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A study of safety and quality of maternity care in freestanding midwifery units

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ORIGINAL PAPERS

This thesis is based on the following three papers, which will be referred to by their Roman numbers:

Paper I **Freestanding midwifery unit versus obstetric unit: a matched cohort study of outcomes in low-risk women.**
Overgaard C, Møller AM, Fenger-Grøn M, Knudsen LB, Sandall J.
BMJ Open 2011;2:e000262.doi:10.1136/bmjopen-2011-000262
(Published)

Paper II **Freestanding midwifery units versus obstetric units: does the effect of place of birth differ with level of social disadvantage?** Findings of a matched cohort study of two different models of intrapartum care for low risk women.
Overgaard C, Fenger-Grøn M, Sandall J.
BMC Public Health 2012, 12:478 doi:10.1186/1471-2458-12-478
(Accepted for publication)

Paper III **The impact of birthplace on women's birth experiences and perceptions of care.**
Overgaard C, Fenger-Grøn M, Sandall J. Social Science & Medicine 2012; 74: 973 - 981. Doi.org/10.1016/j.socscimed.2011.12.023
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CONTENTS

Figure and tables

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ABSTRACT

Background

Childbirth and maternity care services are important issues to society because the clinical and psycho-social outcomes of birth have immediate as well as long-term consequences for the health and well-being of infants, women and families. Our understandings of what is good and right in childbirth and maternity care services are however based on cultural beliefs and they bear the imprint of wider social structures and debates.

The last few decades have seen maternity care services become more centralised and specialised. In most high- and middle-income countries, obstetric units (OU) have become the primary setting for birth, regardless of the woman's risk of obstetric complications. This model of care is dominated by a medical and technological perspective that has led some to question the ability of OUs to meet the needs of all birthing women. While OUs have given increased attention to women's autonomy and the "humanisation" of care, midwifery units have emerged as an alternative to OU care for low risk women, offering low-technology, individualised, and patient-centred care, typically closer to home for many women.

Aims

The aims of this study were:

- To compare perinatal and maternal morbidity, birth complications, interventions, use of pain relief as well as women's birth experiences, care satisfaction and perceptions of care in two freestanding midwifery units (FMU) and two obstetric units (OU) in northern Denmark, all pursuing an ideal of high-quality, humanistic and patient-centred care

- To investigate whether the effect of birthplace on perinatal and maternal morbidity, birth complication, birth intervention, and the relief of pain varies correlates with women's level of social disadvantage

- To investigate the influence of social disadvantage on women's birth experience and care perceptions

Design
Overall, the study was designed as a cohort study with a matched control group. A postal questionnaire survey was undertaken as part of this study.

The study included 839 low-risk women intending FMU birth in the period between March 2004 and October 2008. The women were prospectively and individually matched on nine selected obstetric/socio-economic factors to 839 low-risk women intending OU birth. A sub-group of 218 FMU women, admitted between January and October 2006, and their 218 matched controls, were invited to participate in a questionnaire survey.

Educational level was chosen as the primary proxy for social position. Analysis was by intention-to-treat.

Results
No significant differences in perinatal morbidity were observed between groups (Apgar scores <7/5, <9/5 and <7/1, admittance to neonatal unit, asphyxia, and readmission). Although rare, adverse outcomes occurred in both groups. FMU births were significantly less likely to involve abnormal fetal heart rate, fetal-pelvic complications, shoulder dystocia, occipital-posterior presentation, and postpartum haemorrhage >500ml compared to OU births. Significantly fewer FMU women had caesarean section, instrumental delivery, oxytocin augmentation and epidural analgesia. Transfer during birth or <2 hours after birth occurred in 14.8 % of all FMU births, more frequently in primiparas than in multiparas (36.7 % versus 7.2 %).

Of the 436 women invited to participate in the survey, 375 women (86 %) responded. Birth experience and satisfaction with care were rated significantly more positively by FMU than by OU women.
Significantly better results for FMU care were also found for specific patient-centred care elements (support, participation in decision-making, attentiveness to psychological needs and to wishes for birth, information, and for women's feeling of being listened to).

The FMUs' location in community hospitals in the centre towns of predominantly rural areas offered women a choice of low-technology patient-centred care relatively close to home, an offer which was accepted by women from a far wider range of social backgrounds than seen in most studies of out-of-OU birth.

Subgroup analysis revealed a significant, negative effect of low education and employment levels on birth experience. This effect was found only for the OU group; showing the potential of FMU care to mitigate the effects of social disadvantage on women's birth experience.

A similar effect of FMU care was not found where clinical birth outcomes were concerned. In all cases, FMU women without post-secondary education had comparable and, in some respects, favourable outcomes when compared to OU women with the same level of education while advantaged and disadvantaged women were found to benefit equally well from FMU care. In this restricted sample of low-risk women receiving one of two different models of midwifery-led care in a public health care system, the effect of birthplace on birth outcomes did not vary with women's level of education.

Conclusion

Overall, this study provides strong support for FMU care, even in settings where all frontline care in OUs is provided by midwives and where the humanistic paradigm of childbirth and patient-centred care is prevalent, as was the case in the North Denmark Region.

FMU care appears to offer important benefits for birthing women in terms of improved birth experience and reduced maternal morbidity with no additional risk to the infant; elements of FMU care are thus deemed useful in the development of OU care for low-risk women.

In a public health perspective, FMU care holds great potential for the improvement of maternal health and well-being in populations of low-risk women. It is therefore suggested that FMU care is made available to low-risk women regardless of their social position and parity, and that all women are provided adequate information about different care models, including their benefits and harms, in order to support them in making an informed decision about their preferred place of birth.

BACKGROUND

At the same time as it is both a biological and a cultural phenomenon, childbirth is a significant personal life event shaped by the historical, social and political context in which it takes place [1, 2].

Studies of maternity care services, such as the present work, form part of the multidisciplinary tradition of health services research that involves the integration of statistical, epidemiological, and social and behavioural research techniques [3]. This study is furthermore informed by sociological theories of childbirth, medicine, midwifery and health.

In his recent comparison of different models of maternity care services, one of the pioneering sociologists of childbirth, the American Raymond De Vries concluded that:

> "More than any other area of medical practice, the organization and provision of maternity care is a highly charged mix of medical science, cultural ideas and structural forces. Other medical specialties are marked by a technical uniformity that crosses national borders, but the design of care at birth varies widely and clearly bears the marks of the society in which it is found" [2(p.15)].

Although in many families it is no longer the recurrent and frequent event of earlier times, childbirth and society's response to it, including the care provided for childbearing women, infants and families, is nevertheless an important sociological phenomenon. At the time when the sociological study of childbirth started developing, Raymond Illsley stated that "no biological event has greater significance for society than reproduction and its outcome" [4].

Some years later, Lucile Newman, whose interest focused on childbirth as a ritual practice, would state that:

> Giving birth and becoming parents are important steps in the rites of passage in every society. Because birth is the main form of recruitment to families and kinship groups, the mode of conducting delivery, the acceptable persons in attendance, the degree of intervention for survival, the treatment of the woman herself and then her infant, are all under cultural stricture, set of beliefs, and rules about "how to do things" [5 (p.2)].

A further issue of importance to society is the immediate as well as long-term influence of birth outcomes and birth experiences on the well-being and health of the infant, women and on family dynamics [6-11]. Society's interest in women's and infants' survival and physical well-being after birth is obvious, but this is no less true in relation to the experiences of women and their partners and the way that the parent-infant relationship is supported, or indeed, not supported.

As described in Paper III, positive birth experiences contribute to women's feeling of accomplishment and self-esteem and support psychological growth, empowerment, and easier adaptation to motherhood [9]. Negative experiences, on the contrary, are associated with numerous complications [12] such as postpartum anxiety, depression, posttraumatic stress syndrome, fear of childbirth [13], short-time or unsuccessful breastfeeding [14], reduced future reproduction [15] and request for caesarean section for subsequent births [16]. The psycho-social outcome of birth may thus have a serious impact on the general well-being of a population.

Moreover, the outcomes of birth, in terms of medical as well as psychosocial factors, are closely tied to the wider social structures and restraints in a society. Even in countries with a high level of social equity, supporting a public health care system, birth outcomes vary between social groups. Socially disadvantaged women suffer higher rates of maternal and perinatal morbidity and mortality, preterm birth, low birth weight, low Apgar scores and need for admission to neonatal care compared to advantaged women. Furthermore, disadvantaged women have lower childbirth expectations and their experiences have been found to be more negative than those of more advantaged women [17-19].

The underlying causes of such disparities in birth outcomes are complex. They can be traced to differences in the mother's exposure to a range of material threats, stressful events, and inequalities in access to care or psychosocial support from partner, family and friends and/or care providers. Health care provision may, moreover, be considered a social determinant itself, if health outcomes between groups with different social position are influenced by the allocation of resources, the financing of health care or the quality of health care services [20].

In the research presented here, social inequity[*] is defined as systematic disparities in health or in the major social determinants of health between groups with different levels of underlying social advantage/disadvantage; cf. Braveman and Gruskin [20 (p.254)].

The concept of equity is normative and based on ethical principles, its discussion closely related to the principles of human rights. Inequity results from what is seen as unfair processes in the distribution of resources and other conditions affecting health. The famous definition, established by the British Whitehall studies of civil servants' health, describes health inequities as differences in health that are unnecessary, avoidable, unfair and unjust [22]. It is deemed appropriate to apply the concept of inequity for this study because evidence is mounting that disadvantaged women may not

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[*] The term is occasionally used indiscriminately or confused with the more neutral term [21] equality. The latter also appears in this overview as it is used by references.

only be more vulnerable and have more difficulty in accessing maternity care services. Furthermore, they may also receive lower quality of care and lower levels of continuity and support than socially advantaged women [23-26].

Another group of women that may not have their needs appropriately met in maternity care services is first time mothers (primiparas). Primiparas have more interventions than women who have given birth before (multiparas), and both maternal and perinatal birth outcomes as well as women's experiences / care satisfaction have in some studies been reported as more negative compared to multiparas. Primiparas have a biological disposition for longer and more complicated labour. It is therefore arguable that they have an increased need for close observation and, maybe even more importantly, continuous psychosocial support in labour that has been documented to reduce the need for medical pain relief and interventions and improve women's birth experiences [27].

Changes and current challenges in maternity care services

Over the last century, most middle- and high-income countries have seen great changes to their maternity care services, most importantly the nearly complete hospitalisation of births and the increased use of birth interventions and medical pain relief, in particular induced or augmented labour, caesarean section and epidural analgesia [28-30]. In Denmark, where this study is set, the hospitalisation process occurred relatively late, with 60 % of women giving birth at home in 1960, 13 % in 1970 and 0,5 % in 1985 [31]. This is true, not only when compared to the USA, which saw the earliest and most rapid hospitalisation of births, but also when other Nordic countries, such as Finland and Sweden, are considered [32].

Steadily rising rates of medical birth intervention [28-30] have been the cause of concern and debate. As early as 1985, a consensus statement by the World Health Organisation (WHO) suggested [33] that no additional health benefits were associated with caesarean section rates above 10-15 %.

Rates of intervention, however, vary greatly between settings and between hospital levels [29, 34], and as there is no clear evidence for any benefit from increases in the use of interventions [35, 36], it is generally agreed that "continued increases in the rates of obstetrical intervention are unlikely to result in improvements in birth outcome overall and that they may pose a risk to mothers and their newborns" [30].

Although this agreement has occasionally been challenged [37], a Californian white paper† recently warned about the great financial burden of a caesarean rate above 33 % in the USA [38]. The awareness of obstetricians that obstetric practices are socially constructed and negotiated rather than governed by physical laws is evident in e.g. Gei & Pacheco's explanation of the difficulty of obtaining consensus about the use of interventions:

> "The art of modern obstetrics is one that mandates from obstetricians the attentive vigilance of the development of natural processes and an active intervention when such processes fall outside normally accepted standards. What constitutes the "normal process" and the "accepted standard" is subject to discussion, and international variations in obstetric practice are in part the reflection of such controversies" [39] (p. 323).

It seems clear that achieving a balance between intervention and non-intervention is one of the big challenges in maternity care in developed countries as the overuse of medical birth interventions may pose not only a medical risk; the use of interventions is also associated with two other major challenges in maternity care, i.e., negative birth experiences and fear of childbirth. According to international studies, these occur in 10-20 % [40] and 5-30 % [13, 41, 42] of women, respectively. The complexity of this issue is apparent as women have also been found to value *timely* and *well-founded* intervention [43].

Birth outcomes, including the use of interventions, are influenced by a number of structural factors, such as the organisation of health care services by the public or private sector, the type of care provider (obstetrician/midwife), and the level of specialisation of care. This is clear, especially in respect to the use of interventions, which tend to increase where levels of hospitalisation and specialisation are high and private or consultant-led care is prevalent.

