conducted over the last 20 years, do not include a limited level of Body Mass Index (BMI) as inclusion criteria for low-risk participants in the studies (20,25,26,46,49). There has been a dramatic increase in the prevalence of overweight and obesity among women of child-bearing age worldwide (50). Two large cohort studies, one from Denmark (50) and one from England (51) reveal an increased rate of adverse pregnancy outcomes with increasing BMI, both studies show a significant increase in risk for emergency caesarean sections and low Apgar scores with increasing BMI (50,51). Therefore in summing up, comparisons between studies of low-risk parturients in different birth care settings should be interpreted with caution due to differences in inclusion criteria and definitions of low-risk women.

Cost evaluation of birth care

When investigating different birth care settings for low-risk women the main outcomes are most often medical, related to the mother and the baby (18,26,27). Organisation of birth care has become a political matter as well as a medical matter (52), and it is therefore of great interest to consider the aspect of costs and cost-effectiveness as well as maternal and perinatal outcomes when evaluating possible risks or benefits of alternative birth care settings for low-risk women. Even though a randomised controlled trial from Australia comparing birth centre care to standard care found no difference related to costs (46) others have found that alternative settings for low-risk women is favourable in an economic manner as well as medical (53-55).

Recently the “Cost-effectiveness of alternative planned places of birth in women at low-risk of complications: evidence from the Birthplace in England national prospective cohort study” was published. The results showed an increase in costs parallel to the increase of birth care level (56).

Mode of delivery and interventions during labour are known to influence the short term health care costs of birth care (57). Measuring the “average cost unit” per women for low-risk women predicted by the level of intervention during labour, Tracy and Tracy found that the relative costs of birth increased by up to 50 % for low-risk nulliparous women, and up to 36 % for low-risk multiparous women as labour interventions accumulated (58).

International economic evaluations are not directly applicable to the Norwegian system as the analyses will vary depending on the different structure of health care in different countries, and which costs that are included in the estimations (59). In search for articles on costs regarding birth care in general we were not able to find anything published from Scandinavia. Contacting one of the researchers behind “the Stockholm birth centre trial” (31), we learned that no economic evaluation had been conducted in connection with their RCT.

Birth care for women who are at ‘low-risk’ of complications prior to the onset of labour is mostly provided for in large obstetric units in Norway. Approximately 70 % of all births take place in departments of obstetrics and gynaecology with more than 1500 births per year and 28 % take place in obstetric departments with 400–1500 births per year (14). Some of the largest obstetric units in Norway have established midwife-led alongside units adjacent to the labour ward, similar to the midwife-led unit at Østfold Hospital Trust, but the economic aspects of running separate midwife-led units is not well-known.

Financing birth care

In Norway the state has the overall responsibility for health care services. The health care system is tax-based and built on the principle of equal access for all inhabitants regardless of social status, location or income. Health services are mostly free-of-charge for the users. The Regional Health Authorities are responsible for the delivery of specialised health care services. Financing of the health system is based on block grant from the central state to the regional and local authorities (60 %) combined with an activity based component (40 %) (52). The block grant is determined by the number and age composite of inhabitants in each region and is not dependent on production. The activity based finance system is based on production according to diagnosis-related groups (DRG). All diagnosis are weighted and given a certain weight point. For example, an uncomplicated caesarean section is weighted to represent 1,720 DRG points and an uncomplicated vaginal delivery is weighted to represent 0,460 DRG points. Each DRG point has a value of 36.968,- NOK (2011) and by representing 40 % of expected revenues, each health trust is reimbursed with 14.787,- NOK per DRG point. The DRG is to be reported from each Regional Health Trust to the Norwegian Patient Register (NPR) regularly (60).

Estimating birth care costs

The hospital’s expenditure is related to each procedure or stay and is not always in accordance with incomes triggered by the activity based finance system; hence one has to be aware of the difference between costs of a procedure or stay, and the reimbursement for the same procedures or stay when discussing the economic aspects of care. There is no definite answer to how much a birth costs and there is no mandatory strategy for cost calculations of care in Norway. Nevertheless, cost estimations are usually based on distribution keys for both costs and resources which emphasize the importance of considering costs as cost estimates and not actual costs.

Cost-effectiveness

In order to evaluate if a specific model of care is cost-effective one has to consider both the effects/outcomes and the costs in relation to the model. If an experimental model can demonstrate better outcomes than the compared model and at the same time show that the costs are reduced, the experimental model is known to be cost-effective. In cost-effectiveness evaluations of settings for birth it would be appropriate to measure effect in avoided adverse outcomes (56).

Duration of labour

Predicting the exact length of labour is probably a utopia, still researchers strive to come closer to the expected duration of labour. In 1954 Friedman published the article "The Graphic Analysis of labor" in the American Journal of Obstetrics & Gynecoloy (61). The graphic presentation of the dilating cervix was based on the observation of 100 primigravidas presenting themselves at term and in early labour. To produce a curve representing expected labour progress, rectal examinations were performed every half hour to two hours. The findings were plotted onto a scheme and resulted in a curve with a sigmoid shape (S-shape), later known as Friedman's curve (Figure II).

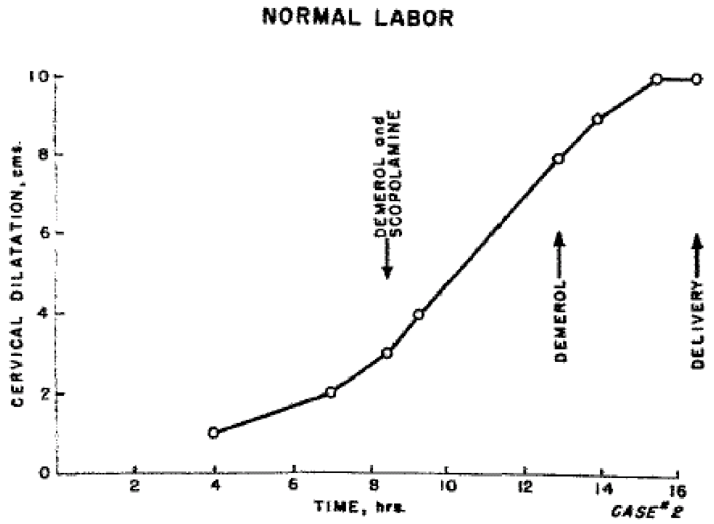

Figure II. Friedman's curve of normal labour in nulliparous women (1954)

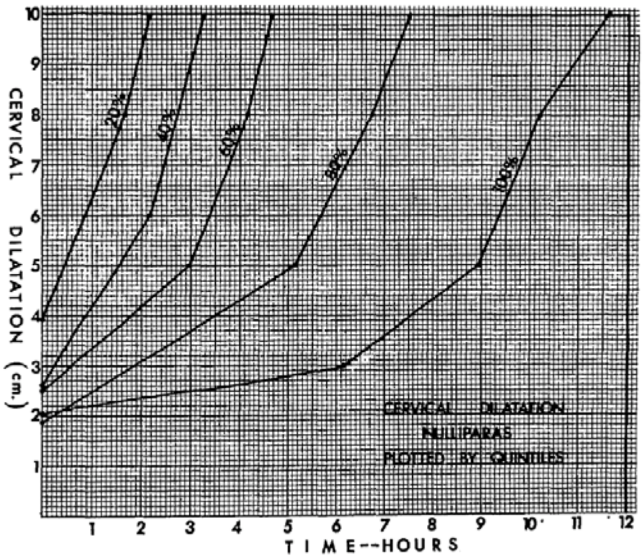

Figure III. Hendricks' curve of nulliparous women in spontaneous active labour (1970)

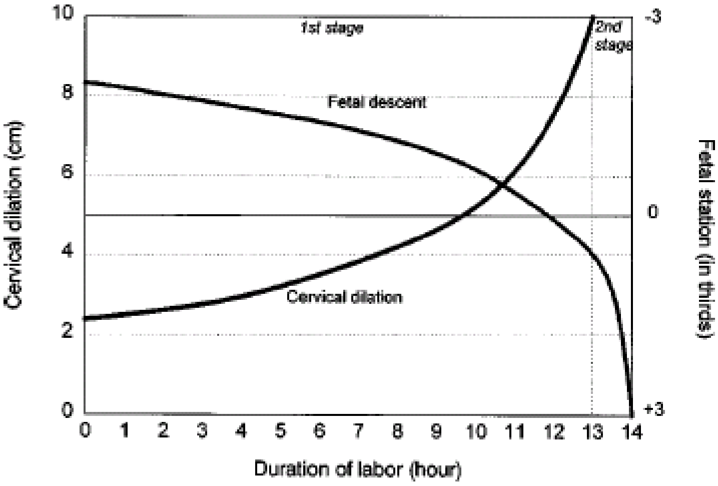

Figure IV. Zhang's curve of cervical dilation and fetal descent in nulliparous women (2002)

Figures II-IV are reprinted with the kind permission from Elsevier Limited 2012

Friedman divided the labour progress in four phases, phase one is the latent phase which lasts until the cervix is dilated 2-2.5 centimetres, phase two is an acceleration phase which is marked by a rapid change in the slope of the cervical dilation, in phase three the cervix dilates linear from 3-3.5 to 8.5-9 centimetres followed by a flattening of the slope until full dilation is reached. In phase four the fetus is descending. The active phase of labour includes phase two, three and four and lasts from 1.8-9.5 hours with a mean of 4.4 hours and standard deviation 1.9. The expected cervical dilation of the active phase based on the

Friedman's curve is approximately 1.5 centimetres per hour (61). Based on an interest in the graphic analysis of labour and an observation of labour progressions among own patients, which differed from what was presented by Friedman, Hendricks et al. published yet another labour curve based on 303 nulliparous and multiparous women I 1970 (62). The curve allowed an even faster progress of active labour than was generally recognised and there was no sigmoid shape of the curve, rather a pattern of constant acceleration (Figure III) (62). When Albers et al. in 1996 published "The Length of active Labor in Normal Pregnancies" suggesting that the active labour lasted considerably longer than the Friedman norms and did not produce excess morbidity (63), a discussion commenced on definition of active labour (64). In 2002 Zhang et al reassessed the Friedman's labour curve pointing out that the cervix dilated substantially slower in the active phase than predicted in Friedman's study (61,65), and no deceleration phase was seen in active labour (65) (Figure IV).

More recently the discussion on labour duration has gained some traction, maybe because the rate of caesarean sections has risen and become a challenge in developed countries and failure to progress is one of the main reasons for caesarean sections (66). It is suggested that cervical dilation accelerates after a dilation of 6 centimetres, and that the previously described acceleration from 4-6 centimetres is in fact far slower (67). Searching for studies published between 1950 and 2008, Neal et al. found that the slowest-yet-normal, linear dilation rate approximates 0.5 centimetre per hour for low-risk nulliparous women (68).

In an attempt to identify the definition of the phases in labour and to identify how duration of labour is described, Norwegian researchers searched books, guidelines and published scientific articles from 1995 to 2008 (69). It was found that books and guidelines were hard to interpret as there were no, or incomplete references to the data-sets and that the inclusion criteria differed widely between the populations described in the articles which made comparisons complex (69).

It is difficult to determine onset of labour as the starting point cannot be identified by objective means. The cervix undergoes structural changes in late pregnancy; hence women start labour with unidentical cervix anatomy (62,63). It is described that the duration of the latent phase of labour can vary between 1.7 to 15 hours (61). There are various definitions on onset of the active phase of labour, still most definitions require regular and painful contractions and a cervix dilation of 2.5-4.0 centimetres (62,63,66,69-72). In a recently published article it is suggested that the active phase may start as late as five cm cervix dilation for multiparous and even later for nulliparous women (66). The second stage of labour is identified more easily and generally known to be the time from full dilation of the cervix until the baby is born (65,73,74).