A Cochrane review has documented that midwifery models of care compared to consultant-led care reduce intervention rates, and result in good perinatal and maternal outcomes, and high user satisfaction [29, 44-46]. WHO and the United Nations advocate midwifery care [47, 48], but the role of midwives varies greatly and is most prevalent in countries with public health care systems. In several high-income countries, including the Nordic countries, the Netherlands, Germany, the UK and New Zealand, midwives are the lead carers for low-risk women, while in countries where private care is dominant, obstetricians typically take this role (in the USA, for example, only 8 % of births are attended by a midwife [49]). Although intervention rates are generally lower in countries with frontline care provision by midwives, rising intervention rates are also seen in these countries. In Denmark,

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† A white paper is an authoritative report that addresses a specific problem; white papers are used to educate readers and aid decision-making, and the publishing of a white paper signifies a clear intention on the part of a government to pass new law.

where the tradition of midwifery care is among the oldest and strongest in the world, and midwives are involved in all births, the rate of caesarean section increased from 11 % to 12.2 % in the 20 years until 2002, after which it nearly doubled to 22 % in 2008. Epidural analgesia was rarely used in Denmark until the late 1990s, since when it has soared from 4 % to 26 % in 2009.

Place of birth holds a prominent position in the debate over rising interventions rates and the quality of maternity care services. Strong claims have been made that high intervention rates reflect the undesirable medicalisation of childbirth and are closely linked to the shift from homebirth to hospital birth. This problem takes centre stage in the present research project.

In the following section, some key concepts and debates that have influenced the sociological and anthropological research on childbirth are outlined in order to provide a framework for understanding the origin of the models of care that are compared in this study, and how these debates influences the ways in which services are delivered and with what consequences.

SOCIOLOGICAL PERSPECTIVES ON CHILDBIRTH

For more than a century feminist scholars and activists have argued for the existence of a connection between on the one hand the conditions under which infants are born and women become mothers and on the other hand women's social position and gender relations in society.

In the early 20th century, women's movements fought for the right of birthing women to be relieved of pain and for access to hospital care in case of complications [50, 51]. Later in the same century, the focus turned toward the medicalisation of childbirth and the overuse of birth interventions [52-55]. The national debate and the sequence of events were linked to the wider cultural, social and historical context of the individual societies. Briefly summarised, both waves of critique originated in the English-speaking world, from which it disseminated to other Western countries. The first wave did not reach Denmark before the 1940s, while the impact of the second was felt from the 1980s. The ensuing struggle for women's right to pain-free labour and caesarean section without medical indication, which reached Denmark in the late 1990s, may be viewed as a third wave of critique. However, feminist terminology and arguments were remarkably absent in the public debate on these questions in Denmark.

A key issue in all three waves of critique has been the role of medical knowledge and technology in childbirth. Furthermore, each of the controversies was embedded in a wider feminist understanding and discourse. For the benefit of this overview, and to contextualise my study of freestanding midwifery units in Denmark, Danish events and perspectives will be given more attention than otherwise seen in international literature.

The early feminists' endeavour to gain access to medical pain relief and hospital birth fits well with the medial and technological optimism following the second industrial revolution and bears a strong relationship to women's overall struggle for access to technology, from which they felt excluded by men and their domains [56]. While some American women [57] saw the new opportunity offered by medication through scopolamine/morphine-induced "twilight sleep"[‡] as a way of freeing themselves from what they had begun to see as enslavement to their bodily processes, Danish women's arguments were levelled at male politicians, whose reluctance to provide public funding of pain relief at home birth was perceived as a classic example of the male oppression of women [50, 60]. Our

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[‡] "Twilight sleep" was introduced as an obstetric pain relief in 1906 and gained wide popularity. Technically, it was an injection with morphine and scopolamine (an amnesia-inducing drug) leading to a state of semi-consciousness in the labouring woman. The drug was associated with depressed respiration in newborns, and as another side effect, it erased women's memory not only of pain but also the birth of the baby [58]. After decades of use, the drug was gradually abandoned for these reasons. In Denmark, the anaesthetic "Trilene" was favoured as it was believed to cause fewer complications and was easily administered by mask, also at home births [59]. The amnesiac effect of "Trilene" can be testified by my mother, who, unaware of this effect, was given this drug when giving birth to me in the late 1960s.

understanding of this difference in perspectives may be informed by the work of the American historian Karen Offen, who outlines two different, major modes of feminist discourse in 20th-century western societies, the "relational" and the "individual". The two discourses coexist in most societies, although the former perspective has dominated most European debate until this day while the individualist perspective gained wide support in the USA, and, to some extent, in the UK as well [61].

According to Offen, the "relationalist" discourse proposed a gender-based but egalitarian vision of society, in which men and women joined in a companionable, non-hierarchical relationship. Women were valued through their *difference* from men and childbirth/motherhood was thus esteemed and valued as women's unique contribution to society. The earlier mentioned struggle by Danish women's rights activists for access to the benefits of modern medicine and recognition of the female contribution to society, as expressed through public funding of pain relief, is in line with this perspective. The wish to be freed from the "bodily enslavement" of childbirth, on the contrary, is associated with the "individualist" discourse, which emphasised women's rights to personal autonomy, citizenship and to the full realisation of their potential as individuals. In this discourse, gender-linked qualities of women's lives were downplayed or dismissed.

While essentialist understandings are inherent in the former discourse, the latter is distinctively non-essentialist, with its focus on what Annandale [62] terms as the *sameness* of men and women. In this perspective difference exists among individuals, not among social groups. It will later become clear how tension between the "relational" recognition of the uniqueness of women's embodied experience of childbirth and the "individualist" denial of this uniqueness has created a dichotomous debate over childbirth and, consequently, in the understanding of maternity care services and how they should be delivered.

With the nearly full hospitalisation of births and new and effective pain relief methods such as epidural analgesia being developed, the goals of the "first-wave" childbirth activists were achieved. However, the strong influence of modern medicine on childbirth, especially the extensive use of "twilight sleep" and similar treatments that erased women's memory of giving birth, later gave rise to the second wave of critique of intrapartum care. This was the expression of interest in "natural" childbirth, understood primarily as childbirth during which women were "aware and awake" and could take an active part in the birth process [63].

In the course of the 1970s and the 1980s, a compelling critique of practises in obstetric childbirth care was raised by feminist scholars, primarily committed to the "relational" mode of argumentation. Their argument was rooted in the wider critique of medicalisation that had developed within

sociology, under inspiration from Marxist perspectives and liberal humanism. Emphasising individual freedom, human rights and social change, the dominant social structure of societies was challenged, one aspect of this being the social role of high-status professions. In this process, medicine came under scrutiny for extending its perspective from the biological body to social problems and social life and exerting unjustified power and control over not only human health but over human life itself [64].

In the 1970s, Zola offered a widely used definition of medicalisation as "a process whereby more and more of everyday life has come under medical dominion, influence and supervision" [65 (p.210)]. Conrad later expanded Zola's definition to distinguish between three levels of medicalisation: the conceptual, the institutional and the interactional level:

> "Medicalisation consists of defining a problem in medical terms, using medical language to describe a problem, adopting a medical framework to understand a problem, or using a medical intervention to "treat" it. This is a socio-cultural process that may or may not involve the medical profession, lead to medical social control or medical treatment, or be the result of intentional expansion by the medical profession" [66 (p. 211)].

This definition drew on the work of, among others, Ivan Illich, who had claimed that rather than improving people's health, medicine undermined it and deprived individuals and societies of their ability to cope with sickness and death – or childbirth, when applied to this area. The concept of iatrogenesis was invoked to explain the harms or "evils" of medicine. According to Illich iatrogenesis operates on three levels [67 (p.33)]. The basic level is a clinical level where unintended damage is inflicted by doctors in their attempt to cure the patient or when doctors' attempt to protect themselves against lawsuits for malpractice. This perspective has been and still is dominant in debates over increasing interventions rates [38, 68].

The two other levels of iatrogenesis are found at social and cultural levels that may both be seen as operating in more subtle ways, with the social level reinforcing an allegedly morbid society that encourages people to become consumers of curative, preventive, industrial, and environmental products, a society in which health is standardised and institutionalised. The cultural level leads people to lose their ability to deal with their human weakness, vulnerability, and uniqueness in a personal and autonomous way and to accept health management designed on an engineering model. Applied to childbirth, the concepts of social and cultural iatrogenesis help explain why the home is no longer an acceptable place for birth and why women would give up autonomy over birth and their own care to health professionals.

The "medicalisation thesis" was extended to the field of childbirth in the 1970s and 1980s, and among others the British sociologist Ann Oakley argued that obstetric hospital care implied a mechanical and androcentric perspective on women's bodies as reproductive machines, a perspective which employed a "series of interventionist techniques to repair faults that may develop in that machine" [52 (p. 35)]. Although the writers in this field used a variety of perspectives, they all worked on the presumption that the medical/obstetric mind-set exerted great power over hospital births and that birthing women were rendered alienated and disempowered [52, 55, 69, 70].

Within the broader childbirth debate, controversy over place of birth and the hospitalisation of birth was prominent. It was argued that most women have uneventful labours and that birth in hospital represented an unnecessary exposure of women to medical routines and procedures that were more suited to meet the requirements of the medical profession, e.g. by congregating women in one place and leaving them in a recumbent position with their legs in stirrups, etc., than to meet the needs of women [71]. By subjecting labouring women to the hospital regime, it was assumed that their needs and wishes would be more easily subsumed under doctors' priorities, and that such changes would lead to faster "processing" through a system primarily concerned with effectiveness. This perceptive posited that the woman, now a patient, was a passive, dependent and subordinate recipient of treatment [64]. Power was perceived as something that was held by doctors as a social group, but also something that was possible for women to free themselves of and reclaim – for example by choosing a home birth.

This perspective on medical power has later been challenged, perhaps most influentially by Foucault, who saw power as a positive and productive rather than as a repressive force, a disciplinary power that provided guidelines on how patients should understand, regulate and experience their bodies and which worked through implementing certain ways of behaving and thinking [64].

This approach may not seem far from the understanding of the social and cultural levels of iatrogenesis and may thus have been embraced by defendants of the "orthodox" medicalisation critique; yet from a Foucauldian perspective, power is not something that can be possessed or reclaimed. Instead, as noted by Gatens, power must "be recognised as constructed by discourses and practices that take the body as their target and as their vehicle of expression" [72].

In their writings on childbirth, the critics of medicalisation provided a link to a wider critique of the bureaucratisation or technologisation of society [73] that was understood in like fashion to have spread to all aspects of life. Among the most influential of such writers was the American anthropologist

Robbie Davis-Floyd who saw obstetrical procedures as rational, ritual responses that were performed in order to:

> "transform the unpredictable and uncontrollable natural process of birth into a relatively predictable and controllable technological phenomenon that reinforces American society's most fundamental beliefs about the superiority of technology over nature" [70 (p.5)].

In the perspective of technologisation and technocracy, which defines society as a hierarchically organised structure in which the ideology of technological progress is used as a source of political power, Davis-Floyd outlined two contradictory models or paradigms of childbirth [74] (cf. Paper III). Elaborating on the work of Rothman and others, who had developed the binary concept of medical versus midwifery/social models of birth, Davis-Floyd characterised the dominant hospital-based model of childbirth as a technocratic model, based on a Cartesian doctrine of mind-body separation and the understanding of the body as a machine. In this model, only technical knowledge is valued, the mother and the baby are seen as separate entities, and childbirth is viewed as a "risky medical process" calling for expert control [70, 74].

As an alternative to the above, Davis-Floyd outlines the holistic model of birth, based on a conception of body, mind and spirit as one and of female reproductive processes as normal and healthy. Intuition, emotional and embodied forms of knowledge are valued and the woman is seen as an autonomous subject; mother and baby are, however, seen to form an inseparable unit with indistinguishable needs. In comparison to other authors, whose alternatives to medicalised care embrace a "social" model of birth, Davis-Floyd's holistic model pays far less attention to birth as a family event and to the significance of birth taking place in the woman's own environment, with its capacity to evoke involvement and support from family and friends.

In the debate the two models of care tended to be identified with the different places of birth (maternity unit versus home birth / birth centre), with their respective providers (obstetricians versus traditional birth attendants or midwives) and with the gender of the care providers (male versus female)[§]. Furthermore, women's choice of provider and birthplace were seen as indicative of their assessment of risk [75] and of their attitude to control in childbirth [76].

The holistic model was widely associated with the concept of "natural" childbirth, introduced in 1933 by the British obstetrician Dick-Read, who advocated "unmedicated and un-interfered-with labour" [70 (p.162)] and spearheaded women's rights not to have drugs or interventions forced upon them in

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§ Some may, however, see it as a contradiction that some of the most important advocates for natural childbirth in clinical practice were male obstetricians (such as Grantly Dick-Read, Michel Odent and Frédérick Leboyer), some of whom introduced this care in hospitals or private birth centres.

labour[**]. Although he valued childbirth as a social event in the family and offered an approach based on antenatal birth preparation, psychosocial support and the use of relaxation technique in labour, his work cannot be enlisted as support for a back-to-nature romanticism, or for the "trust-nature-to-take-its-cause" fatalism [77, 78] of which proponents of "natural" childbirth have later been criticised. Insisting on the importance of motherhood in a woman's life, Dick-Read's approach was in line with the "relativist" argument and it generally gained widest popularity in countries where this perspective had hegemony, such as Denmark.