Diagnostic tools for labour progression

Cervicographs, or partograms are used to monitor labour progression in contemporary birth care. On the basis of Friedman’s labour curve, a tool to diagnose abnormal labour progression in nulliparous women was developed. The tool consists of an alert line drawn on the partogram diagonally expecting a cervix dilation of one centimetre per hour, and an actionline drawn parallel and four hours to the right of the alert line, called the four hour action line (71,75). Prolonged labour is visualised if the action line is crossed. Researchers have found the partogram with alert and action lines to be useful (76), nevertheless there has been a discussion whether a two hour or a four hour action line is most beneficial (70,77). In a Cochrane review investigating the effect of the use of partograms on outcomes for women in spontaneous labour at term, the two hour action line resulted in a higher rate of intervention compared to the four hour action line. When comparing a three hour action line to the four hour action line, caesarean section rate was lowest in the four hour action line group. Nevertheless the authors could, based on their findings, not find evidence for a routine use of the partogram (78). The National Institute for Health and Clinical Excellence (NICE) recommends that if an action line is included in the partogram, a four hour line should be used (48). This also concurs with recommendations from the World Health Organization (36).

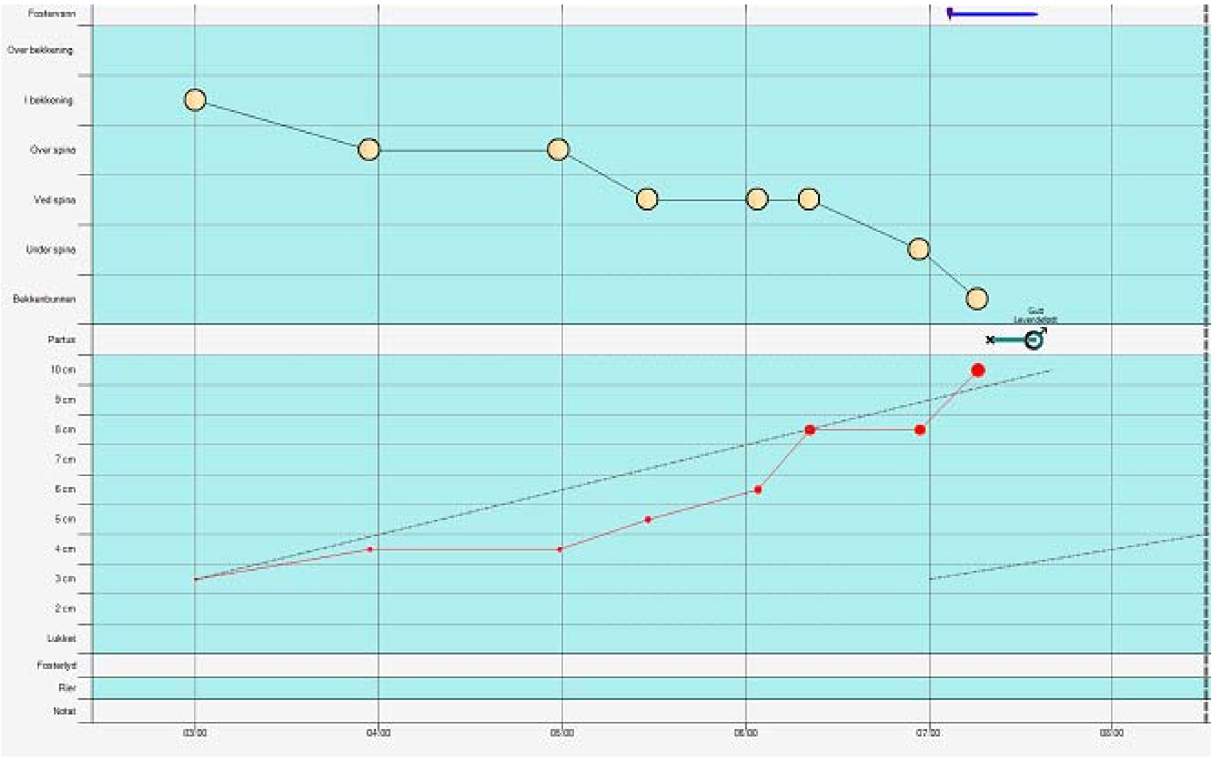

Figure V. Illustration of partogram CESAM-Partus 3.4, 2012, with a 4-hour action line. Reprinted with the kind permission from CSAM Health AS. The upper blue part show the babies head position in the pelvis and the lower blue part show the dilation of the cervix. Each point at the partogram refers to a vaginal exam.

Labour dystocia

Slow progress of labour or labour dystocia (LD) is characterised by abnormally slow progression of the labour process and is among the most common challenges in birth care, especially for first time mothers (74,79,80). LD can be caused by factors related to the passage (the pelvis), the passenger (the baby) or the powers (contractions) (81). The pelvis is rarely the cause of LD, the size of the baby may be too large or there may be a disproportion between the pelvis and the baby due to malposition by a deflexed position of the leading head. However, the most common cause of LD is inadequate uterine contractions (82). Other aspects may also be taken into consideration when discussing causes of LD, e.g. psychological factors, high age, high BMI, infertility, epidural analgesia and stress during labour (83-86).

As there is no universal definition of duration of normal birth, there is no consensus how to define LD (72,74), still the term is often used in medical practice and is likely to be found in the obstetric literature (85). The rate of LD presented in scientific papers varies greatly due to the different definitions, and numbers up to 50 % have been reported (85). Labour dystocia as a phenomenon is of major interest in contemporary birth care as LD is the dominant reason for emergency caesarean sections (72,87-89), and the rate of caesarean sections is high and continue to rise in developed countries (90).

To treat LD caused by inefficient uterine contractions, non-medical methods of treatment have been used throughout history. Amniotomy is a procedure well known for stimulation of contractions and early amniotomy is shown to be associated with a modest reduction in caesarean sections (91). Stimulation of the nipples is widely known and seems to be efficient in 50 % of the cases (92). Acupuncture is shown to reduce the length of birth and the use of oxytocin in a Norwegian RCT (93). Some have claimed that the intake of food during labour could prevent LD, but a randomised controlled trial showed no statistical significant difference in LD between women who were encouraged to eat and drink as they pleased during labour compared to women who were restricted to ice chips during labour (94). Nevertheless, in contemporary birth care, augmentation of labour and stimulation of uterine contractions, are managed to a large extent by oxytocin.

Oxytocin

Studying the nature of the mammalian hormone oxytocin is a complicated matter. There is a markedly variation of secretion and function of the hormone and varying sites of synthesis in the ovary and tissues of the uterus among different mammals. The fact that it is difficult to study oxytocin in human tissues in pregnant women is the reason why most of our knowledge on physiologic regulation and secretion of oxytocin during labour is derived from investigating animal species (95). Mauri et al, however, found that oxytocin is contained in both human fetal membranes and decidua, though in a very low concentration, and that the concentration did not change in relation to labour at term. However, they found a rise in oxytocin levels in the amniotic cavity during term labour (96).

Even though there is an uncertainty concerning the role of oxytocin in initiation of labour (97), the hormone is known for its role in uterine myometrial contractions at parturition and smooth muscle activation when breastfeeding (98).

The American biochemist Vincent du Vigneaud, was the first to sequence and synthesize biochemically the polypeptide hormone Oxytocin. He won a Nobel Prize in Chemistry in 1955 for his work on biochemically important sulfur compounds, especially for the isolation, structural identification, and total synthesis of oxytocin (99,100).

Augmentation with oxytocin

Since synthesized oxytocin became accessible to birth attendants, there has been an increasing use of the potent drug in labour care, but the use of oxytocin was first popularised in the early seventies by O'Driscoll et al. as part of a package of care called "active management of labour" (101). Active management of labour has been modified significantly over time but the core principles remain:

- Early diagnosis following strict criteria, by a senior midwife
- Vaginal examination hourly for three hours, then every two hours, at least. This allows the rate of progress to be plotted on a partogram
- Amniotomy as soon as a firm diagnosis of labour is made
- Augmentation with oxytocin if not dilating at rate of 1 cm/hour
- Women not in labour should be sent home (50 % are re-admitted within 24 hours)
- Personal, psychological support for the woman
- Liberal use of epidural analgesia
- Regular rounds by the obstetrician
- Antenatal education classes
- Regular audit of labour ward process and outcomes (102).

Active management of labour aims to reduce the rate of caesarean sections, nevertheless a Cochrane review comparing active management of labour to routine care, found no statistical significant difference in caesarean section rate between the groups (103). Even though active management of labour as a package is not applied as standard birth care, fragments of the package, often including the use of oxytocin only, are applied in many institutions.

In contemporary birth care, possible benefits and possible consequences of augmentation with oxytocin is widely discussed and studied. Interpretation of the results from previous studies is complicated by different designs and definitions. Some studies compare oxytocin recipient to non-recipients (88,104-106), some investigate early versus delayed use of oxytocin (107), some compare both oxytocin recipients versus non-recipients as well as oxytocin recipients with and without LD (89), and some do not adjust for possible confounders (88,89,104,105). The findings of randomised controlled trials show no difference in operative delivery rate between the compared groups presented in a Cochrane review (80), whilst findings in observational studies tend to show greater discrepancy between the compared groups and higher operative delivery rates in augmented women (88,104-106).

Still it is a major challenge to predict if adverse maternal and neonatal birth outcomes are related to the cause of augmenting or to oxytocin itself (88). A study from Sweden reveals that severe asphyxia considered to be a result of malpractice, in 71% of the cases was due to incautious use of oxytocin (108). This strengthens the role of oxytocin as a potent drug that should be administered with care (109). A Cochrane review from 2011 concluded that the use of oxytocin is associated with a reduction in duration of labour, but showed no significant differences in cesarean delivery rate or other adverse outcomes for the mother or the baby (80).

In Norway almost 32 % of all women were diagnosed with LD in 2010 and the main treatment is augmentation with oxytocin (14).

"Many Western doctors hold the belief that we can improve everything, even natural childbirth in a healthy woman. This philosophy is the philosophy of people who think it deplorable that they were not consulted at the creation of Eve, because they would have done a better job" (Kloosterman 1994).

AIMS OF THE STUDIES IN THE THESIS

The overall aim of this study was to investigate the significance of differentiated birth care. We wanted to investigate the effect of organising birth care for low-risk women in a separate midwife-led low-risk birth care unit on operative delivery rate, costs of birth care and to explore how oxytocin and LD affect birth outcome.

I. The main aim of paper I was to investigate if there were differences in birth outcomes for low-risk women giving birth in an alongside midwife-led unit, compared with obstetric units within the same hospital. Primary outcome was mode of delivery, presented in spontaneous delivery, operative vaginal delivery and caesarean section. Secondary outcomes were augmentation with oxytocin, pain relief (epidural analgesia and acupuncture), postpartum haemorrhage, anal sphincter injury, Apgar score at five minutes, metabolic acidosis and transfer to neonatal intensive care unit.

II. The aim of paper II was to evaluate if organisation of birth care for low-risk women could be favourable in an economic manner by establishing a separate midwife-led unit within the same hospital without jeopardising the medical outcomes.

III. The aims of paper III were to describe the use of oxytocin in nulliparous women who were assessed to be low-risk at onset of spontaneous labour, and to study associations between dystocia and adverse birth outcomes, and associations between the use of oxytocin and adverse birth outcomes.