The competing psycho-prophylactic method, which was introduced by the French obstetrician Lamaze, did not build on an essentialist view. While the technique allowed women control over their own behaviour and responses to it, the labour and its attendant procedures were still controlled by the obstetrician [54]. It appealed not least to American women, who (among others) later have been found to strongly emphasise the perception of personal control in childbirth [79, 80]. Lamaze's method offered women a choice and a perspective that was in line with the "individualist", feminist argument. Furthermore, claims has been made that the Lamaze method became popular because it was easily adapted to the existing obstetric settings and offered no real threat to the technocratic model of birth [70].

Davis-Floyd notes that for the sake of clarity she describes the technocratic and holistic models in a polarising light which make them appear in their extreme forms. Her writings also make clear her personal preference for the holistic paradigm. Her description of the technocratic model employs terms with strongly negative connotations (e.g. *defective, dysfunctional, pathological, the obstetrician as technician and a manager*) while the holistic model is described in very positive terms (e.g. *normal, healthy, empathy, care, the midwife as a nurturer and a skilful guide*) [70 (p.160)]. The overall effect is that the technocratic model is presented as "bad" and the holistic as "good", which more than suggests that her work is based on ideological as well as empirical grounds.

According to Davis-Floyd, the growing interest in natural childbirth eventually gave rise to a third, "humanistic" paradigm of childbirth. Although she finds that the humanistic model offers women real alternatives, she nevertheless concludes that it represents "simply a modification of the technocratic model of birth" in which women are subjected to the same cultural forces and where any deviation from the norm renders them subject to "cascades of interventions" [70 (p.275)]. With time,

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[**] Grantly Dick-Read became the first president of the UK's Natural Childbirth Trust, today the National Childbirth Trust, Britain's leading charity offering information and support in pregnancy, childbirth and early parenthood.

Davis-Floyd has expanded her perception of the humanistic model and the characteristics of the model are described later.

Van Teijlingen has noted that the concept of two diverting model of birth has widespread appeal and is frequently used in the analysis of childbirth and maternity care services [81]. Yet, this understanding does not grasp the complexity of childbirth and the role of medicine in childbirth as well as women's experiences of and response to this and the understanding has been challenged. In the following section, the key arguments in the diverse and multi-faceted critique of the conception of two childbirth models will be outlined.

Arguments in the debates over childbirth

The debate over safety and place

Unsurprisingly, the fierce attack on the "technocratic" model of childbirth has been mirrored by equally strong criticism from the other side, and the "holistic" model of childbirth with its emphasis on out-of-hospital, (lay-)midwifery-based birth has faced severe criticism for ignoring medical risk, jeopardising the welfare of mothers and infants, and representing a romantic utopian dream [77]. Claims and assumptions have flown from both sides, and, as will be discussed later, epidemiological knowledge and clinical research are needed to inform the debate. This is, in fact, one of the intentions of this work.

The distinction between "natural" and "artificial" childbirth

Claims have been made that the idea of "natural" childbirth as being superior to "artificial" childbirth constrained women from requesting pain relief [82] and created an atmosphere in which women were deemed to have failed if they did not comply [83]. While this may very well be true for some women, the argument disregards the clear evidence, that the use of interventions is also associated with negative psychosocial birth outcomes [11, 18, 84].

In fact, it is questionable whether the idea of turning maternity care into a question of intervention versus support is fruitful. Although it seems to be a common understanding that women's choice of birthplace represents a trade-off between medical safety and comfort produced by social support and skilled midwife guidance, it is noteworthy that Norwegian women, in a public hearing in 1999, made it clear that they saw no contradiction between the two models, and that they wanted and were ready to pursue birth models that offered both [85].

The Danish philosopher Steen Wackerhausen may offer important insights in his examination of the concept of the "natural" as it is used in childbirth debates. Wackerhausen turned the debate around by arguing that whether or not childbirth is intervened in, it should be seen as representing a natural process. "Natural" may mean something that is given by itself, self-evolving or unaffected by human intervention, but medical treatment may also be seen as natural phenomena and practices since they are expressions of human nature and its disposition to try to avoid death and disease and to promote well-being and happiness [86]. The weakness of the concept of the "natural" is summarised by Wackerhausen as follows:

> "The uses of "natural" and "normal" in debates about technology and medicine, health care and childbirth are more a burden than a blessing, more a source of confusion than a source of clarification. In the name of nature, unbearable sufferings and misery might potentially be tolerated or even promoted. Yet, inappropriate highly technological treatments and interventions can also be argued for by reference to the natural. What is essential and worth pursuing, is what is good" [86 (p.106)].

Our conceptions of good and bad should *not*, Wackerhausen argues, be based on a fundamentalist, universalist definition insensitive to individual and cultural variation. Neither should we accept definitions of what is good that are so relative or individual that the term becomes ambiguous and worthless as a guide or criterion. What should be sought is an *open* concept of what is good and what is healthy which acknowledges both human relativity and human universality [86].

According to Wackerhausen, the care provider is not in a position to decide what is good or healthy; this should be reserved for the informed and autonomous individual, in this case the woman in pregnancy. What makes the care provider a professional is their knowledge of means and consequences, not their personal views of what is good or bad. Thus, the treatment of the woman in labour should always take into account and respect the genuine and long-term goals and values of the individual woman [86].

Wackerhausen's argument is very much in line with the views underlying what is today a widely accepted and acknowledged concept of patient-centred care (further description to follow), a concept that also forms a key element in the "humanistic" model of childbirth care, as Davis-Floyd describes it in her later work. According to Davis-Floyd, the humanistic model developed as a reaction to the medicalisation critique, driven by professionals working within the medical system aiming at reforming it from within – by making the system "relational, partnership-oriented, individually responsive, and compassionate" [74 (p.10)].

In agreement with Wackerhausen's open concept of the "good", Davis-Floyd describes the humanistic model as a model that builds on common ground between two poles. The key characteristics of the humanistic model of birth are an emphasis on the body as an organism (rather than a machine), the mind-body connection, shared information, decision-making and responsibility and a balance between the needs of the institution and the individual. Wackerhausen's perspective differs from the humanistic model of care most importantly by placing the ultimate authority and autonomy more clearly with the labouring woman.

The debate over feminist perspectives - or the issue of essentialism
From within the field of feminism itself, the concept of the two models of care has been criticised for championing a view of women as simple, instinctive, close to nature while men are seen as rational and scientific-minded [87], views that reflect an essentialist approach to birth and gender that perpetuates the repression of women [77].

By deconstructing gender categories, post-structuralist feminism aimed to "destabilise gender as a hierarchical binary opposition and find the ground in between so that men can no longer be associated with all that is valued and women with all that is de-valued in society" [62 (p.39)].

Some writers applying this perspective, such as Annandale and Clark, have questioned the "relational" feministic discourse and its inherent essentialism, suggesting that the "potential for women to conceive and bear new life has played an important role in maintaining the binary division of gender, since it homogenises all women as mothers, and locks women into reproduction as central to everyone's lives, echoing medicine's determinacy" [62 (p.29)]. This, they argue, led to universalism. By defining all women as mothers they were denied individuality. Instead all women become the same – mothers – which immediately characterises them as "different" from men [62 (p.28)].

Developing their argument on the basis of "individualist" feminist argumentation, Annandale and Clark argued that medicine may help women to overcome the gendered notion of their bodies [62]. Disregarding the fact, that many women have been found to derive a strong sense of meaning from mothering [88, 89], they tried to re-set the debate by drawing attention to studies concluding that some women are quite positive about their "medicalised" birth experiences, and even may find them empowering or liberating [70, 90]. Whether women's satisfaction with or even strive for technological birth is proof of the overlooked benefits of the model – or rather should be seen as proof of (from a modernist perspective) social or (from a post-structualist perspective) cultural levels of iatrogenics or the hegemony of a medical discourse is still debated [91-93].

Lupton, from a more balanced perspective, has argued that the medicalisation critique offers little recognition of the ways in which medicine (or obstetric care) may contribute to good health, the relief of pain and the recovery from illness, or to women's emancipation by offering control over fertility [87]. Within a holistic paradigm of childbirth, women's desire and fundamental need for medical safety and effective pain relief may thus be overlooked.

Post-structuralist feminist writers have raised an important awareness of the diversity of women's birth experiences but have, in general, encountered serious problems in explaining what their perspective has to offer. While defendants of the medicalisation thesis fear that this could offer a "rehabilitation of obstetrics" [93 (p.352)], more attention should perhaps be devoted to another expressed concern: that the post-structuralist rejection of the existence of objective `"reality", "truth" and the possibility of finding a guiding logic for social change, will dislodge our ability to judge evidence for treatments/care and decide what should be done to improve the quality of services and the health and autonomy of those giving birth [93].

The issue of care provider
The holistic model of birth presupposed that the care provider would not impose their medical perceptions of birth (e.g. standards for the progress of labour) or interventions on the birthing women but instead introduce "experimental and emotional knowledge" [70] and leave birth "un-interfered-with", i.e. "natural". For such a task, the best suited would be the non-hospital-based midwife or, perhaps even more so, the lay midwife, whose skill was based on experience and intuition and not on medical training.

As childbirth was understood within a "relational", feministic discourse, it was seen as an event that signified women's difference from men. The female gender of the midwife was her entry pass to this "women's world". In contrast to the obstetrician, who was associated with technical control, male dominance and painful procedures, the midwife represented traditional female attributes such as patience, care, empathy and warmth. Her personal, embodied knowledge of childbirth and the female body and her role as a "bearer" of female culture contributed to her status in the birth situation [60, 94].

Within this perceived female universe, the "thesis" or "myth" of a universal sisterhood among women as women and women as midwives developed. Kitzinger's explanation of the special relationship between women and midwives and the role of midwifery in women's liberation may help us understand how midwifery came to be so highly valorised in the described holistic alternative to obstetric care:

..."midwifery has a vital part to play in the woman's movement and is at the very centre of the great creative upheaval which is taking place as we reclaim our bodies and come to learn about, understand and glory in them. This new midwifery gives vivid expression to the way in which women are discovering strength and sisterhood as we turn to help and support one another during the intense, exhilaration and powerful experience of childbirth [69] (p.18).

It seems that the proponents of the holistic model of care had overlooked that obstetricians, as well as certified and lay midwives used a wide range of methods for intervention in childbirth[††], although low-technological techniques might be less prevalent in obstetrics [78, 95].

The debate over the holistic birth model's inherent essentialism also informed discussions of care provision, which lead to a rejection of the sisterhood-thesis and the favouritism of midwifery over obstetrics. Annandale and Clark even took their post-structuralist critique as far as to claim that the alternative to obstetrics (midwifery) was "extremely poorly drawn" and that its precepts carried "little meaning" [62] (p.30). It was also argued that the holistic model served to reinforce social inequity as many women would not be in a position to avail themselves of "alternative" care models, should they want to.

From a Danish point of view, the debate appeared to be informed almost exclusively by American perspectives. Many issues seemed less relevant in a society with public funding of all maternity care services and midwifery care as the norm. Formal education of midwives in a direct-entry programme has taken place since 1787, and midwives, rather than obstetricians, provide frontline care for women in hospitals as well as in the home. It appears paradoxical that a debate among sociologists and other social scientists has given such scarce attention to the influence of the structural and organisational dimensions of maternity care and health care systems on the care provided and its outcomes for women and infants.

The issue of universalism and insensitivity to social difference
Another important but equally overlooked issue in the childbirth debates was women's social position. In her exploration of the plurality of women's birth experiences and choices, Davis-Floyd turned her attention towards those with a choice: white, middle-class women with private care. In doing so, she became blind to social difference; appearing to assume that she could extract universal elements of women's experiences and that her findings could be extrapolated to underprivileged

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†† E.g. castor oil induction of labour, breathing technique, massage, or use of water for pain relief, and nipple stimulation or kissing to argument labour, but also obstetric procedures such as manipulation of the fetal position, vaginal examination and amniotomy

women who had to accept to be ".. assigned for birth to whatever residents happen to be on duty, and who were usually given little or no choice as to how their births are managed" [70] (p.4).

In emphasising control and informed consumer choice, Davis-Floyd tacitly assumed what Martin has categorised as "a middle-class rationalist economic ideology" [96] (p.308). In the perspective of a private American health care system, Martin argued that the holistic childbirth model turned the woman into a buyer with a relatively free choice between options and a sense of control, as she can "take it or leave it" [96] (p.308). She contended that this model appealed to middle class women while many working class women would reject or resist it.

Following their "individualist" line of argument, Annandale and Clark rejected the idea that any unitary position, or common ground, could be uncovered in women's experiences and their perspectives on birth. They found that this excluded the possibility of proposing a particular model of birth as preferable. Eventually, they exposed the holistic model of birth as elitist and universalistic, branding it as a model that was insensitive to social difference, favoured middle-class women and glossed over the differences among women, created by e.g. age, class or race [62].

On the background sketchily drawn above, the conception evolved that the holistic model of birth aimed at white, middle-class women and that it was of little interest to working-class women (or other less privileged groups of women). In a widely cited 1983 study, Nelson went as far as maintaining that middle- and working-class women had different "birthing styles" [90] (p.296). While structural and organisational factors continued to receive little attendance, a rather stereotyped picture of social difference in childbirth experiences and perceptions emerged, a picture that seemed as universalised and restricting as the one from which it had developed. This picture was challenged by Green et al., who could establish little social difference in women's birth expectations and the emphasis they placed on control. On the other hand, they found that the women with the lowest childbirth expectations were likely to have the worse experiences [7, 17].

Towards an understanding of quality in maternity care services

In the debates over childbirth that have taken place since the 1960-70s, the focus has mostly been on questions such as the use of technology, type of provider, place of birth and the more general role of childbirth and motherhood in women's lives. The impact of women's social background has attracted comparatively little attention, and this aspect of the discussion has generally painted a rather stereotyped picture of the protagonists on both sides: Images of advantaged women who want either an exhilarating home birth or a planned caesarean section have been juxtaposed to images of disadvantaged women eager to hand over control of their birth to professionals and to have a fast and pain-free labour.

Two simple but important insights can be gleaned from the debates: the enormous *variation* that characterise the spectrum of women's birth experiences should be recognised [62], and what is more important than adherence to any birth model is that *a woman's individual needs are addressed* [97] – however she may experience or define them. Other factors that have yet to receive careful consideration are the structural and organisational aspects of care; how the system within which women receive their care and the way care is organised impacts on clinical as well as psycho-social birth outcomes.

In working towards a new "humanised" birth model, guided by the long-term goals and values of birthing women and professional care providers' knowledge of means and consequence, three changes are called for: a redefinition of the relationship between professionals and birthing women, a hitherto unseen flexibility on the part of the hospital as an institution and organisation and an a renewed perspective on the quality of care [70, 74].

These challenges have created an interest in the concept of patient-centred care, a concept that reaches far beyond childbirth to engage with the broader field of medicine. Patient-centred care is informed by insights from medical anthropology and emphasises a strong consideration of the patient's subjective experience of illness. Furthermore, it involves a perspective in which the patient and the health professionals are seen as collaborators with a shared responsibility for defining goals and making decisions about treatment [98].

While focus was initially directed at the patient-professional relationship, the work of the Picker-Commonwealth Program for Patient-Centered Care contributed to a turn towards the organisational and structural level, as it became clear that hospitals' traditional organisation and procedures had a negative influence on patient care – and that an integration of patients' perspectives in policies and practices would improve care and accommodate patients' needs more effectively [98].

In Gerteis et al.'s influential definition, patient-centred care must be respectful of patient's values, preferences and expressed needs, offering emotional support and providing physical comfort to patients. Further characteristics are a strong focus on information, communication and education of patients and the priority given to ensure continuity, coordination and integration of care [98].

In their comprehensive account of strategies for achieving a substantial improvement in the quality of American health care, published in 2000, the Committee on Quality of Health Care in America included patient-centredness as one of six key dimension of quality in health care services [99]. Today, system responsiveness and patient-centredness is considered an important quality indicator of national health services in large parts of the world [99, 100]. The committee's definition of quality of care integrates three major, global health service concerns: evidence-based medicine, patient-centredness and social equity in health and health care. The perspectives that guided the report were subsequently adopted by the WHO and were integrated, sometimes in a modified version, in quality definitions in many WHO member states, including Denmark [101, 102]. The original definition is used to guide the present study of maternity care services, although some elements are emphasised more than others.

The committee's six quality aims are quoted below. They called for health care to be [99 (p. 6)]:
- "Safe – avoiding injuries to patients from the care that is intended to help them.
- Effective – providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.
- Patient-centered – providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.
- Timely – reducing waits and sometimes harmful delays for both those who receive and those who give care.
- Efficient – avoiding waste, including waste of equipment, supplies, ideas, and energy.
- Equitable – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status".

In the field of maternity care services, the "humanistic" paradigm of childbirth, described by Davis-Floyd in 2001, was supported by the general trend towards patient-centred care and user involvement in health care provision. Since the mid-1980s, the concept of patient-centredness has exerted a strong influence on the philosophies behind and the delivery of maternity care services [103-105].

DEVELOPMENTS IN CHILDBIRTH POLICIES AND THE ORGANISATION OF MATERNITY CARE SERVICES IN DENMARK

In Denmark, along with a number of other countries, the late 1960s brought an end to the era when out-of-hospital birth was a common choice for women. As early as in the mid-1950s, full hospitalisation of birth had been advocated by Danish obstetricians. Birth in the home, or in one of the many private clinics, run and owned by individual midwives, was discouraged as it was no longer considered safe [106, 107]. Consequently, a comprehensive reform of maternity care services, including the organisation of midwifery, was carried out in the early 1970s [108].

With the intention of furthering hospital birth on the grounds of safety, the new policy phased out the option of midwifery clinic birth and gave Danish women free choice between *home* and *hospital birth* while retaining the right to receive midwifery services free of charge during pregnancy, birth and the postpartum period[‡ 106]. Until the time of the reform, the majority of midwives had been private practitioners with individual caseloads of births (their services fully funded by the public). It now became the responsibility of the regional councils to establish a net of midwifery teams with six or seven midwives providing a full range of antenatal, intrapartum (home- or hospital-based, depending on the woman's choice) and postpartum services for their catchment area. This organisation was chosen to ensure that the Danish tradition for a high level of continuity of care and familiarity with the midwife at birth was continued; yet the level of continuity of care saw a rapid decline. In less than a decade the small midwifery teams were transformed into large midwifery centres where women were no longer attended at birth by a midwife that they were familiar with.

At the institutional level, the new legislation meant a wide-scale growth in the number of maternity beds in hospital order to:

> "(…) foster a development, which may be feasible in the long-term perspective and which in the opinion of the obstetric expertise is desirable, towards a scheme that would allow for every birth to take place in a specialised department." [106 (p.16)§§]

The maternity care reform placed the responsibility for midwifery and the provision of services with the regional councils, which were to base the organisation of services on recommendations issued by the National Board of Health. The recommendations reflected the international childbirth debate of which a summary was given in the previous chapter and signalled a shift toward a *slightly* more

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‡ The legislation also specified women's right to have three antenatal and two postnatal consultations with their general practitioner and post natal home visits from a health visitor.
§§ Author's translation.

holistic paradigm of birth [31]. An increasing emphasis on patient-centred care was also evident. As later policy development has largely been absent, the recommendation has served as policy documents [31] although their perspective is clearly medical and none of them has been subjected to national debate at a parliamentary level or received or government approval.

Although births in Denmark were now largely hospitalised, many low-risk births took place in small maternity units that lay within the bounds of a surgical department at a community hospital. Moreover, home birth remained an alternative possibility. In an international perspective, the specialisation and centralisation of maternity care services occurred relatively late, and was seen by Danish obstetrician as an important cause of the higher rate of perinatal mortality in Denmark when compared to e.g. Sweden [109] although this connection could not be substantiated by any strong evidence [110, 111]. Further specialisation of services was thus advocated by the Danish College of Obstetrician [112] and supported by the National Board of Health. By 1990 the centralisation process escalated and the number of maternity units decreased from 67 units in 1992 to 43 units in 2003. At present, (2011) the number is 26. Over the period 1992-2011, homebirths have comprised a stable proportion of 1 % of all births.

In several cases the closure of maternity units was accompanied by strong protests from local citizens, user groups and midwives, occasionally supported by general practitioners and surgeons involved in community maternity care services and by local politicians. By this time (the 1990s) the focus of Danish debates had turned away from the theme of home birth to the decreasing accessibility of services and lack of responsiveness and family-oriented care in the obstetric units. The English *Changing Childbirth* report [103], often described as a watershed policy document came to play an instrumental role [113]. The report and the ensuing British debate effected a turn in the attention of local government politicians, health professionals and users, a development that brought into focus a new, in Denmark hitherto unknown, model of care. This was the freestanding midwifery unit.

Midwifery units (MUs) have developed from the "alternative" birth centres of the 1970s and 1980s into today's often publicly financed units forming part of established birth services [104, 114]. The National Perinatal Epidemiology Unit in England defines a midwifery unit as:

> "a clinical location, offering care to women with straightforward pregnancies during labour and birth in which midwives take primary professional responsibility for care." [115 (p12)]

Freestanding midwifery units (FMUs) may be found in a community hospital setting or with no attachment to a hospital. Medical services such as obstetric, neonatal and anaesthetic services are not immediately available during the woman's labour or for birth diagnostics and treatment, but may

be accessed on a separate site should they be needed. Where a birth unit is located on the same site as an obstetric unit it is defined as an "alongside" midwifery unit (AMU); transfer to the OU usually takes place by trolley, bed or wheelchair [115].

FMU care is based on principles of thorough clinical assessment and referral of patients. When complications occur or there are indications of complications, women and/or newborns must be transferred to an obstetric unit (OU), most often by ambulance. An OU is a specialist maternity unit, where obstetricians take primary responsibility for high risk women and women with complications, midwives do however offer care to all women in an OU, regardless of their risk status and take primary responsibility for low risk women[115]. In case of FMU emergency, assistance from the local ambulance service is summoned; however, some level of medical emergency treatment, for example in case of need for advanced neonatal resuscitation or maternal collapse, may be available if the centre is situated nearby or within a hospital. Midwives who work at FMUs are required to possess updated resuscitation skills and in some settings they have extended authorisation to perform interventions such as ventouse delivery.

FMUs provide decentralised care at low technological level and aim to optimise their services by improving continuity and labour support, giving priority to individual preferences and needs, supporting informed choices, promoting empowerment and the development of parenthood. As a result the physical environment of FMUs tends to be family-friendly or even home-like. When assessed in relation to Davis-Floyd's definitions of childbirth models, FMUs of this kind represent a *humanistic* model of care for childbearing women [74]. They are most prevalent in countries with a public health care system such as the UK, Germany, New Zealand, Norway and Denmark, where they form an established element of mainstream maternity care services [116, 117].

The first freestanding midwifery unit in Denmark was opened in 1994 on the site of what was formerly the small maternity unit of a community hospital in north-western Jutland. The opening followed more than a year's heated debate in the area about safety but also about the allocation of health care resources and women's access to maternity care services. The opening was carefully prepared through studies of English and Norwegian FMUs. After four years, the new service was carefully evaluated and found to deliver good quality care compared to the other maternity units in the council [113]. As a result of cost-cutting measures the unit was closed in 2001.

The same year local health authorities in the adjoining North Denmark Region took an even more drastic step in deciding to turn two of its four maternity units into freestanding midwifery units. The first FMU opened in 2001, the second in 2004. Both were hosted by community hospitals with small

emergency wards offering acute, anaesthetic services to the FMUs. The opening of the two FMUs was part of an overall reform of the Region's maternity care services, which aimed to ensure all low-risk women easy access to high-quality maternity care services closer to home. On several occasions prominent politicians made it clear that they did not consider childbirth to be an illness and policy documents reveal a perspective emphasising the quality of care, patient-centredness and a turn of focus towards what may be called active consumerism and support of women's informed choice [118]. In general, policies appeared to be strongly inspired by the ideas informing *Changing Childbirth*.

The opening of the FMUs prompted a debate over safety [119, 120] that mirrored similar debates in Norway and the UK, the main point of criticism being the lack of immediate access to medical emergency treatment and the transfer time from birth centre to the nearest OU being 30-40 minutes at minimum as this may potentially postpone necessary medical treatment such as the performance of a caesarean section.

Evidence on safety and quality of FMU care

As discussed in Paper I, the evidence for the safety and quality of FMU care is scarce.

A Cochrane review comparing AMUs and OUs found that there were no significant differences in perinatal mortality or perinatal and maternal morbidity but that AMU care led to significantly fewer medical interventions and better maternal satisfaction among women intending birth there when compared to women intending birth in an OU [121]. But as AMUs have immediate access to specialised medical treatment, the conclusions cannot be extended to free-standing birth centres.

A systematic search of the literature identified no reports of randomised controlled trials (RTC) and only two peer-reviewed publications of controlled, prospective cohort studies of FMUs, both of which were conducted in the USA. One had studied what was until recently the largest sample used for a controlled study of FMU care, including 1808 socially disadvantaged women receiving FMU care from midwives and 1149 controls receiving consultant-led OU care [122]. No difference in perinatal and maternal morbidity was found between the two study groups, but the use of interventions was significantly lower in the FMUs [122]. The other study found similar results among its somewhat restricted number of women including 69 FMU and 77 OU women [123]. The reporting of this study was moreover of poor quality.

At a lower level of evidence a wide range of retrospective, population-based and/or uncontrolled studies from a variety of countries support the conclusion that FMU care is safe, associated with low

maternal and perinatal morbidity and leads to fewer birth interventions [124-132]. However, the evidence may be said to be somewhat conflicting, as one study found an increased "need for ventilation of infants" [126] in FMU settings compared to OU settings while another saw a decrease in this intervention [132]. A third study reported a significantly lower Apgar score at 1 minute but not at 5 minutes among FMU infants compared to OU infants [130].

As discussed above FMU care is pursued primarily by a comparatively homogenous group of socially advantaged women, with the effect that little attention has been devoted to the influence of social position on birth outcomes. The so far largest FMU study by Jackson et al. was however carried out in a population of low-income women [122]. A German register study found no difference in the outcome of FMU care compared to OU care when social position was taken into account [133].

For first-time mothers the suitability of AMU care has been questioned by Gottvall et al., who found increased perinatal mortality in births among Swedish women intending AMU birth compared to women intending OU birth [134]. These findings, however, are disputed as some of the perinatal deaths in the AMU group occurred among women who had not been categorised as at low risk, or were later judged by independent assessors to be due to suboptimal care after transfer to an OU [135]. For FMU care in general, no effect of parity on birth outcomes has been found although it should be added that this aspect is rarely reported on.