MATERIAL AND METHODS

All data presented in the three papers included in this thesis were collected at the Østfold Hospital Trust between September 2006 and February 2010. The study involved 1111 low-risk women who were randomised to one of the three birth care units, the MU, NU and SU. A comparison between the three units, on medical outcomes, is presented in paper I. To investigate cost-effectiveness of the MU, a comparison between the MU, and NU and SU combined was conducted merging outcomes of the RCT to the hospital's activity-based costing system, CPP, presented in paper II. The unexpected high rate of low-risk nulliparous women who were augmented with oxytocin in the RCT prompted us to investigate the use and consequences of augmentation with oxytocin in low-risk nulliparous women further and resulted in a cohort study presented in paper III.

Power calculation

Operative delivery rate was the basis for the power calculation. We hypothesised that it was possible to reduce the operative delivery rate, with the same or better results for mother and child, if low-risk women were delivered in a separate low-risk unit. We considered that a reduction in operative delivery rate from 10 % to 5 % would be of clinical importance. To detect a statistically significant reduction from estimated >10 % in standard care units, to approximately 5 %, which is closer to the estimated rate in freestanding birth units, a power calculation was conducted. With a power of 80 % and a probability of $p < 0.05$, we would have to include 1642 low-risk women.

Recruitment and inclusion process

Information about the trial was sent to all women planning to give birth at the Østfold Hospital Trust when being called for routine ultrasound examination. In connection with this examination at 18 – 20 weeks of pregnancy, all women roughly suited for participation received additional written and verbal information about the trial. If eligible and willing to participate, the woman was recruited and signed a written informed consent. If still fulfilling the inclusion criteria at onset of spontaneous labour, the woman was included in the trial and randomised to one of the three birth care units.

To participate in the trial, each woman had to fulfil the inclusion criteria which were similar to the selection criteria at the MU: healthy, low-risk women without any disease known to influence the pregnancy, one fetus in cephalic presentation, pre-pregnant BMI ≤ 32, not smoking more than 10 cigarettes per day, no prior operation on the uterus, no prior complicated deliveries and spontaneous onset of labour between gestational week 36^1 and 41^6.

The inclusion process proceeded slower than expected and unfortunately the funding was running out; hence the inclusion stopped the first week of February 2010. During the trial period, 10 902 women gave birth at Østfold Hospital Trust. At the point of recruitment 2884 were eligible and willing to participate. Six hundred ninety-seven of the recruited women were not considered low-risk at onset of spontaneous labour, 300 changed their mind and refused to participate, 254 gave birth during the summer or Christmas holidays when the MU was closed and the trial was on hold, and 522 women were not included for other reasons. This left 1111 women both eligible and willing to participate at onset of spontaneous labour. Four hundred twelve women were randomised to the Midwife-led unit, 417 to the Normal unit and 282 to the Special unit. There were five, nine and six women who did not start labour at the unit they were randomised to at the MU, NU and SU respectively (Figure VI). Reasons for not receiving the allocated intervention were mainly due to labour progressing very fast after randomisation and it was considered unethical to transport the women to the allocated unit.

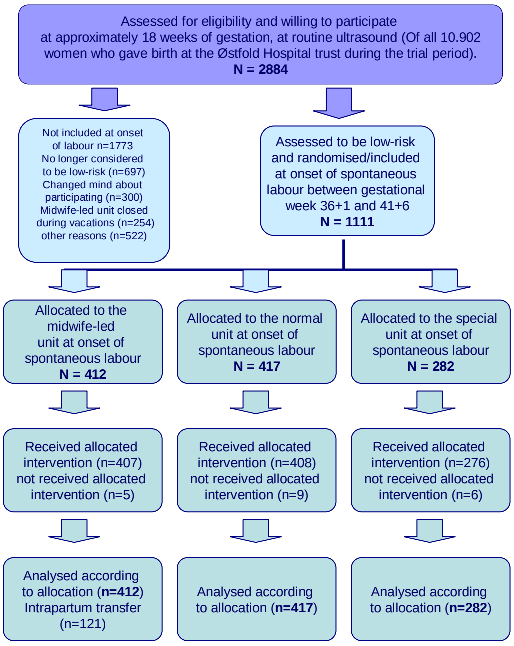
Assessed for eligibility and willing to participate
at approximately 18 weeks of gestation, at routine ultrasound (Of all 10.902 women who gave birth at the Østfold Hospital trust during the trial period).
N = 2884
Not included at onset of labour n=1773
No longer considered to be low-risk (n=697)
Changed mind about participating (n=300)
Midwife-led unit closed during vacations (n=254)
other reasons (n=522)
Assessed to be low-risk and randomised/included at onset of spontaneous labour between gestational week 36+1 and 41+6
N = 1111
Allocated to the midwife-led unit at onset of spontaneous labour
N = 412
Allocated to the normal unit at onset of spontaneous labour
N = 417
Allocated to the special unit at onset of spontaneous labour
N = 282
Received allocated intervention (n=407)
not received allocated intervention (n=5)
Received allocated intervention (n=408)
not received allocated intervention (n=9)
Received allocated intervention (n=276)
not received allocated intervention (n=6)
Analysed according to allocation (n=412)
Intrapartum transfer (n=121)
Analysed according to allocation (n=417)
Analysed according to allocation (n=282)

Figure VI. Flowchart of recruiting and inclusion process

The randomisation process was done through a digital randomisation database developed by the Department of Clinical Research at the University Hospital of North Norway. It was a simple randomisation and the allocation was concealed. The midwife who administered the randomisation entered the women's name and checked for eligibility before receiving the randomisation number and unit from the database. The randomisation stratified between primiparous (para 0) and multiparous (para 1+) women. The distribution of low-risk women who participated in the trial was 37.5 %: 37.5 %: 25.4 % to the MU, NU and SU respectively. We assumed that this distribution would allow the trial to go on without interfering with daily operations at the SU as the SU has less capacity to care for low-risk women.

Documentation process

All the participants' data were registered by the delivering midwife in the department's electronic journal system, Partus (Clinsoft^R), as routine at all births. As a second documentation control a designated midwife at each unit, who were responsible for the documentation in connection with the trial, monitored the entries and cross-checked electronic data with any other documented data. As a third and last documentation control, all the participants' data were checked by a midwife not working at any of the three units.

All data from the electronic journal system was anonymised and copied into the SPSS database (SPSS Inc. Chicago, IL, version 18) which was used for the analyses. The partogram was converted from a paper version to an electronic version in January 2007, data included in the paper version partograms was manually entered into SPSS.

Methods Paper I

To investigate if there were differences in birth outcomes for low-risk women giving birth in an alongside midwifery-led unit, compared with obstetric units within the same hospital, differences in outcomes between the MU, NU and SU were compared.

Outcome measures:

- Operative delivery (ventouse + forceps + caesarean section)
- Operative vaginal delivery (ventouse + forceps)
- Caesarean section
- Dystocia
- Augmentation with oxytocin
- Pain relief: Epidural analgesia, nitrous oxide (N_2O) and acupuncture
- Postpartum haemorrhage
- Episiotomy
- Sphincter injury
- Outcomes of the newborns (Apgar score, metabolic acidosis, and transfer to the intensive care unit (NICU))

For continuous data, cut off was set by medical considerations and guidelines. Postpartum haemorrhage was described as haemorrhage 500-999 ml and > 1000ml, (1000-1500ml and >1500ml). Haemorrhage > 1000 ml was used in the analyses as > 1000 ml is considered to be a significant postpartum haemorrhage, and defined as severe, by the Norwegian Gynecological Association presented in the obstetric guidelines in Norway (110). Outcomes of the newborns were measured by a subjective assessment of the baby made by the midwife, obstetrician or paediatrician, if involved, presented as Apgar scores 0-10, and by pH and BE (base excess) retrieved from a blood sample taken from the umbilical cord within two minutes after delivery. Apgar score was presented in scores < 7 at 5 minutes as this is considered normal. This cut off is also in accordance with other studies assessing health of the newborns (27,31,32). Metabolic acidosis was defined as an umbilical artery pH < 7.05 and BE < -12 mmol/l equal to the definition of metabolic acidosis at the Women's clinic, Østfold hospital Trust which also concurs with other's definitions (111).

Statistical analyses

All outcomes were presented in frequencies and percentages and differences between the three units were analysed by Chi-squared tests. Pearson's two-sided asymptomatic significance level of 5 % was used.

Relative risk (RR) was calculated with MU set as reference and all primary and secondary outcomes were compared with the outcomes at the NU and the SU. RR was presented with a 95 % confidence interval (CI).

As blinding of the participants or of the care givers did not seem feasible in the RCT, the statistician who performed the analyses in this paper was blinded to the participant's affiliation to the birth care units. All data was analysed according to the principle of "intention to treat".

Methods Paper II

To evaluate if organisation of birth care for low-risk women could be favourable in an economic manner by establishing a separate midwife-led low-risk birth care unit within the same hospital without jeopardising the medical outcomes, a cost-effectiveness analysis was conducted based on the findings of the RCT, a "piggyback" economic evaluation (112). As the NU and the SU combined is considered to be a standard obstetric unit the economic analyses were conducted comparing results at the MU to results at the NU and SU combined. The combined unit is named SCU (standard care unit) in this paper.

All birth care costs of 1110 of the 1111 participants in the RCT were registered. One woman randomised to the MU was excluded from the analyses as she was hospitalised for more than 12 days due to a diagnosis not relevant to labour that occurred two days postpartum.

The effect of introducing MU compared to SCU was measured as avoided clinical procedures between MU and SCU, procedures assumed to be correlated with length of stay and costs; Caesarean sections, instrumental vaginal deliveries, complications requiring treatment in the operating room, epidural analgesia and augmentation with oxytocin. All procedures, except the complications, could of course be considered unavoidable or necessary in some cases. Avoided clinical procedures for low-risk women were expected to improve health, and consequently favourable for establishing MU and the effect was therefore expected to be negative.

For each participant from the perspective of a health care provider, costs were calculated both according to birth care unit and to mode of delivery, interventions and complications. All costs in this analysis are presented in 2011 Euro (€1=NOK7.86), and costs per day are calculated based on a capacity of 90 % at each unit. The observation period extends from the women’s admission to the hospital at onset of spontaneous labour until discharge. To estimate birth care cost, cost per patient (CPP), which is the hospital’s activity-based costing system, was used. All economic data were retrieved from the Financial Department at the Østfold Hospital Trust and copied into the SPSS database.

CPP calculates all hospital costs for each patient according to outpatient consultations or an inpatient stay (113-115). The costing model includes both bottom-up and top-down approaches, separately or in combination. In a bottom-up approach, the starting point is the activity (such as ultrasound, laboratory tests and surgical procedures) and the costs are calculated separately for each of them. In a top-down approach, the starting point is the financial expenditure, for instance annual accounts, for a hospital or a department. The financial expenditure is distributed by different formulas and algorithms to the different activities. The CPP system is transparent in a way that allows users to analyse and follow the activities and the related calculated costs throughout the stay. The CPP costing system is a step-by-step process as illustrated in Figure VII.

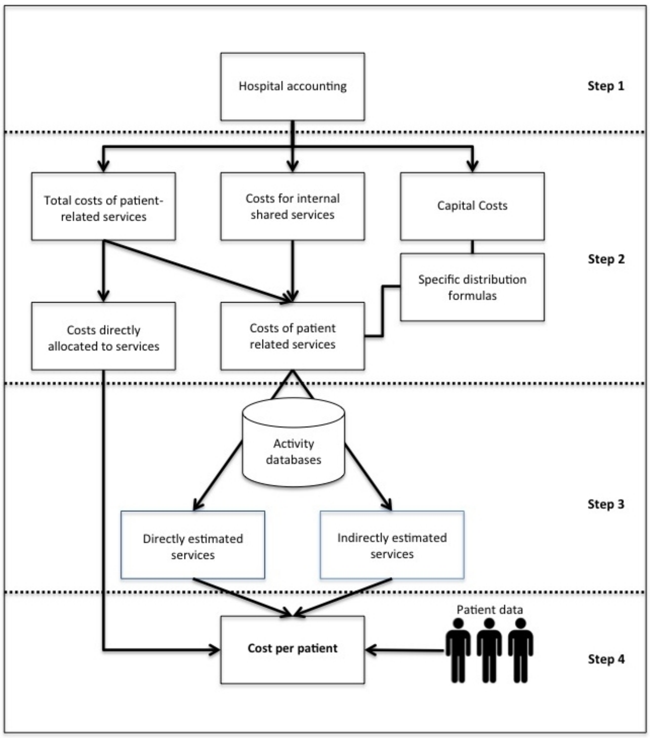
Hospital accounting
Step 1
Total costs of patient-related services
Costs for internal shared services
Capital Costs
Step 2
Specific distribution formulas
Costs directly allocated to services
Costs of patient related services
Activity databases
Step 3
Directly estimated services
Indirectly estimated services
Patient data
Cost per patient
Step 4

Figure VII. Illustration of the calculation of Cost Per Patient

In Step 1 hospital cost account data which are relevant for patient activities are extracted from the administrative registers. Therefore, costs such as research and teaching are not included. In Step 2 the data are split in three, costs related to patient specific services, costs related to internal shared services (for instance administrative support, cleaning and food) and capital costs (for instance interest rate and depreciation). These three components are then reduced to two groups, costs directly allocated to services (such as blood, medication and implants) and costs of patient related services (operations, physiotherapy and care). The latter consists of a combination of costs that are impossible to allocate directly to a specific service, the costs of internal services and capital costs. Formulas or algorithms are used to allocate capital costs and internal shared services to a specific activity (such as operation and radiation). An example of such a formula is the allocation of cleaning costs to costs per day by use of the department's square meters and number of beds. Costs to a department are then allocated according to the department's proportion of total square meters at the hospital. Further, the costs could be distributed to costs per day by dividing the total cleaning costs within the department with the total capacity (number of beds) during a year. In Step 3, the unit costs for each service are estimated. Costs that could be directly allocated to a service, are estimated directly by means of, for instance, prices (medication, blood and implants), while the other costs are estimated both directly (by the bottom-up approach), such as operation costs for a caesarean section and indirectly (by the top-down approach), such as costs of care per day. In Step 4 activities registered in the patients' electronic journal are merged with the unit costs for each service to estimate total costs per patient for each stay (Figure VII).

Costs per day are estimated for an average patient including average use of midwife and obstetrician resources. Costs for epidural analgesia, instrumental vaginal delivery and augmentation with oxytocin are included in costs per day; hence the separate costs for these procedures are not visible in the CPP system. Multiplying costs per day with length of stay presented in days and hours, defines costs per length of stay. Costs of procedures performed outside the units are estimated by means of a bottom-up approach, e.g. operations as caesarean sections, repair of sphincter injuries and laboratory tests. Total costs per stay are the sum of costs per length of stay and costs of procedures outside the birth care unit. CPP was calculated using Ecomed KPP ™, Datawell AB.

The analysis of costs and outcomes are presented by the incremental cost-effectiveness ratio (ICER) (112) defined by:

$$\frac{\text{Total costs MU - Total costs SCU}}{\text{Percentual outcome MU - Percentual outcome SCU}} = \frac{\text{Incremental total costs}}{\text{Incremental in percentual outcome}}$$

When calculating the ICER, all outcomes are expressed as a percentage, thus the ICER is defined as the incremental costs per one percent improved health outcome, such as a percentage avoided augmentation with oxytocin. When incremental costs are negative, the MU is a cost saving alternative to the SCU. Normally, in economic evaluations, new interventions are expected to cause positive incremental outcomes, while in this study the incremental outcomes are expected to be negative, as avoided use of augmentation with oxytocin. Hence, a negative difference is an argument for choosing MU. MU is a dominant strategy if both incremental costs and incremental effects are negative.

Statistical analyses

In this evaluation Pearson's chi-squared test was used to test for differences in medical outcomes between the MU and the SCU. To test for differences between the units in length of stay, costs according to length of stay, operations and total costs per stay, an independent sample t-test has been used. To investigate to what extent costs of interventions, not visible in the hospitals costing system, affect the total costs per stay, an independent sample t-test was used to test for the differences between the MU and the SCU according to mode of delivery in combination with the use of epidural analgesia and augmentation with oxytocin. Results are presented in means, 95 % CI and p-values.

In the sensitivity analysis related to the cost-effectiveness analysis, heterogeneity in the composition of patients with regard to costs and outcomes were explored. As cost-effectiveness often is skewed, the non-parametric bootstrap method was chosen to illustrate the heterogeneity. The bootstrap method is applied to create new samples (1000 repetitions) by drawing a random sample with replacement and constructing a given number of equally sized resamples of the existing dataset (116) The mean from the 1000 new samples are plotted in a cost-effectiveness plane.

Costs per day at the SCU are based on caring services for both high and low-risk women whilst the costs per day at the MU are based on caring services for low-risk women only. In order to test what effect an adjusted costs per day rate for the SCU that also includes low-risk women has, the mean costs per day at the SCU were weighted according to the formula below and presented in an additional sensitivity analysis. At the Østfold Hospital Trust the annual distribution of women between the MU and the SCU is 600 and 2400 respectively, whilst the costs per day are €579 and €682 respectively. The weighted costs per day at the SCU was €661 ((2400 x 682) + (600 x 579))/3000.

All calculations were conducted according to the principal of "intention to treat" using SPSS 18.

Methods Paper III

One finding in paper one, was that 139 of all 559 primiparous women included in the study without dystocia, according to the definition of dystocia at the Østfold Hospital Trust, were augmented with oxytocin. This prompted us to investigate the use and effect of oxytocin further in all nulliparous participants as the effect of oxytocin augmentation in women without dystocia can only be explored in a cohort study. To investigate possible associations between oxytocin and dystocia on birth outcomes for low-risk nulliparous women, all 747 nulliparas participating in the randomised controlled trial were analysed in a cohort (Figure VIII). Women with no dystocia, augmented with oxytocin were compared to women with no dystocia, not augmented with oxytocin, and women with dystocia, augmented with oxytocin were compared to women without dystocia, augmented with oxytocin.

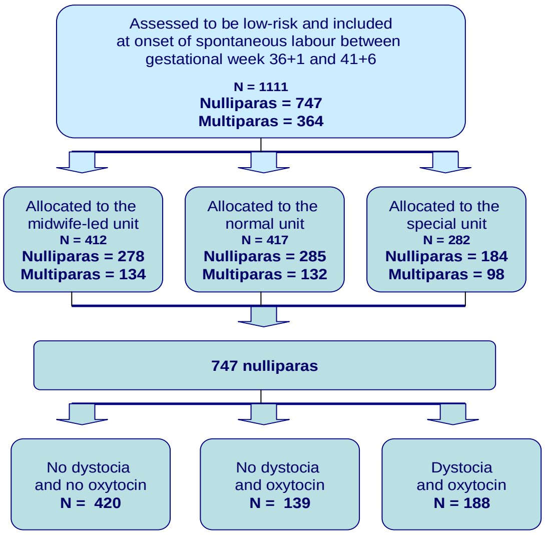
Assessed to be low-risk and included at onset of spontaneous labour between gestational week 36+1 and 41+6
N = 1111
Nulliparas = 747
Multiparas = 364
Allocated to the midwife-led unit
N = 412
Nulliparas = 278
Multiparas = 134
Allocated to the normal unit
N = 417
Nulliparas = 285
Multiparas = 132
Allocated to the special unit
N = 282
Nulliparas = 184
Multiparas = 98
747 nulliparas
No dystocia and no oxytocin
N = 420
No dystocia and oxytocin
N = 139
Dystocia and oxytocin
N = 188

Figure VIII. Flowchart of inclusion process

Dystocia was defined according to the hospital's criteria based on labour progression in active labour. Active labour is defined from the point when regular progressive contractions are established at least every 5 minutes and the cervix is dilated at least 3-4 centimetres, until the cervix is fully dilated. An alert-line is drawn on the electronic partogram when in active phase expecting a cervical dilation of 1cm/hour. Parallel to the alert line and two hours to the right, an action line is drawn, predefined in the electronic documentation system Partus. Dystocia in the first stage is diagnosed if the action-line is crossed. The second stage is defined from the point where the cervix is fully dilated until the baby is born. The second stage is divided into the latent phase and the expulsion phase. Dystocia in the second stage is diagnosed for nulliparous women if lasting longer than two hours, three hours for women with epidural analgesia, or if the expulsion phase lasts longer than 60 minutes.

An intervention is considered if the action line is crossed. An amniotomy is conducted if the membranes are intact and if this procedure does not affect the progression and there is a normal fetal heart rate pattern and no malpresentation, oxytocin infusion is administered by a midwife following the department's guidelines. If dystocia occurs in the second stage, an obstetrician is to be consulted before initiating oxytocin infusion. Prescribed dose of oxytocin infusion is 10IU (10000mU) in 1000 ml physiological saline with an initial dose of 5 mU/minute. The dose is increased by 5 mU every 30 minutes until 5 contractions in 15 minutes are reached. Maximum dosage is 30 mU/minute. At the Østfold Hospital Trust a 2-hour action line is used which is common in Norwegian obstetric departments though a 4-hour action line is recommended internationally if an action line is included in the partogram (36,117).

The primary outcome in paper III was mode of delivery, presented as cesarean section, instrumental vaginal delivery and spontaneous delivery. Secondary outcomes were hemorrhage >500 ml, episiotomy, anal sphincter injury, transfer to the NICU and Apgar score <7 at 5 minutes.

Statistical analyses

To describe characteristics and outcomes of the participants, proportions, means and standard deviations (SD) were calculated. To compare outcomes, crude and adjusted odds ratios (OR) with 95 % confidence intervals (CI) were calculated. A significance level of 5 % was used and presented as a difference. Binary logistic regression was used on dichotomous data. Univariate analyses were performed to estimate associations between the covariates and the outcomes, and multivariate analyses were performed to adjust for confounders. Colinearity between independent variables was measured by the VIF statistic; variables with

VIF > 5 were not included as independent variables. In each multivariate analysis, the number of independent variables was kept below 10 % of the number of cases in the dependent variable. For outcomes with less than 15 cases (Apgar score < 7 at five minutes, hemorrhage > 500 ml, and anal sphincter injuries) multivariate analyses were not performed. A one-way anova was used to compare means. All analyses were conducted using SPSS 18.

Dependent variables were cesarean section, instrumental vaginal delivery, spontaneous vaginal delivery, transfer of newborns to the NICU, episiotomy and postpartum hemorrhage. Independent variables were oxytocin augmentation (no versus. yes), dystocia (no versus. yes), birth weight, birth care unit, epidural analgesia, gestational age, cervical dilation upon admission and duration of labour. Duration was estimated from the onset of the active phase of the first stage or from admission to the labour ward if already reached this phase.