Many studies suffer from a limitation of their validity and generalisability due to factors such as small sample size, inclusion of high-risk women, limited control of bias and confounding, loss of participants to follow-up, and inadequate description of inclusion and exclusion criteria, medical assistance (if any), and transfer criteria. Several studies were uncontrolled or their data were not analysed by actual birthplace (intention-to-treat principle). Furthermore, there are good reasons for observing the available evidence with considerable caution if generalising to public health care settings. For example, the variation is great when considering the standard of the care provided, the training of midwives, cooperation between FMUs and OUs, particularly where American studies are concerned. As also was concluded in two recent English and Norwegian national reviews of FMU care, the level of evidence is weak and the need for further research considerable.

Evidence on psycho-social outcomes of FMU care

Women's psycho-social outcome of FMU care have consistently been reported as very positive, leading to control and satisfaction with care [128, 131, 136, 137]. In two of these studies, concern was however expressed for women's birth experiences when transferred from FMU to OU care in that they could report negative feelings stemming from fear, lack of continuity and/or disappointment [136, 137].

The literature search identified two controlled study of women's perception of care in FMUs versus OUs, both performed as part of cost-effectiveness studies [138, 139]. Evaluating the introduction of midwifery care in Canada, the researchers found that women in the FMU group felt more in control of their delivery, more self-confident in caring for the baby and rated the overall quality of their care higher than was the case for women in the OU group. The generalisability of the Canadian study is however limited as it was conducted under unusual conditions (the introduction of midwifery in Canada). FMU care was therefore far from mainstream and confounding related to women's self-selection to midwifery care can therefore not be excluded.

A Cochrane review has documented that AMU care compared to OU care leads to improved psycho-social outcomes for women in the form of a more positive birth experience, greater performance feel and increased experience of control, participation in decisions and support during labour. Factors which, along with the experience of partner support, have a significant impact on women's subsequent psychological well-being and their experience of empowerment. Also patient satisfaction levels have been found to be significantly higher among women receiving AMU care [121]. As the philosophy of care entertained in AMUs are generally shared by FMUs, the results may to some extent be generalised to FMU care although it should be noted that quicker transfers from AMUs to OUs may imply that reservations should be made in relation to transferred FMU women.

As has already been discussed, there are claims that socially disadvantaged women give comparatively lower priority to choice and personal control in childbirth and that "alternative" models of maternity care may be of little relevance or interest to this group of women [19, 62, 90]. Another interpretation may be that this view represents a stereotyping of disadvantaged women's preferences and needs in relations to childbirth [17]. Professionals' have been found to influence and restrict women's access to care elements such as water birth and the use of upright position, sometimes simply by not offering it [140] and disadvantaged women may not themselves be aware of all care options, or lack the personal confidence or strength [141] that in some settings is required to get access to e.g. the birthing pool or other less traditional procedures [142]. As suggested by other

authors, socially disadvantaged women may in comparison to more advantaged women face the risk of receiving a lower quality of care [24], including lower levels of support and continuity [26].

Furthermore, the conditions that cause their social disadvantage such as low education and income, dyslexia, or lack of a supportive social network may restrict women's access to and understanding of information about childbirth and different models of care [97, 141].

The effect of social position is often an unexplored aspect of studies of women's childbearing experiences; possibly as a result of the tendency to universalism and elitism that Annandale and Clark claim to see as an inherent trait of debates over childbirth[62]. In the studies that have investigated this issue, results are mixed. While some studies find no impact of social position[143], others, among them a recent Swedish survey [18, 19], find that disadvantaged women's birth experiences are more negative compared to advantaged women's [144].

Only a single study has been found to explore disadvantaged women's perception of FMU; a qualitative study that challenged the perception that this group of women was little occupied with psycho-social birth aspects and willing to accept interventions. This study concluded that the women from many different backgrounds receiving care from an American inner-city FMU, had shared needs and desires to for example establish a supportive interpersonal relationship with their care provider and "thrived in the humanistic environment that treated them with respect and dignity" [145 (p.124)].

The organisation of birth care in the North Denmark Region at time of the initiation of this study offered a unique opportunity to study the impact of birthplace in an environment where key factors such as the fundamental access to maternity care services was secured through public funding and a choice between OU, FMU and home birth was offered, while the variable introduced by provider was stable in that all frontline care was given by midwives. Together these factors afforded a unique opportunity to isolate the effect of place.

AIM

The present work aims to provide new evidence to inform the debate concerning the influence of place of birth by comparing safety and quality of care in two different settings for birth: free-standing midwifery units and obstetric units.

The objective of the study is:

- To investigate statistical associations between intended place of birth at the start of care in labour and perinatal and maternal morbidity, birth complication, birth intervention, and the relief of pain for low-risk women and their newborns.

- To describe transfer rates and causes of transfer from FMUs to OUs.

- To investigate whether the effect of birthplace on perinatal and maternal morbidity, birth complication, birth intervention, and the relief of pain differs by women's level of social disadvantage.

- To investigate statistical associations between place of birth at the start of care in labour and women's experience of birth, satisfaction with care and perception of specific patient-centred elements of care.

- To explore the influence of specific medical and socio-demographic factors on women's experience of birth in FMUs versus OUs.

HYPOTHESES

On the basis of the study of the referenced literature, it was hypothesised, that FMU care, with its emphasis on support of the physiological birth process, psycho-social well-being, individualised care and shared decision-making compared to OU care would be associated with:

- A higher rate of spontaneous, vaginal birth, intact perineum, and increased use of non-pharmacological pain relief
- Fewer interventions (including caesarean section) and less use of pharmacological pain relief but increased use of water for pain relief and upright positions for birth

No differences in perinatal or maternal morbidity between the FMU and OU group were hypothesised.
(Reported in Paper I on clinical outcomes)

For disadvantaged women, it was hypothesised that FMU care compared to OU care would be associated with:

- Increased likelihood of spontaneous, uncomplicated birth, water birth and use of water tub and upright position for birth when compared to OU care.

No overall relationship between social disadvantage and perinatal or maternal morbidity between FMU women and OU women were predicted.
(Reported in Paper II on clinical outcomes and social disadvantage)

It was hypothesised that FMU care compared to OU care would be associated with:

- Higher ratings of women's overall birth experience, care satisfaction, and their perception of key patient-centred care elements such as support, participation in decision-making, the feeling of being listened to and information

Furthermore, it was hypothesised that:
- the association between birthplace and birth experience would be influenced by a differential use of interventions between groups
- the woman's education and employment level would correlate positively with her birth experience and perception of care elements

(Reported in Paper III on women's birth perceptions and the effect of social position)

METHODS

The overall study design

The study was designed as a cohort study with a matched control group. A questionnaire survey was undertaken as part of the research process.

An evaluation of the effectiveness of a service requires use of systematically acquired evidence to judge whether one model produces a better outcome than an alternative does. The randomised controlled trial (RCT) ranks highest among study designs in the research of clinical outcomes because randomisation and blinding reduce the risk of misinterpretation of associations between interventions and effects due to bias and confounding [146]. In the present research, the possibility of undertaking an RCT was excluded for two main reasons. First of all, it is documented that women have strong preferences in their choice of place of birth [147, 148] and it seemed highly unlikely that women would give up their free choice of place of birth. Secondly, only a small number of women (on average 300 a year) gave birth at one of the two Danish FMUs, which were both situated in middle-size towns in rural areas. Serious barriers for recruitment of the necessary number of participants for an RCT would therefore have to be expected. The limited possibilities for undertaking a RCT in out-of-hospital birth settings have been an acknowledged concern in maternity care research for decades [149]. A cohort study was therefore judged to be the most robust study design achievable.

The decision to undertake a questionnaire survey was based on an assessment of the available knowledge on women's birth experiences and perceptions of care in FMUs. On the overall level, the debate over childbirth and the drive for more patient-centred services has generated an interest in women's childbearing experiences, which is now a fairly well researched field. Considerable insights has been produced by use of both qualitative and quantitative methods and although our understanding of what matters to women in childbirth can certainly still be improved, it has, as shown above, proved possible to uncover some "common ground" in women's experiences. The literature study showed that qualitative, in-depth studies of organisational, structural and interrelational aspects of FMU care were already available, including one on Danish women's birth experiences and birth narratives [150]. As only one controlled, quantitative comparison of women's experience by place of birth was identified, it was judged that new insights generated by use of a questionnaire survey in relation to the cohort study would provide an important contribution to the existing knowledge.

Participants

The overall study population consisted of 1678 women: 839 low-risk women receiving FMU care and a matched control group of 839 low-risk women receiving standard OU care in the Region of North Denmark during a three-and-a-half year study period between 2004 and 2008.
(Reported in Paper I and Paper II)

All women who were included in the FMU group between 1 January 2006 and 30 October 2006 (218 women) and their 218 matched controls were invited to participate in a questionnaire survey.
(Reported in Paper III)

Low-risk criteria

According to the multidisciplinary, regional guidelines for referral and transfer, women were considered as at low-risk of obstetric risk if they had had an uncomplicated pregnancy, presented in spontaneous labour between 41+6 weeks and had no conditions increasing obstetric risk. The low risk criteria defined here were similar to the criteria later outlined in the English National Institute for Health and Clinical Excellence (NICE) Intrapartum Guidelines with the exception that healthy multiparous women were considered as at low risk regardless of their age and BMI provided their previous birth had been uncomplicated.

Inclusion

The study included all women admitted in labour to the FMUs on the basis of the regional multidisciplinary admission criteria during the study period, and their individually matched controls, who were identified among low-risk women intending birth in the nearest OU.

The women in both groups were thus rigorously judged to be at low risk and to fulfil criteria for FMU birth. All participants were included at the start of care in labour.

Women who were admitted in labour to the birth centres for emergency treatment but did not satisfy the regional criteria for birth centre care were excluded from the study.

Study setting

Four maternity units in the Region of North Denmark participated in the study, two freestanding midwifery units and two obstetric units.

Characteristics of the participating freestanding midwifery units

As mentioned both FMUs were located in connection with community hospitals in middle-size towns in predominantly rural areas; in Frederikshavn FMU the approximate annual number of births was 130, in Hobro FMU 170. In contrary to some FMUs, the community hospitals in this case provided 24-hour onsite assistance from an anaesthesiologist or resuscitation-capable specialist nurse in case of emergencies such as maternal collapse, severe postpartum bleeding or need for advanced neonatal resuscitation. There was no obstetric service on site and women and/or infants were transferred in case of complications or need for pharmacological pain relief during labour. The minimum transfer time to the nearest in-region obstetric units were 25 (Frederikshavn - Hjørring) and 35 minutes (Hobro - Aalborg). From Hobro FMU, women could also be transferred to two out-of-region obstetric units, located in the nearby towns of Viborg and Randers, if requested. This option was used by approximately 5 % of the women transferred from the Hobro FMU.

The two FMUs provided antepartum care for all women in the area (the region's "standard packet" of care), intrapartum and postpartum care for low-risk women who opted for this care model. Postpartum care was additionally offered to women who had given birth elsewhere but wished to be transferred to one of the units for postpartum care.

The midwives did antenatal care one day a week during the daytime; their remaining hours were used in 24-hour duties during which they would provide intrapartum care and out-of-hours postpartum care for women in the FMU. The midwives would accompany women and infants who were transferred from their FMU to the OU and continue their work there if their presence was not required at the FMU. Workloads in the FMUs permitting, FMU midwives could be called upon to assist at the nearest OU. This arrangement ensured the FMU midwives a workload of 40 (- 70) births a year.

At the opening of the FMUs in 2001 and 2004, midwives were recruited from among the employees of the maternity units of the community hospitals. They were required to have at least two years' experience and training in obstetric emergencies, including ventouse delivery.

In agreement with the reigning humanistic paradigm of birth, many MUs offer facilities that were aesthetic, family-friendly or even homely. As both FMUs had taken over the premises of former maternity units, the birthing rooms were equipped in a traditional fashion (e.g. with an obstetric bed as their central feature) compared to most midwifery units of the day. The FMUs did however actively encouraged women to be mobile and make best use of the units' facilities that included a living-room, a resting room, bathrooms, a hallway and a kitchen. Light foods and drinks were available and women were encouraged to bring additional foods and drinks of their own choice for themselves and their birth companions. Often women did not enter the birthing room/traditional birthing area of this room until late in the second stage of labour. Continuous support in labour and one-to-one care was almost always available; if not actually in the same room as the woman or couple, the midwife on duty would normally be visible in the FMU. The condition of the fetus was monitored by auscultation; on admission a cardio-tocolytic (CTG) test was recommended to all women. In Paper I, additional information on the FMU setting was provided in the online-only Table A, *Characteristics of freestanding midwifery units.*

Characteristics of the participating obstetric units

Aalborg University Hospital, located in the regional capital, is a highly specialised hospital offering a specialist obstetric unit 24-hour on-site service with approximately 3500 births a year. The unit was staffed by consultant obstetricians, paediatricians and anaesthesiologists.

Vendsyssel Hospital, located in the main town of the municipality of Hjørring, has ten clinical specialities including a generalised paediatric ward and an obstetric unit that provides care for low-risk and most high-risk women (approximately 1400 births a year). The out-of-region OUs in Viborg and Randers had similar characteristics.