Missing values in the dataset (BMI 36/747, social status 5/747, education 13/747, gestational age 2/747, cervical dilation at onset of labour 7/747) was handled by multiple imputations using STATA (118). As the imputed analyses did not show any difference in OR and only minimal changes in CI, the complete case data set was used in the presented analyses.

SUMMARY OF RESULTS AND MAIN FINDINGS

Paper I

“Is the operative delivery rate in low-risk women dependent on the level of birth care? A randomised controlled trial”.

The main outcome measure in this paper was mode of delivery. At the MU, NU and SU the total operative delivery rate was 16.3 %, 18.0 % and 18.8 % respectively which represent no statistical difference. The rates of instrumental vaginal delivery were 10.0 %, 12.0 % and 11.0 % at the MU, NU and SU respectively, caesarean section rates were 6.0 %, 6.0 % and 8.0 % at the MU, NU and SU respectively. There were no significant differences in the use of nitrous oxide, postpartum haemorrhages > 1000 ml, episiotomies or anal sphincter injuries.
There were also no significant differences in outcomes for the newborns presented as number of Apgar scores < 7 at 5 minutes, metabolic acidosis or transfer of newborns to the NICU.

Significant differences were found between the three units for augmentation with oxytocin ($p < 0.001$), epidural analgesia ($p < 0.001$) and for acupuncture for pain relief ($p < 0.001$).

When calculating relative risk (RR) there were statistical significant differences in augmentation with oxytocin, epidural analgesia and in acupuncture for pain relief in the comparison between the MU and NU and in the comparison between the MU and SU. No other outcomes represented a significant difference in RR (Table 2).

Table 2. Relative risk (RR) assessments, with Midwife-led Unit set as reference

Variable	Midwife-led Unit vs Normal Unit RR 95% CI	Midwife-led Unit vs Special Unit RR 95 % CI
Operative vaginal delivery	0.85 (0.58 – 1.25)	0.98 (0.65 – 1.52)
Caesarean section	1.01 (0.58 – 1.75)	0.71 (0.41 – 1.24)
Oxytocin augmentation	0.73 (0.59 – 0.89)	0.69 (0.56 – 0.86)
Epidural analgesia	0.68 (0.51 – 0.90)	0.64 (0.47 – 0.86)
N2O	0.99 (0.90 – 1.09)	0.92 (0.83 – 1.02)
Acupuncture for pain relief	1.45 (1.25 – 1.69)	1.45 (1.22 – 1.73)
Postpartum haemorrhage > 1000ml	0.79 (0.30 - 2.09)	0.59 (0.20 - 1.41)
Episiotomy of all vaginal deliveries	0.85 (0.66 – 1.09)	0.78 (0.60 – 1.02)
3rd or 4th degree tear of all vaginal deliveries	0.56 (0.19 – 1.66)	0.67 (0.20 – 2.28)
Apgar score <7 at 5 min	0.68 (0.19 – 2.37)	2.74 (0.31 – 24.37)
Metabolic acidocis*	0.78 (0.25 – 2.42)	1.10 (0.30 – 4.0)
Transfers to NICU**	1.25 (0.76 – 2.05)	1.15 (0.67 – 1.99)

* Metabolic acidosis: sample taken from umbilical cord showing arterial pH <7.05 and BE<-12
**Transfer of new-born to Neonatal Intensive Care Unit NICU within the first two hours postpartum

Main findings

The operative delivery rate, the risk of having a postpartum haemorrhage > 1000 ml, rates of episiotomy and anal sphincter injuries and the outcome for newborns are not affected by level of care for low-risk women without prelabour preferences for level of care. The participants randomised to the MU had a significantly higher chance of giving birth without interventions like augmentation with oxytocin or epidural analgesia compared to the participants randomised to the NU and the SU.

Paper II

"Economic evaluation of birth care in low-risk women. A comparison between a midwife-led birth unit and a standard obstetric unit within the same hospital in Norway. A randomised controlled trial".

In this paper we investigated the costs and cost-effectiveness in birth care for low-risk women at the MU compared to the SCU. The results showed that mean total costs per stay for all participants were higher at the SCU compared to the MU. The mean total costs were also higher for those who delivered spontaneously and for those delivered by caesarean sections at the SCU compared to the MU. Mean total costs per stay for participants who had an instrumental vaginal delivery did not differ significantly between the units (Table 3).

Table 3. Costs (€) at the midwife-led unit (MU) and at the standard care unit (SCU) presented in means with 95 % confidence interval (CI)

Costs (€) per unit	MU Mean costs (95 % CI)	SCU Mean costs (95 % CI)	p-value
Costs per day, 90 % capacity	579	682	
Day costs per length of stay			
Spontaneous deliveries	1450 (1392-1508)	1632 (1581-1682)	<0.001
Instrumental vaginal deliveries	1812 (1647-1976)	2025 (1886-2165)	0.06
Caesarean sections	1938 (1831-2045)	2659 (2480-2838)	<0.001
All deliveries	1515 (1461-1569)	1746 (1696-1797)	<0.001
Costs for operations			
Caesarean sections	1663 (1530-1795)	1662 (1552-1772)	0.99
Vaginal deliveries with complications *	1745 (1450-2040)	1499 (1251-1747)	0.26
Total costs per stay			
Spontaneous deliveries	1487 (1420-1555)	1671 (1615-1728)	<0.001
Instrumental vaginal deliveries	2065 (1748-2382)	2473 (2203-2744)	0.07
Caesarean sections	3705 (3524-3885)	4430 (4236-4625)	<0.001
Primiparous women	1845 (1736-1955)	2190 (2088-2291)	<0.001
Multiparous women	1313 (1220-1406)	1461 (1379-1543)	0.02
All deliveries	1672 (1589-1755)	1950 (1872-2027)	<0.001

* Complications which require treatment in the operating room (anal sphincter injury, suture of complicated perineal rupture or retained placenta)

In the cost-effectiveness analysis, the ICER was calculated for caesarean sections, instrumental vaginal deliveries, complications requiring treatment in the operating room, epidural analgesia and augmentation with oxytocin. The incremental costs were €278 (based on the total costs and the incremental effects). The ICER for all the effect-outcomes were €253 (caesarean sections), €253 (instrumental vaginal deliveries), €214 (complications requiring treatment in the operating room), €33 (epidural analgesia) and €25 (augmentation with oxytocin). The ICER of €25 is to be understood as; for each percentage of augmentation with oxytocin avoided, there is a cost saving of €25. Hence allocating low-risk women to MU implies both a reduction in costs and improved health.

When the costs per day were based on the weighted approach, the incremental cost savings were €227 while the incremental effects were the same. Hence, the ICER for caesarean sections, instrumental vaginal deliveries, complications requiring treatment in the operating room, epidural analgesia and augmentation with oxytocin are still dominant strategies with the ICER’s €206, € 206, €175, €27 and €20, respectively.

Main findings

The analyses showed that the MU is more cost-effective than the SCU for low-risk women without prelabour preference for level of birth care provided equal capacity at the units, which supports the organising of birth care for low-risk women in a separate midwife-led unit.

Paper III

“Augmentation with oxytocin and dystocia as risk factors for adverse birth outcomes in low-risk nulliparous women”.

The objectives of this paper were to describe the use of oxytocin in nulliparous women who were assessed to be low-risk at onset of spontaneous labour, and to study associations between dystocia and adverse birth outcomes, and associations between the use of oxytocin and adverse birth outcomes.

The results showed that 327 of 747 (43.8 %) of all the low-risk primiparous women were augmented by oxytocin and that 139 of 327 (42.5 %) of these did not fulfil the criteria for dystocia.

When investigating women without dystocia, those augmented with oxytocin had a higher risk of caesarean section, instrumental vaginal delivery, episiotomy, haemorrhage >500 ml and dystocia as documented reason for operative delivery. There were no differences in anal sphincter injury rates, number of newborns with Apgar score < 7 at 5 minutes or transfer to the NICU among women without dystocia regardless of being augmented or not. For vaginally delivered women without dystocia, those augmented had a longer duration of the active phase and the expulsion phase compared to women not augmented. There was no difference in duration of labour for women without dystocia who were delivered by caesarean sections regardless of being augmented or not.

When investigating women augmented with oxytocin, those who had dystocia, according to the hospital criteria, had a higher risk for caesarean section and a lower risk for spontaneous vaginal delivery. For vaginally delivered women augmented with oxytocin, the duration of the active phase was longer among those with dystocia than without dystocia. The expulsion phase did not differ between women with or without dystocia among augmented women. Mean duration of labour for augmented women delivered by caesarean section was higher among those with dystocia than those without dystocia. Mean duration for augmentation with oxytocin was higher for those with dystocia compared to those without dystocia, no other differences in outcome measures were found.

The regression analysis showed that among women without dystocia, where oxytocin was the predictor of the outcomes, there was a higher risk for an instrumental vaginal delivery, a higher risk of having an episiotomy and a lower probability of having a spontaneous delivery if augmented with oxytocin even after adjusting for possible confounders. There was no difference in cesarean section rate or the rate of hemorrhage >500 ml after adjusting for possible confounders. In the regression analysis among oxytocin recipients where dystocia was the predictor, there was no difference in cesarean section rate or spontaneous delivery rate after adjusting for possible confounders (Table 4).

Table 4. Crude and adjusted odd's ratios (OR) for birth outcomes with oxytocin as predictor for women without labour dystocia n = 559; and with dystocia as predictor for women augmented with oxytocin n = 327

Oxytocin as predictor

Outcomes	Crude OR (CI 95 %) p-value	Adjusted OR (CI 95 %) p-value
Caesarean section	2.61 (1.22-5.56) 0.013	0.80 (0.30-2.13) 0.650 a
Instrumental vaginal delivery	4.54 (2.65-7.77) 0.000	3.73 (1.93-7.21) 0.000 b
Spontaneous vaginal delivery	0.23 (0.14-0.36) 0.000	0.40 (0.22-0.71) 0.002 c
Transfer of newborn to NICU	1.38 (0.68-2.80) 0.378	1.12 (0.46-2.71) 0.800 d
Episiotomy	3.68 (2.42-5.60) 0.000	2.47 (1.38-4.39) 0.002 e
Haemorrhage > 500 ml	1.97 (1.02-3.80) 0.042	0.83 (0.36-1.94) 0.669 d

Dystocia as predictor

Outcomes	Crude OR (CI 95 %) p-value	Adjusted OR (CI 95 %) p-value
Caesarean section	2.62 (1.34-5.12) 0.005	2.00 (0.94-4.27) 0.073 a
Instrumental vaginal delivery	1.26 (0.77-2.07) 0.359	1.12 (0.65-1.93) 0.678 b
Spontaneous vaginal delivery	0.51 (0.32-0.79) 0.003	0.65 (0.39-1.08) 0.095 c
Transfer of newborn to NICU	1.55 (0.75-3.22) 0.241	1.03 (0.46-2.29) 0.947 d
Episiotomy	1.26 (0.78-2.04) 0.342	0.89 (0.49-1.60) 0.691 e
Haemorrhage > 500 ml	1.13 (0.57-2.21) 0.732	0.84 (0.39-1.80) 0.655 d

Analyses were adjusted for:

a) birth weight, duration of birth, birth care unit and epidural analgesia
b) birth weight, duration of birth, birth care unit, epidural analgesia and smoking
c) birth weight, duration of birth, birth care unit, epidural analgesia, smoking and gestational age
d) birth weight, duration of birth, birth care unit, epidural analgesia and operative delivery
e) birth weight, duration of birth, birth care unit, epidural analgesia, instrumental vaginal delivery and cervix dilation on admission

Main findings

For low-risk primiparous women without dystocia we found a higher risk of operative vaginal delivery ($p < 0.001$) and episiotomy ($p = 0.002$) if augmented with oxytocin. It is of importance to pay careful attention to criteria for labour progression and guidelines for augmentation with oxytocin to avoid unnecessary use, and to prevent excess instrumental vaginal deliveries, as low-risk primiparous women are often augmented with oxytocin without apparent indication. Possible factors associated with oxytocin augmentation in women not having dystocia need further investigation.

DISCUSSIONS

General discussion

This thesis consists of three original papers all based on data collected in the RCT. The main aims of the trial were to investigate if there were possible differences in mode of delivery between the MU compared to a standard obstetric unit represented by the NU and the SU and to evaluate if organisation of birth care for low-risk women could be favourable in a cost-effective manner by establishing a separate midwife-led low-risk birth unit within the same hospital. One of the secondary outcomes: augmentation with oxytocin revealed that low-risk nulliparous women were augmented in an unexpected amount at all three units, and that oxytocin, to some extent, was given without apparent indication. These findings prompted us to further investigate the use of oxytocin in low-risk nulliparous women.

Paper I

The main aim of this paper was to investigate if there were any differences in operative delivery rate for low-risk women randomised to the MU compared to the NU and SU. Operative delivery rate is often used as a quality indicator in birth care (18,24,26,27,33,34,37,44,59,119,120), it is a subtle way of measuring quality as it predicts poor quality if the operative delivery rate is low and gives a negative outcome, or if the rate is high without improving the outcome or even increase complications for the mother or newborn, yet it predicts good quality if preformed when needed. The balance point or the right level of operative delivery rate is unknown and difficult to determine, as the justification of the intervention in many cases is revealed only after the baby is born. Operative delivery rates differ between countries and institutions, in Norway the overall operative delivery rate in the 18 largest institutions with more than 1000 births per year varied from 15.4 % to 35.7 % in 2010 (14). The high operative delivery rate in our study, including low-risk women only, and regardless of birth care unit affiliation, was unexpected and is not easy to explain. One reason may be due to the fact that there were more primiparous (67.2 %) women included compared to the distribution of nulliparas (42.2 %) and multiparas (57.8 %) in the population in general (14). Nevertheless our study showed no significant difference in operative delivery rates between the compared units, which are in accordance with the results of prior RCT’s investigating alongside units for low-risk women (18).

Three cohort studies on alongside units from Norway and Sweden show inconsistent results regarding mode of delivery. The Swedish study shows a significantly lower caesarean section rate in the birth centre group compared to the standard delivery ward (32), one of the Norwegian studies shows no significant difference in caesarean section rate between the midwife-led ward and a conventional care unit (33), and the second Norwegian study shows a significantly higher risk of caesarean section if giving birth in a separate low-risk maternity unit compared to a standard care unit (34). The studies include low-risk women only, but differ in inclusion criteria, adjusting variables, time of inclusion and women’s choice of birth place which could bias a comparison between them (34).

All studies included in a structured review reported benefits for women intending to give birth in a freestanding low-risk birth care units and all studies reporting on caesarean sections showed a significant higher risk of the intervention in the control group compared to the freestanding low-risk birth care unit (37). A matched cohort from Denmark regarding a freestanding midwife-led unit showed a significantly higher chance of having a spontaneous vaginal delivery if giving birth in the freestanding midwife-led unit (30). In the Birthplace in England study, freestanding and alongside units were evaluated and results showed a significantly higher chance for a spontaneous vertex birth at both, compared to an obstetric unit, nevertheless the odds were higher in the freestanding units. Significantly lower rates for caesarean sections and instrumental vaginal deliveries were found in the midwife-led low-risk birth care units and lowest in the freestanding units (21). The National Birth Center Study conducted in the USA between 1985-1987 including 84 “freestanding” birth centres concludes that it is safe for low-risk women to deliver at birth centres and it will even lead to fewer caesarean sections for multiparous women (120). It is worth noting that the birth centres included in the National Birth Center study are both freestanding units and units adjacent to the labour ward (121). No RCT’s comparing freestanding low-risk birth care units to obstetric units were found. An RCT on freestanding low-risk birth care units would be difficult to conduct in Norway as there are low numbers of parturients at the units and those who are eligible to deliver at the units would probably be reluctant to participate as it would imply a possible longer transport to the delivery department if randomised to hospital birth.

For augmentation with oxytocin, the use of epidural analgesia and the use of acupuncture for pain relief, significant differences were found between the compared units. Results of prior randomised controlled trials comparing alternative birth care settings adjacent to standard obstetric units show that women randomised to alternative settings have an increased likelihood of reduced medical interventions (18,26,27). If it is availability or necessity that affects the decision of intervening with oxytocin and epidural analgesia the most, is a relevant issue when observing the lower use of epidural analgesia and augmentation with oxytocin at the MU compared to both the NU and SU in this homogenous group.

This trial is strengthened by the timing of inclusion when comparing intrapartum care and birth outcomes. All participants were defined as low-risk parturients at onset of spontaneous labour prior to being randomised to any of the three units, allowing only those fulfilling the inclusion criteria to be included. Two randomised controlled trials including low-risk women at onset of spontaneous labour were found, one from the, USA (27), and one from Hong Kong (26), but no trial was found conducted in Europe over the last two decades. Most randomised controlled trials on birth care settings for low-risk women include participants during pregnancy which implies that a certain number of included women do not fulfil the selection criteria for midwife-led units at onset of labour, and therefore do not attend these units at all (18). Following the important principle of “intention to treat” they still are analysed according to the group they were allocated to. This may lead to an incorrect comparison of intrapartum care between midwife-led units and standard care units when concerning low-risk women, leaving us to realise the importance of randomisation at onset of labour when investigating intrapartum care in different settings for low-risk women. A possible limitation of this trial is the number of participants included which was lower than estimated in the power calculations. Nevertheless, the differences in operative delivery rates between the units were so small that it is considered unlikely that the differences would be significant even if the estimated number of participants were reached. Recruiting low-risk women to studies on birth place is difficult today since many women want to choose their place of birth when given the opportunity (122). This limits the results to be generalised only to low-risk women without preference of birth place.

Paper II

An economic evaluation is defined as the comparative analysis of alternative courses of action in terms of both their costs and their consequences/effects. Costs have to be identified, measured, valued and compared to the identified, measured and valued consequences in the alternatives being considered (112). Costs of birth care may be identifiable, but to measure and value the costs are a greater challenge. Costs of birth care are presented in this paper as cost estimates as an accurate calculation of costs is almost impossible to conduct and would require a thorough mapping of each resource used throughout each stay.

The effects in this study are clinical procedures (caesarean sections, instrumental vaginal deliveries, complications requiring treatment in the operating room, epidural analgesia and augmentation with oxytocin) selected as they are assumed to be correlated with length of stay and costs.

Costs of birth care are influenced by several factors, for example length of stay and procedures performed during the stay. Costs per length of stay will be reflected in the cost per day, estimated in the CPP system which also goes for procedures performed outside the birth care units, like caesarean sections and anal sphincter injury repair. Costs according to procedures performed within the units like the use of epidural analgesia, augmentation with oxytocin and instrumental vaginal deliveries will not be visible in the cost per day even though these procedures requires more resources and probably lead to extended length of stay. In this analysis we showed that the total costs per stay in fact increased with increasing intervention rate which is also in accordance with prior research (58).

The increased operative delivery rate over the last decades in developed countries (57) has become a challenge both in a health, and in an economic perspective. In Norway the caesarean section rate has increased from 12.7 % in 1990 to 17.0 % in 2009 and the rate for operative vaginal delivery has increased from 7.7 % in 1990 to 9.5 % in 2009 (14). An increase in operative delivery rates will lead to an increase in birth care costs (57). Even though there were no significant differences in mode of delivery between the compared units in our trial, the total costs per stay for women who underwent a caesarean section were higher than for those who delivered spontaneously and the total costs were higher for women randomised the SCU compared to the MU among those delivered by caesarean section.

Length of stay will necessarily affect the costs of birth care, our results show that low-risk women randomised to the MU had a longer, though not significantly, stay than women randomised to the SCU. This does not correlate with prior research which shows the opposite results (32,123) and is difficult to explain. One reason might be that the available capacity at the MU allowed the staff to offer women an extend stay if desired.

In the cost-effectiveness analyses we showed that delivering in the MU implied a reduction in costs compared to SCU without jeopardising the outcomes when compared to delivering at the SCU. These findings were similar to the findings of the cost-effectiveness analysis of the Birthplace in England study (56). In the sensitivity analysis, the bootstrapped ICER's confirmed that allocating low-risk women to the MU both is cost saving and reduces the use of epidural analgesia and augmentation by oxytocin. Even though the effect on caesarean sections, instrumental vaginal deliveries and complications requiring treatment in the operating room are ambiguous, the total costs per stay are significantly lower at the MU compared to the SCU which present MU as a cost-effective alternative.

A strength of this analysis is the use of the hospital's well established CPP system which allows a thorough presentation of cost estimates linked to each specific participant to her specific stay. Limitations are presented by the lack of a detailed human resource utilisation, which would allow a more nuanced estimate for costs per day, and the lack of long term cost effects.

Paper III

Both dystocia and oxytocin augmentation are possible contributing factors for operative deliveries (80). In this study we aimed to investigate a possible association between the use of oxytocin and birth outcomes by studying low-risk women without dystocia both augmented with oxytocin and not augmented. The increased risk of instrumental vaginal delivery found among oxytocin recipients strengthens the association between oxytocin and instrumental vaginal delivery. By studying oxytocin recipients both with and without dystocia we aimed to investigate the association between dystocia and birth outcomes, nevertheless we did not find associations between dystocia and caesarean sections or spontaneous vaginal deliveries in the adjusted analysis.

Due to different study designs and definitions of dystocia, results from previous studies are complicated to interpret. Some studies compare oxytocin recipients to non-recipients (80,88,105,106), some investigate early versus delayed use of oxytocin (107) some compare both oxytocin recipient versus non-recipients as well as oxytocin recipients with versus without dystocia (89) and some lack adjustment for possible confounders (88,89,104,105). The findings of randomised controlled trials show no difference in operative delivery rate between the compared groups presented in a Cochrane review (80), whilst findings in observational studies tend to show greater discrepancy between the compared groups and a higher operative delivery rate in augmented women (88,104-106). Finding the optimal design for a study on the impact of oxytocin may be difficult as the risk of crossover tend to be likely in randomised RCT's (80). The knowledge that oxytocin can shorten the length of labour today, could make inclusion of participants to an RCT comparing oxytocin versus no oxytocin difficult, and women would probably be reluctant to participate. As retrospective studies are plagued by selection bias, valuable information on the topic could be retrieved from a large prospective cohort including women with similar baseline characteristics only.

The discussion on risk factors for operative deliveries is complex. There are possible risk factors in addition to dystocia and oxytocin that should be considered carefully to elucidate the impact on birth outcomes. We found that duration of labour was longer for women augmented with oxytocin among those without dystocia implying that duration as well as oxytocin may affect the mode of delivery even without dystocia. The effect of duration is somewhat ambiguous as for women augmented with oxytocin there was no difference in mode of delivery even if those without dystocia had shorter duration of labour compared to those with dystocia.

In our study, main outcomes were adjusted for epidural analgesia as epidural analgesia are assessed to be a possible confounder even though the literature is inconsistent (124). Epidural analgesia is known to increase the risk of dystocia in nulliparous women (125) and to increase the number of instrumental vaginal deliveries (125,126), and the duration of the second stage (126).