Mothers and infants with severe illness were transferred to Aalborg University Hospital. The treatment of rare diseases, including some forms of congenital malformations, is centralised to one of four, highly specialised hospitals in Denmark (involving transfer distances of 100, 250 or 400 km).

In Danish OUs, midwives are responsible for care to all women, regardless of the woman's obstetric risk status, and midwives take primary responsibility for low-risk births. Furthermore, the OU midwives in this study provided antenatal care (the Region of North Denmark's "standard packet" of care) for all women in the area. Most midwives worked a mixture of eight-hour duties and 24-hour on-call duties. Their level of experience varied, but support from consultant midwives or more senior colleagues was always available.

The birthing rooms at both OUs were conventionally equipped with a labour bed as the central feature and some of the rooms where quite small. Electronic fetal monitoring was not routinely used in low-risk births. As in the FMUs, birthing pools were used both for pain relief and water birth. U and FMU midwives were employed by the same regional authority and had attended the same courses, e.g. in acupuncture for obstetric pain relief, which was widely used in both settings. Epidural analgesia was available 24 hours a day. Fetal well-being was monitored by auscultation unless complications arose or epidural analgesia was administered. Admission CTG was not used in the OUs.

Especially the obstetric unit at Aalborg University hospital was often busy, and in both OUs one-to-one care and continuous support in labour was typically not available until late in the first stage of labour. Women had access to a living-room but would spend most of their time in the birthing rooms during labour. In Paper I, additional information on the OU setting was provided in the online-only Table A, Characteristics of the OUs

Figure 1 Unit locations

Figure 1 shows the location of the two FMUs and two OU involved in the study, and the two neighbouring units.
Danish health care is administered by five regional authorities. For economical and organisational reasons, referrals between hospitals most often occur between hospitals in the same region. As seen on the map, the distance between Hobro FMU and the out-of-region OUs at Viborg and Randers Hospitals were shorter than the distance between Hobro FMU and Aalborg OU. Five percent of the women transferred out of Hobro FMU chose referral the OUs in Viborg and Randers because these units were closer to where the women lived.

Study procedures

Data collection

One or two midwives from each of the participating units were engaged as project staff to conduct the data collection. Project staff members were responsible only for data collection from their own units. On the basis of written instructions, data gleaned from patient records as soon as possible after birth were entered into study-specific data forms along with selected data from the region's patient administration system on e.g. readmissions. After checking and quality testing, data were entered into the study's dedicated and encrypted internet database.

During the study period, the author undertook the role of project manager, coordinating data collection and training and supervision of project staff. The work included regular checks of the project database for missing or inconsistent data, posting of data queries, monitoring of data completeness and survey response rates from each participating unit, and close communication with project staff throughout the study period by email, phone and regular visits to the units.

The data on socio-demographic, medical and clinical outcomes for all 1678 participating women were collected in connection with the births while data on neonatal and maternal readmissions/outpatient visits were collected 28 days after birth. Data on women and infants who had been transferred during labour or the postnatal period were collected from the obstetric units (including the few cases involving out-region hospital units). Areas of data collection are presented in Table 1 below.

Table 1 Socio-demographic and clinical fields of inquiry

Medical and obstetrical background data	Information on medical and/or psychiatric conditions, earlier pregnancies and births, if any, and current pregnancy *to assess the woman's risk status and eligibility for inclusion in the study*
Socio-demographic characteristics	Age, native language/ethnicity, education, occupation, cohabitant status
This pregnancy	Parity, BMI before pregnancy, smoking status, term, gestational age at admission in labour, chosen birth setting
The course of birth	Cervical dilatation on admission and at amniotomy (if performed) Duration and course of birth, length of labour admission, length of postnatal stay Number of midwives involved in care Intrapartum and postpartum examinations, diagnostic and procedural codes for diagnoses, interventions, treatments (including pain relief) Colour of amniotic fluid Postpartum blood loss In-hospital referral to paediatric or anaesthesiological unit (if any)

The child	Apgar score, weight, length. Diagnoses and treatments
	Admission to neonatal intensive care unit (NICU), and if relevant, length of stay
Transfers from birth centre	Indication for and duration of transfer (if performed). Care and treatment during transfer. (Dis-)continuity of care in relation to transfer
Re-admissions	Number and duration of readmissions and outpatient visits to hospital for mother and/or child 0-28

Data on psycho-social outcomes

All women admitted to one of the two studied FMUs between 1 January 2006 and 30 October 2006 and their matched controls were invited to participate in a sub study on women's birth experience, care satisfaction and perceptions of patient-centred care elements and postnatal care. Data were collected by use of a postal questionnaire distributed 28 days after birth. Fields of inquiry are presented in a section below discussing the development of the questionnaire tool.

Matching as control for confounding and matching procedure

The internal validity of a study, and thus its level of evidence [146], is a reflection of the extent to which the observed differences in outcomes between two comparison groups can be attributed to the intervention rather than other factors [151, 152]. As participants in a non-randomised study such as the present cannot be allocated by chance to comparison groups, measureable and non-measurable factors related to women's choice of birthplace may result in uneven distributions of factors, potentially influencing the measured outcomes, whether clinical or psycho-social. Control for confounding factors has therefore been a major concern in this study, as discussed in all three papers.

Matching effectively address confounder-related distributional imbalance problems at the design stage of a study rather than at the analysis stage [152]. In this study, matching was judged to offer advantages over multivariate analysis because of the existing non-linearity and inter-correlation between the study variables [153-155]. Furthermore, the difference in the catchment areas of the FMUs and the OUs in terms of urbanisation, employment and education levels were of a magnitude that a disproportionate distribution of confounding factors between the two study groups had to be expected.

Through literature studies and discussion with the staff at the Department of Biostatistics, Aalborg University (no longer existing) and the obstetrical teams at the participating OUs, a number of relevant confounders for which it would be possible to match were identified. Decisions on the

choice of matching categories and sufficient ranges to allow "to even out" differences between a primary participant and a control participant were reached in the same way. The strong associations between social factors and birth outcomes are discussed in all three papers, but especially in Paper II, which examines whether the effect of birthplace on birth outcomes differs by women's level of disadvantage.

Listed in accordance with their priority, matching was performed for the following criteria, displayed in Table 2.

Table 2 Matching characteristics

Low obstetric risk status	All women included were low risk
parity	Primiparity Multiparity
smoking	No smoking 1-9 cigarettes 10 or more cigarettes
Body Mass Index (BMI)*	Range of +/- 5
Age*	Range of +/- 5
First language / ethnicity	Nordic Western European Eastern European Asian Arab or African
Education	No post-secondary training/education qualifying for the labour marked Vocational training 1-2½ years of post-secondary training/education 3-4 years of post-secondary education 5-6 years of post-secondary education or more
Occupation	No paid work Unskilled work Vocational work or equivalent Other, higher level skilled work Academic work/ manager or senior official
Co-habitation status	Living with / married to partner Not living with partner

* Meaning that a BMI or an age of 22 could be matched with scores between 17 and 27.

Other possible confounders for which matching was unobtainable included psycho-social variables, e.g. women's birth expectations, personality traits such as anxiety, and the level of social support from the woman's partner and her network. These aspects are briefly addressed in Paper III.

The matching procedure

For each of the 839 women included in the FMU group, a data form containing anonymised information on matching data was sent to the project staff at the nearest OU. Women in Hobro FMU were thus matched with women in the OU at Aalborg University Hospital; women in Frederikshavn FMU were matched with women in the OU at Vendsyssel Hospital, Hjørring.

The control participants were selected from the region's patient administration system, which contains detailed information on all pregnant women in the region. They were all included at the start of care in labour on criteria that were identical to those used for the FMU women (e.g. low obstetric risk status).

Outcomes measures

Clinical

In the overall cohort study, Apgar scores of <7/5 min and caesarean section were defined as primary outcomes. A range of secondary outcome measures were defined during the planning stage of the study. The secondary clinical outcomes measures are described in Table 3 below.

Table 3 Secondary clinical outcome measures

Perinatal morbidity	Apgar scores of <9/5 min and <7/1 min asphyxia admission to neonatal intensive care unit (NICU) admission to NICU >24 hours and >48 hours
Maternal morbidity	postpartum haemorrhage >500 and >1000 ml first and second degree tears 3rd/4th degree tears puerperal complications maternal readmission 0-28 days postpartum
Birth complication	abnormal fetal heart rate leading to action dystocia intrapartum fetal-pelvic complications shoulder dystocia meconium-stained amniotic fluid birth of the infant in an occipital posterior presentation postpartum haemorrhage >500 and >1000 ml

	$3^{rd}/4^{th}$ degree tears
	postpartum mammary complications
Positive birth outcome	uncomplicated, spontaneous birth with good outcome for mother and infant
	spontaneous vaginal birth
	intact perineum
Birth interventions	amniotomy
	oxytocin augmentation
	treatment for shoulder dystocia
	Instrumental delivery
	episiotomy
	uterotonics
	perineal suturing
	intrauterine palpation
Pain relief	epidural analgesia
	water immersion and water birth
Other	non-recumbent position for birth and upright position for birth
	birth weight
	cervical dilatation on admission in labour
	duration of admission for labour care
	discharge <6 hours after birth

The primary outcome measures, Apgar scores of <7/5 min and caesarean section, and several secondary outcome measures are included in the national obstetric quality indicator index. More measurement details are given in Paper I.

In the elaborate analysis on the impact of social position and parity, the composite outcome "spontaneous, uncomplicated birth, leaving both mother and infant in good condition" was chosen as primary outcome. The formulation of this outcome measure was based on WHO's definition of normal birth [156] and determined the optimum outcome of birth while taking into account all serious perinatal and maternal morbidity. The following criteria applied: birth following spontaneous onset of labour in 37th to 42nd gestational week leading to spontaneous birth of an infant with a minimum Apgar score of 9 or 10 at 5 minutes; no shoulder dystocia, 3rd-4th degree perineal tear or uterine rupture, caesarean section, instrumental delivery, medical augmentation of labour, episiotomy or retained placenta; bleeding not exceeding 500 ml. Women who had epidural analgesia, CTG monitoring and amniotomy were included if they did not experience any of the mentioned complications or interventions.

Psycho-social

Birth experience was defined as the primary outcome in the part of the study concerned with psycho-social outcomes, which is reported in Paper III. The choice of birth experience and secondary outcome measures are discussed later. The psycho-social outcomes measured are shown in Table 4.

Table 4 Psycho-social outcome measures

Intrapartum

Primary outcome	Birth experience
Secondary outcome	Care satisfaction
	Supportiveness of midwife
	Midwife presence when wanted
	Attentiveness towards psychological needs
	Feeling of being listened to
	Information
	Participation in decision-making
	Consideration for birth wishes
	Usefulness of suggestions for pain relief
	Staff support for partner
	Undisturbed contact with infant after birth
	Support from partner
	Loss of internal and external control
Postpartum	Postnatal staff allocating sufficient time
	Opportunity to rest
	Staff care for mother
	Staff support of parents in care for infant
	Staff support for breastfeeding
	Overall perception of postpartum care
After discharge	Perception of care from health visitor 0-28 days
	Full breastfeeding 28 days postpartum

The socio-demographic variables used were age, parity, education, employment, mother's first language and co-habitation. Both socio-demographic and medical data were obtained from medical records and the North Denmark Region's birth database.

Intended place of birth at the start of care in labour was considered the exposure.

Power and sample size calculations and changes to the study protocol

Power calculations and consequently sample size were established on the basis of pre-defined, clinically important differences in all primary study outcomes.

Clinical outcomes

The frequencies used in the calculations originated from the 2004 North Jutland birth database (figures for the Robson groups one and three [157]) and international literature. The present study was originally scheduled to include 1027 primary participants and the same number of control participants.

For the two primary clinical outcomes (Apgar score of <7/5 min and caesarean section) a sample of 1027 women in each group would have provided sufficient power (5 % significance level, 80 % power) to detect a) an increase in Apgar score <7/5 min from an expected 1.07 % in the OUgroup to 2.89 % in the FMU group, and b) a reduction in the rate of caesarean section from 8.80 % in the OU group to 5.50 % in the birth centre group. An Apgar score <7/5 min was the rarest outcome measured in the study, the study power was, however, also checked for several infrequent secondary outcomes such as shoulder dystocia and 3rd-4th degree tears.

Psycho-social outcomes

Also for the survey-part of the study power calculations were performed, based on conservative estimates derived from a regional maternity report [158] and literature studies as no Danish estimates were available. On this basis the survey was initially planned to include 830 women in each group.

For the primary outcome, birth experience, the inclusion of 830 women in each group would provide power (5 % significance level, 80 % power) to detect an increase in the number of women rating their birth experience as positive from the expected 90.0 % in the OU care group to 93.9 % in the FMU group.

For secondary outcomes such as good support by midwife, this sample size would provide power to detect an increase from 92.0% in the OU group to 95.5 % in the FMU group.

Study challenges and changes to the study protocol

The present study was designed in 2004. As the largest number of participants was required for the study on clinical outcomes, this was initiated first, starting 1 January 2005. A study period of approximately 3.5 years would be required for inclusion of the planned sample size and the data collection was thus expected to be completed by the summer of 2008. The same closing time was planned for the sub study initiated 1 January 2006 on women's birth experiences.