Among participants without dystocia, we found that vaginally delivered women had a higher risk of having an episiotomy if augmented with oxytocin compared to those not, even when adjusting for instrumental vaginal deliveries. Even though the use of oxytocin was associated with episiotomies, oxytocin itself is unlikely a risk factor, but probably a confounding factor. The association between oxytocin augmentation and episiotomies is rarely investigated. Carvalho et al. found no difference in episiotomy rate between women augmented with oxytocin and those not (127).

The medicalisation of labour and the increasing use of oxytocin in contemporary birth care are often subject of attention (11,16). Four Scandinavian studies revealed a high rate of oxytocin use among nulliparous women (89,128-130). Two of the studies also showed that women are augmented despite apparent indication in accordance with our findings (89,130). At our hospital the midwives are to a major extent responsible for initiating oxytocin infusion when caring for low-risk women, and the high intervention rate found does not correlate with the intention of keeping birth normal which we believe is common among midwives. Even with a two-hour actionline a substantial proportion of low-risk women were augmented without having dystocia, and women were diagnosed with dystocia without fulfilling the criteria. There might be various reasons for birth attendants to initiate oxytocin infusion before the criteria for dystocia are met. In our study we found that BMI, birth weight, duration of labour and the use of epidural analgesia were factors associated with oxytocin augmentation for women without dystocia. Both the use of epidural analgesia and birth weight >4,000 g have been described as risk factors for dystocia (72,74) but no studies were found that investigated factors associated with oxytocin augmentation for low-risk women without dystocia. Moen et al. found no differences in BMI or birth weight between recipients and non-recipients of oxytocin (130). Other explanations why women are augmented by oxytocin without apparent indication may be an inconsistent perception of duration of labour, or a lack of knowledge on normal variation of duration of labour. It could also be due to an expectation of unrealistic progression in labour, or the lack of guidelines on augmentation with oxytocin (131). In a Swedish study it was found that 62 % of the labour wards did not have any policy regarding how to diagnose uterine inertia, and in 31 % of the labour wards there was no policy concerning how to treat uterine inertia (132). It is shown that implemented guidelines for oxytocin use reduces the rate of augmentation with oxytocin and increases the documentation on indication (133). However, even when criteria for progression in labour and guidelines for augmentation with oxytocin are in place at our hospital, more than four out of ten of the augmented women were given oxytocin without fulfilling the criteria for dystocia.

Our study is strengthened by being prospective and including well-defined low-risk women only. Analysing women without dystocia both with and without augmentation with oxytocin and by analysing oxytocin recipients both with and without dystocia allowed us to investigate associations between oxytocin and birth outcomes and dystocia and birth outcomes. Our department has criteria for progression in labour and guidelines for augmentation which ensure a good basis for comparison. There are however possible methodological limitations in this study which should be considered and these are presented in the section below. There also might be unrecognized confounders with impact on birth outcomes and it is of major interest to investigate factors that might influence augmentation with oxytocin when there is no stated dystocia.

Methodological considerations and limitations

When planning a clinical trial, statisticians emphasize the importance of selecting the right design to answer the research question, because “Without the solid foundations of a good design the edifice of analysis is unsafe” (134, page 5).

The randomised controlled trial design

The key to a successful clinical trial is to avoid biases in the comparisons of the groups. A random allocation is one of the fundamental principles of experimental design (134), and the method which at present commands the most respect when the effectiveness of different treatments is to be compared, is the randomised controlled trial design (13). Even if the key idea of a clinical trial is the fact that we want to compare groups of participants who only differ in respect to their treatment, there are some aspects which should be considered concerning recruitment, inclusion and interpretation of results in this trial.

Internal and external validity

The validity of a trial refers to what extent we measure what we really claim to measure (internal validity), and if we are able to generalise the results to the population in general (external validity). Random allocation prevents the compared groups to be different which strengthens the internal validity, the rate of possible confounders will be equal in each group. The external validity, on the other hand, is the validity of the generalised inferences or findings (135), and the way the data are collected is as important as the data collected (136). Today pregnant women have expectations and requests ahead of the coming birth, information concerning birth care and care options is easily accessible through books, magazines and on the internet. Women who clearly stated that they wanted epidural analgesia, those who chose to give birth at the MU and those who did not want to deliver at the MU were not included. Many women had a preference of place of birth in early pregnancy which correlates with prior research stating that women strongly value their autonomy of choice (122). By recruiting participants with no outspoken preference of birth place, the results of our trial should only be generalised to this group. Another aspect to consider regarding external validity is the fact that the MU had been running for approximately one and a half year before initiating this trial. Even though the staff consisted of experienced midwives and doctors, the organisation was relatively new and the lack of experience with midwife-led care could affect the outcomes.

Distribution of participants

When planning this trial we were concerned that the limited capacity for admitting low-risk women in the SU would not allow 1:1:1 randomisation and we therefore chose an allocation of 37.5 % to the MU, 37.5 % to the NU and 25 % to the SU, which led to the need for a higher overall number of included participants. In retrospect, realising that the inclusion of participants proceeded slower than expected and that the SU could withstand a larger share of low-risk women in the trial period, a 1:1:1 randomisation could have been possible allowing an estimated inclusion number of approximately 1200 participants.

Missing data on metabolic acidosis

Departmental guidelines require that a blood sample, taken from the umbilical cord, shall be extracted within two minutes after every delivery. In this material an umbilical cord sample was taken in 57.7 %, 68.8 % and 77.3 % of the cases at the MU, NU and SU respectively. The low number of samples could bias the results and therefore allow no conclusions to be drawn. An analysis based on imputed data was considered and rejected due the to missing data, more than 40 % from the MU and more than 30 % from the NU was considered to be too substantial for further analysis.

The significance of planned place of birth

RCT's of alternative settings for birth show no significant differences in operative delivery rates (18) whilst observational studies tend to show greater discrepancies (21), the question is whether this is caused by possible confounders in the cohorts only, or if the planning of birth place also could affect the outcome (23). If any of the possible participants in our trial expressed a desire to deliver at the MU at the time of recruitment, she was not recruited. In the Stockholm Birth Centre Trial the situation was opposite as participating in the trial was the only way to enter the birth centre at its opening in October 1989 (31). Still our findings are in accordance with those of the Stockholm Birth Centre Trial concerning intervention rates and health outcomes. It would be interesting to investigate and present outcomes from low-risk women choosing to deliver at the MU compared with those randomised to the MU in this trial.

Blinding

In a clinical trial it is desirable that neither the participant nor the caregiver know which group the participant is allocated to (134). Blinding of the caregivers did not seem feasible in this trial, as low-risk women usually are guided to the MU and NU, and at the SU there is limited capacity for low-risk women. The non-blinding of caregivers represents a possible risk that the caregivers judgement and decisions were affected by knowing that the women were enrolled in the trial (135). Blinding the participants was considered almost impossible as the three birth care units are placed on separate floors, organised differently and have signs at the entrances telling the name of the unit. It is for example possible that participants randomised to the MU awaited the request for epidural analgesia knowing that it would imply transfer to another unit. It is hard to say in what other ways non-blinding of the participants could affect the outcome.

Power calculations

As there is no consensus of how to define low-risk women, we faced a challenge in estimating operative delivery rates for our defined group in the population in general. Estimates were retrieved based on the operative delivery rates in freestanding midwife-led units in Norway. In addition rates in similarly defined groups in Norwegian materials from two standard obstetric units were obtained. Definitions of “low-risk” in these groups were obtained retrospectively and might therefore be biased. A possible limitation of this trial is the fact that the number of included participants was less than estimated by the power calculations, based on the primary outcome: operative delivery. This also might be the reason for the wide confidence interval for the primary outcome. However, the differences between the units were so small that even if the estimated number of participants were included, it is considered unlikely that the differences would be significant.

Estimating birth care costs

Østfold Hospital Trust uses a well established activity-based costing system, CPP which allow a thorough presentation of cost estimates (115). All human resources as time spent with each woman, surveillance and number of doctor’s visits during birth are not counted, as this would imply a thorough mapping of all activity at all times. Nevertheless, a detailed resource utilisation would allow a more nuanced estimate for costs per day. We did not include costs of antenatal care, possible long-term costs, or costs in connection with transfer of newborns to the Neonatal Intensive Care Unit which would be interesting in future investigations.

Effects

The outcome measures used in the cost-effectiveness analysis were clinical procedures; proportions of caesarean sections, instrumental vaginal deliveries which correlate with the main outcomes in the RCT. Additionally complications requiring treatment in the operating room, epidural analgesia and augmentation with oxytocin were chosen as these outcomes are assumed to be correlated with length of stay and costs. Generally in economic evaluations, outcomes are measured by a generic instrument, like health-related quality of life (HRQoL) (112). A generic measure would make it easier to compare the cost-effectiveness of this RCT with other interventions in the health care sector. In addition, the HRQoL would have given us more information about the women's health, even though we do believe that it is correlated with the outcomes included in this paper.

Cohort design

In a cohort study the study group consists of people with common characteristics. Most often the cohort group is compared to the population in general from where the cohort was drawn, but can also, as in this study, be divided in subgroups that are compared with each other (135). In a cohort design there are some challenges regarding validity. The challenges concerning external validity in this study are equal to the challenges mentioned above in the discussion of the method in the RCT. The internal validity on the other hand is threatened when comparing participants with and without dystocia and with and without being augmented by oxytocin. Even though the study population consists of a selected group of low-risk nulliparas fulfilling strict selection criteria, some attributions may differ between the compared groups and affect the results.

Confounding bias

In an observational study like the cohort study, there is a risk of confounding factors affecting the outcome. Confounding factors are factors that can distort the association between two variables (137). It can mask an actual association or incorrectly display an apparent association even though the association does not exist. The effect of confounding may be reduced by multivariate methods like regression analyses. In a regression analysis factors that may affect the outcome are controlled for in order to estimate the effect of the explanatory variable more accurate (134). In our study we adjusted for variables with known or suspected relation with both the dependent and the independent variable to reduce confounding. Nevertheless, associations found could also be caused by or affected by unknown variables not included in the regression analyses.

Causal inference

The relationship between events, cause and outcome are described as causality, but an observed association does not necessarily imply that there is a causal relation (134).

In paper III we wanted to investigate if the outcome was predicted by augmentation with oxytocin or if the outcome was predicted by the cause of augmentation which has been suggested in prior research (88). Our findings show associations between augmentation with oxytocin and instrumental vaginal deliveries and episiotomies for women with no dystocia which cannot be explained as oxytocin being the only cause of these outcomes. A well-conducted RCT where any difference in outcome could be taken as causally related to the difference in treatment would more safely be able to make such an inference (134). Such a trial could be difficult to conduct firstly because women might be reluctant to participate knowing that oxytocin is likely to shorten birth (80) and secondly because there is a risk of crossover (80). Conducting a large prospective matched cohort study with restrictive selection criteria could provide valuable information.