In September 2006 the North Denmark Region suddenly and unexpectedly decided to close the two free-standing birth centres in focus of the study. A full explanation of why the political climate in the region took this sudden turn has not been proposed, but it seems to have been related to the persistent and increasingly strong criticism from the National Board of Health expressing concern over the region's introduction of a new and not fully evaluated model of intrapartum care in Denmark (FMUs). The decentralised organisation of maternity care services had long been a point of conflict between the National Board of Health and regional authorities. The closure was not justified on grounds of economy; neither does it seem to have been related to any specific event in the FMUs.

As a consequence of the closures, it was no longer possible to include the planned number of participants. By 30 October 2006, when the FMUs closed, 550 of the planned number of 1027 FMU participants had been included in the study of clinical outcomes, and only 217 of the 830 women projected for the study on birth experiences and perceptions of care.

The potential strength to detect differences between the study groups was consequently reduced. A thorough reconsideration and revision of the study protocol was therefore carried out during the autumn of 2006. This overwhelming challenge to the study as well as strategies to overcome them were thoroughly discussed with the senior statistician at the Department of Biostatistics, Aalborg University, and advice was sought from experienced senior sociologists, epidemiologist and obstetricians in the field of health service research.

To obtain the best achievable power under the circumstances, it was decided to make a backwards extension of the study period by including women who had given birth at the FMUs between 1 March 2004 and 1 January 2005, i.e. before the start of original study period for the study part on clinical outcomes. On the basis of exactly identical criteria, 289 participants, admitted to the FMUs in 2004, were included in the study. A total sample of 839 women in each group could thus be obtained for the sub study concerning clinical outcomes. The 289 FMU participants from 2004 were prospectively matched with OU participants on the basis of the usual procedures.

For the sub study of women's birth experiences, there was no possibility of including patients prior to the start of data collection (1 January 2006), as the protocol required participants to receive the study questionnaire 28 days after birth.

Table 5 illustrate consequences of the reduced sample sizes for power calculations. Examples are given of selected endpoints and percentage differences between the two groups, and of the projected sample sizes (with 80 % power and a 5 % significance level) would have been able to detect.

Table 5 Detectable differences between study groups. Projected and actual sample sizes

Outcomes		Differences in outcomes (%)			Percentage-wise differences (%)
		OU	FMU	change	
Apgar score <7/5					
	1027 women	1,07	2,89	1,82	170,1
	839 women	1,07	3,10	2,03	189,7
Caesarean section					
	1027 women	8,80	5,55	3,25	36,9
	839 women	8,80	5,50	3,30	37,5
Positive birth experience					
	830 women	90,00	93,91	3,91	4,34
	217 women	90,00	97,10	7,10	7,89
Very good support from midwife					
	830 women	92,00	95,50	1,03	1,13
	217 women	92,00	98,30	6,30	6,85

Validity and reliability of data

The data were recorded in accordance with measurement standards and guidelines for the Danish National Birth Register and the North Denmark birth register covering all four units. The sources and procedures were familiar to both the midwives and doctors involved. When possible, outcome data were generated on the basis of procedural and diagnostic codes, in accordance with recommendations in the *International Statistical Classification of Diseases and Related Health Problems, 10th revision* (ICD-10).

The selection of control participants was conducted in accordance with strict guidelines by project staff who were not engaged in birth care for the group of women in question. The result of the matching process was blinded until the selected control had given birth. As almost all women admitted to the FMUs were included in the project, blinding of participation was not practicable. The likelihood that the study would influence midwives' care at the birth centres was deemed to be minimal in view of the protracted study period, the almost total inclusion of women and, lastly, data collection by study staff with no involvement in care.

The delayed inclusion of the FMU participants who gave birth in 2004 could potentially introduce information and selection bias in the study although this risk was considered to be very limited. This assessment was based on a number of factors: the study involved no interventions; all control

participants were prospectively included; strict, exactly identical principles for inclusion were applied for all participants; individual and project-specific data collection was performed for all participants. Moreover, patient records were excellent. To detect any important changes in practice in the units, obstetric quality indicators were monitored.

Statistical analyses

Analyses were based on the intention-to-treat principle and carried out by use of STATA software, version 11.

Baseline characteristics of the group of women intending FMU birth and the individually matched (1:1) group of women intending OU birth were described on the basis of predefined matching groups. Data were given in percentages. The number of intrapartum and postpartum transfers from FMUs to OUs as well as the reasons for transfers were summarized and given in percentages in all three papers (in Paper I, Table 4, transfers and causes for transfer are reported by level of parity).

To take full advantage of the matched design, paired tests were used in all overall comparisons between study groups.

Paper I

In Paper I, that investigated the effect of birthplace on a range of clinical birth outcomes, McNemar's tests were used for comparison of paired binary data (i.e. medical data on the birth process) and Wilcoxon signed-rank tests for comparison of paired continuous data (e.g. birth weight and cervical dilatation on admission).

A supplementary regression analysis adjusting for the matching characteristics were performed to check for residual confounding. For ease of interpretation (e.g. calculation of confidence bands), ordinal outcomes were dichotomized. Checking of agreement between obtained results and test results based on the original data were performed.

To check for bias introduced by the inclusion of FMU women giving birth in 2004, supplementary subgroup analyses were performed (2004 data versus main data).

For all comparisons, relative risks (RR) with 95 % confidence intervals (CI) were calculated. All reported P-values were two-sided. The level of statistical significance was 5 %.

Paper II

This paper explored whether the effect of birthplace on perinatal and maternal morbidity, birth interventions and use of pain relief and upright position for birth among low-risk women intending to give birth in two FMU versus two OU in Denmark differed by level of social disadvantage

The education variable was dichotomised and the analysis was performed on paired, binary data

For all outcomes a conditional logistic regression grouped on match-pairs was applied to estimate and test the effect of birthplace overall and in education-induced subgroups as well for assessing effect differences between subgroups.

Analysis not reported in one of the papers but planned for future publication:
When data reviled large differences in the rates of transfers between primiparous and multiparous women, the same analysis was performed by parity.

Paper III

For this analysis, the Wilcoxon signed-rank test was also used to compare paired continuous data. For incomplete pairs, the missing part was multiply imputed using a logistic or, where relevant, an ordered logistic regression model on the outcome of the observed party. The findings were compared with those of a supplementary complete-case analysis, performed on only the fully observed pairs, to check for concordance.

As responses were generally very positive in both the FMU and the OU group, all primary ordinal outcomes (including the multiply imputed observations) were dichotomised into "Optimal" (Score 6) and all other scores (Scores 5-1) in order to compare the two groups by use of McNemar's test for paired binary data, thus allowing for the calculation of odds ratios and confidence bands. Findings were subsequently compared with the findings of the primary analysis.

The influence of selected socio-demographic factors (parity, age, education, and employment) on women's birth experience and psycho-social care elements was tested by logistic regression. Separate subgroup analyses were performed for the OU and FMU groups.

To control for a possible effect of medical factors the dichotomised data on birth experience, birthplace, medical factors and socio-demographic factors was entered into a logistic regression model. Multiple imputation was deemed irrelevant as the analysis was unmatched and data virtually complete.

Development and validation of study questionnaire

At the planning stage of the study in 2004 /2005, no previously validated questionnaire that fitted the study aims to investigate birth experience, care satisfaction and patient-centred elements of intrapartum care was identified. The focus in the study was on women perception of the (patient-centred) care provided by midwifes as midwives psycho-social support for women in labour is closely associated with women birth experience and care satisfaction [159]. Also the ability of the midwife to form a meaningful caring relationship with the woman and to provide support through "human presence" is a key aspect of midwifery care [160-162]. Some of the tools identified did however give emphasis to physical-technical conditions or medical competence, others to negative thoughts after childbirth [163], etc., parameters which seemed inappropriate for an evaluation of an FMU setting and a population of healthy low-risk women.

The outcome "patient satisfaction" is extremely frequently used in evaluations and comparisons of health care, including maternity care services [164], but the usefulness of the variable has been strongly questioned. The main points of criticism relate to the limited theoretical basis of the concept and the consistently very positive evaluations [165]. As suggested by Ware [166], satisfaction ratings may actually reflect the women's ratings of care, but it seems that there is a rising awareness of a close link between patient's expectations and their value preferences. The information and education that childbearing women receive during antenatal classes and consultations with staff may thus have a strong influence on their later evaluations of care.

To best capture the special characteristics of intrapartum care as it is given in Denmark, and to take into account the understandings of women in the North Denmark Region, the development of the study questionnaire was based not only on literature studies but also on semi-structured interviews with eight mothers one month after they had given birth in one of the FMUs or OUs in Winter 2004/spring 2005. All women had and were at low risk of obstetric complications at the start of labour and eligible for participation in the study. In order to obtain maximal variation of experiences and perceptions, women with different socio-economic characteristics and different clinical birth outcomes were chosen. During the interviews, the full range and dimensions of the women's birth experiences and perceptions of care were explored and attention was given to the wordings and imagery used by the women in their birth narratives.

The analysis of the interviews generally confirmed the key aspects of women's birth experiences as identified through the literature, such as support, information and pain. As noted in Paper III, the concept of control in childbirth proved to be an aspect that required special attention in that the

women had very different understandings of the concept. Notably, some had no appreciation of the idea of birth as being "controllable".

On the basis of literature and interviews, a first draft of the questionnaire, with various options of measurement scales, was prepared and presented to the women in a group interview session. During the interview the specific questions and two different scales, a Likert-type scale and a continuous rating scale, were tested and discussed along with key concepts and formulations used in the questionnaire. In the course of the women's enthusiastic discussions, it became clear that some of them felt quite alienated to consumer-style discourse about e.g. birth plans and informed choice. As stated by one woman, these ideas seemed to her "to belong more in films and women's magazines than in the actual world of a delivery unit". Several women mirrored De Vries observation in his study of Dutch women [2] in saying that they relied on the midwife to guide them and suggest the best solutions. However, presented with a concrete example of a birth plan and examples of common wishes for birth, it became evident that the women all had preferences and that there were certain things they wanted to avoid or wished to happen such as use of water for pain relief, ambulation, being asked permission before vaginal examination or other procedures, continuous information, and holding the baby right away. Although in particular Anglo-American studies have repeatedly found the concept of control to be relevant for women's birth experiences [7, 80], as described in Paper III, the interview gave basis for turning the focus of this study more towards implicit expressions of control such as "opportunity to participate in decision-making" and "the feeling of being listened to".

On the basis on recommendation in the methodological literature [167-169], the respondents were encouraged to give a chronological account of their perceptions and to ponder various aspects of the birth experience before assessing their overall experience and satisfaction with care. With the aim of exploring respondents' understanding of questions and the response options, the questionnaire was validity-tested and revised during pilot studies that included interviews with women from different social backgrounds. Furthermore, 24 women participated in a questionnaire test-retest analysis requiring them to answer the questionnaire twice with two weeks' interval. Cronbach's alpha value for internal consistency reliability was >0.9 and the test-retest reliability coefficient (Spearman) 0.95 for birth experience and between 1 and 0.8 for all other questions. Pilot testing led to further revision of the terms used in describing medical issues and additional text clarifying the intended meaning of some questions.

The final version of the questionnaire contained 15 questions on the intrapartum period. Responses were based on a 6-point (13 questions) or 5-point (two questions) Likert-type scale with no neutral,

middle point between positive and negative scores but a separate "don't know / not relevant for me" option. Numbered points are presented horizontally, with verbal definitions.

The primary question, "Overall, how would you describe your experience of giving birth?" had response options ranging from Score 1:"Very negative" to Score 6: "Outstanding". In rating satisfaction, answer options ranged from Score 1: "Extremely dissatisfied" to Score 6: "Extremely satisfied" and for patient-centred care elements from Score 1: "Unacceptable" to Score 6: "Optimal".

The two questions relating to loss of control used a 5-point scale ranging from Score 0: "No loss" to Score 4: "Control lost all through birth". For all 15 questions the option "Don't know"/"Irrelevant", was available. No open-ended questions were used but respondents were invited to elaborate on their answers in a blank space (data not included in the work presented here). Table 6 shows questions and response options.

Procedure

All 218 women admitted to one of the two studied FMUs between 1 January 2006 and 30 October 2006 and their 218 matched controls were invited to participate in this part of the study.

On the day the questionnaire and written study information was sent by land mail, women were introduced to the study by project staff via telephone. In both cases, women were informed that participation was voluntary and anonymous, that their caregivers would have no access to their individual answers and that their decision as to participation would have no influence on their care. Women consented to participation by returning the signed questionnaire.

A stamped envelope was enclosed with an information sheet informing women that participation was voluntary and anonymous. Women consented to participation by returning the questionnaire. After three weeks non-responders were reminded by telephone to ensure an optimal response rate.