IMPLICATIONS OF FINDINGS AND SUGGESTIONS FOR FURTHER RESEARCH

We found no difference in operative delivery rate for low-risk women randomised to the MU, NU or SU, still, women randomised to the MU were more likely to experience labour without medical interventions like epidural analgesia and augmentation with oxytocin compared to the NU and SU. For this homogenous low-risk group there might be a tendency that the risk of being exposed to interventions is more dependent on availability rather than necessity of the intervention. Midwives and doctors should be very careful when assessing the situation before initiating actions, to avoid unnecessary interventions at all units. Realising that 25.3 % of the low-risk primiparous participants had an operative delivery in contrast to only 1.6 % of the multiparous, attention needs to be paid to primiparous women to avoid every excess operative delivery. Patient safety strategies have been proved to be effective in reducing adverse events in obstetrics (138). Further studies should be conducted to investigate possible actions that are associated with a reduction in operative delivery rates. When assessing quality of birth care using caesarean section as a quality indicator it is of importance to perform case-mix adjustments to enable understanding of factors influencing the caesarean section rates (139). One-to-one continuous midwife support during labour have been found to be associated with a reduction in caesarean section rates (140,141) and it would be interesting to concentrate further research on the topic. The results of this trial should only be generalised to low-risk women without outspoken preference of birth place and future research should aim to reveal the significance of planned place of birth (23).

Our study showed that organising birth care for low-risk women in a separate midwife-led unit is cost-effective. In future organisation of birth care these findings should be taken into consideration. Future research should also include long term costs, costs in connection with transfers to the NICU, both long and short term and detailed resource utilisation to allow a more nuanced estimate for cost per stay.

This trial and prior research have shown that women are augmented with oxytocin without apparent indication and that the use of oxytocin in the amount it is used does not improve birth outcome. Maybe it is time for a paradigm shift. Maybe it is time to concentrate on implementing and following criteria and guidelines based on findings of prior research instead of further investigating the consequences of augmentation with oxytocin. Nevertheless it would be interesting to study factors that predict augmentation with oxytocin for women with normal birth progression further.

When discussing if future organising of birth care for low-risk women should be differentiated and organised in separate midwife-led birth care units, it is of relevance to consider different quality indicators: operative delivery rates, intervention rates, perinatal and maternal morbidity, and cost-effectiveness. Additionally patient satisfaction and the importance of choice of birth place could contribute to valuable information.

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PAPER I

Stine Bernitz, Rune Rolland, Ellen Blix, Morten Jacobsen, Katrine Sjøborg, Pål Øian

Is the operative delivery rate dependent on the level of birth care?

A randomised controlled trial.

BJOG An International Journal of Obstetrics and Gynaecology 2011;118:1357-1364

PAPER II

Stine Bernitz, Eline Aas, Pål Øian

Economic evaluation of birth care in low-risk women. A comparison between a midwife-led birth unit and a standard obstetric unit within the same hospital in Norway. A randomised controlled trial.

Midwifery 2012; epub ahead of print

PAPER III

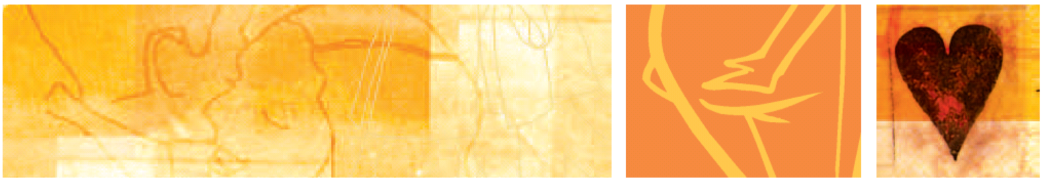
Stine Bernitz, Pål Øian, Rune Rolland, Leiv Sandvik, Ellen Blix

Dystocia and augmentation with oxytocin as risk factors for adverse birth outcomes in low-isk nulliparous women.

Submitted

APPENDICES

Sykehuset Østfold



INVITASJON TIL INFORMASJONSSAMTALE ANGÅENDE EN STUDIE VED FØDE-BARSELAVDELINGEN SYKEHUSET ØSTFOLD

I forbindelse med rutine ultralydundersøkelse som du nå innkalles til ved svangerskapspoliklinikken på Sykehuset Østfold, setter vi av litt tid til informasjon om en vitenskapelig studie som pågår ved Føde-barselavdelingen.

Studien har som mål å se på resultater etter normale fødsler ved de tre enhetene som Føde-barsel-avdelingen består av; Fødestuen, Normalenheten og Spesialenheten. Vi søker kvinner med normalt svangerskap og forventet normal fødsel. Du er ikke egnet til studien dersom du tidligere har hatt keisersnitt eller har en kronisk sykdom som påvirker svangerskap og fødsel eller venter mer enn ett barn.

I fagmiljøer både nasjonalt og internasjonalt er det noen som mener at utstrakt bruk av teknologi til alle fødende gir de beste resultatene. Andre mener at dette fører til flere unødige operative forløsninger og dermed flere komplikasjoner, og at fødselsomsorgen derfor bør være behovstilpasset og differensiert. Det finnes i dag ingen studier som kan gi oss et sikkert og vitenskapelig svar på dette. Det er derfor spesielt spennende å kunne gå i gang med slik forskning her ved sykehuset. Praksis på avdelingen vil ikke endres på noen måte under studien og alle som er med vil få den samme trygge behandlingen som tidligere.

Du vil få ytterligere opplysninger om studien når du kommer til informasjonssamtalen.

Alle som inkluderes i denne studien blir med i trekningen av et reisegavekort på kr. 10.000,-
Vi trekker en heldig vinner for hver 500 inkluderte deltager.

Vi ønsker deg velkommen og håper studien kan bidra til et enda bedre fødetilbud.

Med vennlig hilsen for studien

Stine Bernitz
Prosjektleder

Sykehuset Østfold

FORESPØRSEL OM Å DELTA I ET FORSKNINGSPROSJEKT

ved Føde-barselavdelingen, Sykehuset Østfold, Fredrikstad

«Kan et differensiert fødetilbud gjøre fødselshjelpen enda bedre?»

Her ved føde-barselavdelingen, Sykehuset Østfold, ønsker vi å gi den gravide og hennes familie den beste omsorgen.

I 2004 opprettet vi tre helt nye, kombinerte føde-barsel enheter delt inn etter grad av risiko. Denne omorganiseringen ble satt i verk på bakgrunn av Stortingets behandling av akuttmeldingen i 2001, hvor det ble vedtatt at fødselsomsorgen i Norge skulle være differensiert. Hensikten med den differensierte fødselsomsorgen er at omsorgsnivået til den fødende skal avspeile hennes behov. Omorganiseringen er også i tråd med Verdens Helseorganisasjons prinsipper for perinatal omsorg. I debatten om fødselsomsorg er det delte meninger om hva som er den beste behandling. Noen mener at dagens fødselshjelp er den beste, med utstrakt bruk av teknologi til alle fødende. Andre er av den oppfatning at dette fører til for mange operative inngrep og dermed komplikasjoner og at omsorgen i stede bør være differensiert og tilpasset kvinnens behov. Det er ikke mulig i dag, på et vitenskapelig grunnlag, å si hvilket omsorgsnivå som gir best utfall for mor og barn etter normale svangerskap, siden det ikke er gjort lignende studier tidligere.

Det er derfor spesielt spennende og interessant å kunne gjennomføre en såkalt randomisert studie på SØF, nå hvor vi har tre nivådelte fødeenheter. For å kunne delta må du være frisk og ha gjennomgått et normalt svangerskap. **Hvilken av de tre enhetene du skal føde på vil bli bestemt etter et gitt system når du kommer inn til fødsel.** Alle dine ønsker og behov under oppholdet vil etterkommes som tidligere, og den medisinske beredskapen vil være like tilgjengelig for alle uansett enhet.

Denne studien vil gi oss ny og verdifull kunnskap. Resultatene av dette forskningsprosjektet vil publiseres og kan forhåpentligvis føre til endret og bedre omsorg for de fødende.

Din deltagelse i studien er frivillig og forutsetter at du skriver under på denne samtykkeerklæringen. Alle opplysninger vil hele veien bli fortrolig behandlet og vil ved studiens slutt, desember 2010, bli anonymisert. Du kan avslå og være med i studien eller trekke deg uten at du behøver å oppgi grunn. Dette vil ikke på noen måte påvirke ditt opphold ved føde-barselavdelingen.

Du blir med dette forespurt om å delta i denne studeien. Du vil følges i svangerskapet på vanlig måte. Har du spørsmål angående studien er det mulig å treffe jordmor Stine Bernitz på mail stiber@so-hf.no eller på tlf.: 69 86 12 89.

Jeg har lest informasjonen og samtykker i å delta i studien:

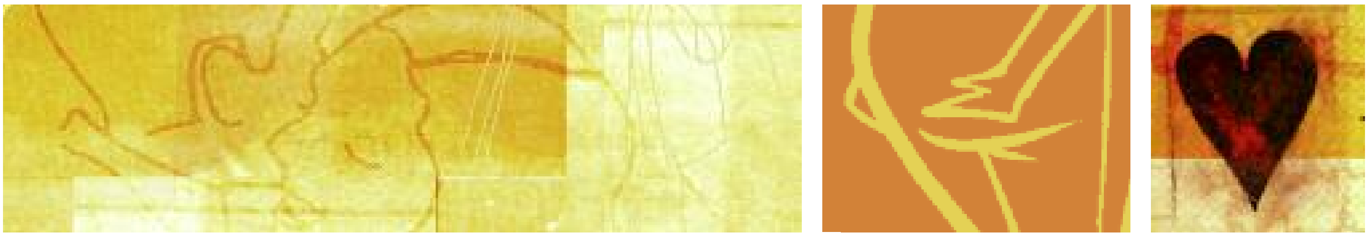
Navn (blokkbokstaver) ....Dato/sign.......................................

Rune Rolland
Avdelingssjef

Stine Bernitz
Fag og forsk.jordmor

Pål Øian
Prof./ Leder Nasjonalt råd
for fødselsomsorg

Sykehuset Østfold



FØLGESKRIV TIL RANDOMISERT STUDIE VED FØDE-BARSELAVDELINGEN SYKEHUSET ØSTFOLD, FREDRIKSTAD, 2006-2010

Para: .....

TUL: ...../....../......

Personalia (klistrelapp)

Tidligere forløsning: Normal ☐ Atoni bl. > 1000ml ☐ Perinealrupt. gr : ☐

EGNETHET FOR DELTAGELSE I STUDIET (NORMALTFØDENDE)

	Egnet til studien	Ikke egnet til studien	Angi grunn fra liste under	Dato	Sign.
Vurdering rutine ultralyd:	☐	☐	nr..........	....	....
Vurdering uke 36:	☐	☐	nr..........	....	....
Vurdering v/innkomst i fødsel:	☐	☐	nr...........	....	....

Fødselsforberedende samtale:	ja ☐	nei ☐	Dato:..........	Sign:.................
Omvisning i avdelingen:	ja ☐	nei ☐	Dato:..........	Sign:..................
Utdelt informasjonsskriv.	ja ☐	nei ☐	Dato:..........	Sign:..................
Ønsker pasienten å delta i studien	ja ☐	nei ☐		
Er samtykkeerklæringen underskrevet	ja ☐	nei ☐		

GRUNNER TIL AT KVINNEN IKKE ER EGNET TIL STUDIEN

1. Tidligere sectio/operasjon på uterus
2. Tidligere komplisert fødsel (vanskelig tang/vacum, skulderdystoci osv)
3. Kronisk sykdom hos mor som påvirker svangerskap /fødsel
4. Komplikasjoner i aktuelt svangerskap (vekstretardasjon, preeklampsi ect)
5. Flerlinger
6. Avvikende leie
7. Overtid (>41.6 uker)
8. Preterm fødsel (< 36 uker)
9. Induksjon av fødselen
10. Eget ønske
11. Annet

Pregravid BMI: ......

UNIVERSITY OF TROMSØ

ISBN xxx-xx-xxxx-xxx-x