Table 6 Questionnaire: questions and response options

RESPONSES*

Intrapartum care	
During labour, how was your possibility to have a midwife present, when you would like her to be with you?	6-point scale: Unacceptable (1) to Optimal (6)
How did you perceive the support and care that you received from your midwife/midwives during labour?	6-point scale: Unacceptable (1) to Optimal (6)
How did you perceive consideration of staff for your wishes for birth?	6-point scale: Unacceptable (1) to Optimal (6)
How did you perceive the attentiveness of your midwife/midwives towards your psychological needs?	6-point scale: Unacceptable (1) to Optimal (6)
How was your opportunity to participate in decision-making when or if, you wanted to?	6-point scale: Unacceptable (1) to Optimal (6)
How helpful did you find your midwifes suggestions/initiatives to relieve your labour pain?	6-point scale: Unacceptable (1) to Optimal (6)
During labour, did you at any point have a feeling of loss of control over your body, behaviour or reactions?	5-point scale: No (1) to Yes, all though birth (5)
During labour, did you at any point have a feeling of loss of control over staff actions or what was done to you?	5-point scale: No (1) to Yes, all though birth (5)
How did you perceive the information that you were given during labour?	6-point scale: Unacceptable (1) to Optimal (6)
Do you feel that during labour, you were listened to by staff?	6-point scale: Unacceptable (1) to Optimal (6)
How did you perceive the support the staff provided for you partner/birth companion during labour?	6-point scale: Unacceptable (1) to Optimal (6)
How did you perceive the support you partner/birth companion was able to provide for you during labour?	6-point scale: No support (1) to Unequalled support (6)
After giving birth, how was your opportunity to have undisturbed contact with you baby?	6-point scale: Unacceptable (1) to Optimal (6)
Overall, how would you describe your experience of giving birth?	6-point scale: Very negative (1) to Outstanding (6)
Overall, how satisfied are you with the care you received during labour and birth?	6-point scale: Extremely dissatisfied (1) to Extremely satisfied (6)
Postpartum care	
During your postnatal stay, did the postnatal staff have the time for you that you needed?	5-point scale: Not at all enough time (1) to Fully enough time (5)
During your postnatal stay, how were you opportunity to rest?	6-point scale: Unacceptable (1) to Optimal (6)
How did you perceive staff care and support for your personal needs?	6-point scale: Unacceptable (1) to Optimal (6)
How did you perceive staff support and guidance in relation to your care for your baby?	6-point scale: Unacceptable (1) to Optimal (6)
How did you perceive staff support and guidance in relation to breastfeeding?	6-point scale: Unacceptable (1) to Optimal (6)
Overall, how is your perception of your postnatal stay?	6-point scale: Unacceptable (1) to Optimal (6)
Care after discharge	
If you have had any contact with a community health visitor during the first four weeks of your baby's life, overall, how is your perception of this contact?	6-point scale: Unacceptable (1) to Optimal (6)

ETHICAL CONSIDERATIONS AND DATA SECURITY

The present project is approved by the Danish Data Protection Agency (reference number: 2005-41-5352) and the health authorities of the North Denmark Region.

According to Danish legislation, an observational study of this nature requires neither ethical approval nor obtainment of informed consent for participation as it poses no risk or inconvenience to patients [170, 170, 171].

The process of seeking and obtaining consent may introduce bias in the composition of the comparison groups. The liberal Danish legislation allows for full inclusion of all eligible women, which lends further strength to a cohort study such as the present.

Data were treated in strict confidentiality and according to Danish legislation on the use of patient data in research. Data were entered into an internet-based encrypted database constructed for the study by the department for information technology development at Aalborg University Hospital.

One of the project midwives checking data (presented with permission).

Women invited to participate in the questionnaire survey received both oral and written information concerning the survey. All patient information observed the guidelines on research ethics in the social sciences issued by the Danish Social Science Research Council [172] and the Danish Data Protection Agency. The care offered to women was in no way affected by their accepting or declining participation in the study survey.

PATIENT CHARACTERISTICS

The overall study

For each of the 839 women intending birth in an FMU, a matched control participant was identified among low-risk women intending to give birth in an OU. Of the 839 FMU women, 713 (85.0 %) gave birth as planned in the unit, and 20 (2.4 %) in the home, assisted by an FMU midwife. Home births were included as women were free to change their decision about place of birth any time. The same selection criteria applied to home and OU births and women could change their choice of birthplace at any time. Nine FMU (1.1 %) women gave birth before reaching the FMU. Transit births were included if the woman had consulted a midwife <24 hours before giving birth and had been advised to stay at home longer or return to home, as the case might be.

Ninety-seven FMU women (11.6 %) were transferred intrapartum, among these two gave birth in the ambulance. Eleven of them, who were in early labour, were transported in their own vehicle. Twenty-seven transfers (3.2 %) took place <2 hours after birth, another thirteen (1.5 %) during the postnatal stay. The total number of transfers was 137 (16.4 %). Further information on transfers is provided in the Findings section of this overview and in Paper I.

Of the 830 women in the OU group, 834 (99.4 %) women gave birth in the OU, and 5 (0.6 %) gave birth before reaching the OU. Transit births were included on the same criteria as described above. Full follow-up was obtained for all 1678 women. A flow chart is shown in both Paper I (Figure 1) and Paper II (Figure I).

Socio-demographic and obstetric matching factors

Information on the socio-demographic and obstetric characteristics of the study participants was provided in Paper I (Table 1) and Paper II (Table 1). The most comprehensive description is provided in Paper I, giving a detailed account of methodological aspects of the study, whereas Paper II presents the participants' characteristics in a summarised form.

As shown in Paper I (Table 1), the matching produced two fully comparable groups in terms of key socio-demographic and obstetric factors. Three fourths of the women in the study were multiparas; one out of four primiparas. Mean age was 29.4 and 30.2 years in the FMU and OU groups, respectively. Almost all women had as their first language a Nordic or West European language (FMU 96 %; OU 96.4 %) and were married or cohabiting with a partner (FMU 97.1 %; OU

97.6 %). Education and income levels in the North Denmark Region are among the lowest in Denmark [173], conditions which are reflected in the characteristics of the pregnant women in the peripheral and predominantly rural catchment areas of the two FMUs. Thus, 27.4 % of the women had no post-secondary education, 63.8 % either had low-level employment (doing unskilled or vocational work) or were unemployed while smokers made up 18.6 %. Mean BMIs were 24.2 (FMU) and 24.0 (OU).

Matching characteristics for questionnaire survey participants

Of the total group of 1678 women in the study, 436 were invited to participation in the questionnaire survey. As shown in Paper III, Figure 1, 375 women (86 %) returned the questionnaire; 185 were FMU women (85 %), 190 belonged to the OU group (87 %). Full background information on the socio-demographic characteristics of all invited women was obtained.

In Paper III, Table 1, the characteristics of the 436 women invited versus the 375 respondents are compared. No differences in parity, age or BMI were found between responders and non-responders. Significantly lower response rates were obtained from women whose first language was other than Danish (p-value (p) <0.000), women without post-secondary education (p<0.000), or low employment level (p<0.000), women living alone (p<0.000) and smokers (p-value (p) <0.006). A significantly higher response level was obtained among women with 3-4 years of post-secondary education (p<0.000). Of the 21 FMU women who were transferred to an OU, 16 returned the questionnaire.

Of the 375 responders, the majority of 366 (97.6 %) had Danish as their first language; 368 (98.1 %) were married or cohabiting with a partner. Eighty-seven (23.2 %) were primiparas; 62 (26.5 %) were smokers. Seventy-two women (19.2 %) had no post-secondary education; 233 (62.1 %) had a low-level employment and 18 (4.8 %) were in academic/managerial positions.

Respondents by study group

Although participants were matched in the overall study, different response rates may have altered the distribution of socio-demographic characteristics (potential confounders) between women in the two groups. As shown in Paper III, Table 2, an equal distribution of characteristics was maintained for the two groups of respondents.

FINDINGS

Paper I reports the clinical birth outcomes in 839 women intending birth in an freestanding midwifery units and in 839 women intending birth in an obstetric unit (Paper I, Table 2).

Overall clinical outcomes (Paper I)

Primary outcomes

No statistically significant differences between the two study groups were found for the rate of infants with an Apgar score <7/5 min (RR 1; 0.3-3.4). Caesarean section was significantly less frequent among women in the FMU group than in the OU group (RR 0.6; 0.3-0.9).

Against protocol, due to umbilical cord prolapse, one infant in the FMU group was delivered by caesarean section in one of the community hospitals where the FMUs were located. A sensitivity analysis was subsequently performed to test the hypothesis that the infant would have had an Apgar score <7/5min had the mother been transferred. As the analysis showed no significant differences between study groups (RR 1.25; 0.3-4.6) the overall study results were unaffected.

Other outcomes (perinatal)

No statistically significant differences between the two study groups were found in the rates of infants born with Apgar scores <7/5 min, <9/5 min, <7/1 min; neonatal asphyxia; total number of NICU admittances; NICU admittance >48 hours; and neonatal readmission to hospital 0-28 days postpartum. The absolute number of cases in each category is shown in Figure 2.

Figure 2 Secondary perinatal outcomes
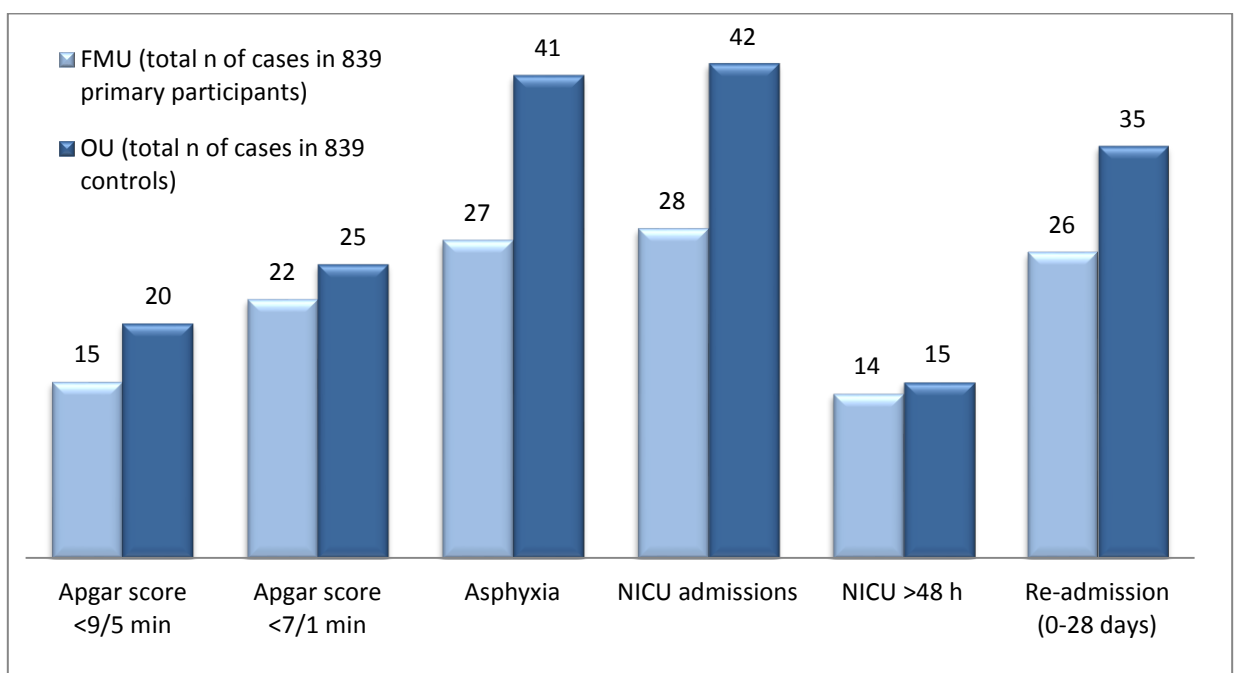
Other outcomes (maternal)

Compared to OU women, the women in the FMU group were significantly less likely to experience morbidity such as abnormal fetal heart rate leading to action (RR 0.3; 0.2-0.5), dystocia (RR 0.4; 0.3-0.5), intrapartum fetal-pelvic complications (RR 0.2; 0.05-0.6), shoulder dystocia (RR 0.3, 0.1-0.9), occipital posterior presentation (RR 0.5; 0.3-0.9), 1st-2nd degree tearing (RR 0.9, 0.8- 0.97), postpartum haemorrhage >500ml (RR 0.4, 0.3-0.7), and postpartum complications related to lactation and mammary glands (RR 0.1; 0.01-0.6).

Interventions were significantly less frequent in the FMU group compared to the OU group. They included instrumental delivery (RR 0.4, 0.3-0.6), oxytocin augmentation (RR 0.5, 0.3-0.6), treatment for shoulder dystocia (RR 0.1, 0.01-0.8), perineal suturing (RR 0.8, 0.7-0.9), and intrauterine palpation (RR 0.3, 0.1-0.9). Moreover, the use of epidural analgesia (RR 0.4, 0.3-0.6) and pudendal nerve block (RR 0.1, 0.0-0.5) for pain relief was less frequent among FMU women.

Comparing the two groups, the women in the FMU group were significantly more likely to experience spontaneous vaginal birth (RR 1.06, 1.03-1.09), intact perineum (RR 1.1, 1.02-1.2) and water immersion for pain relief (RR 1.4, 1.2-1.6).

No significant differences between groups were found for infant birth weight, the occurrence of meconium-stained amniotic fluid, the use of uterotonics, and non-recumbent positions for birth, postpartum haemorrhage >1000 ml, 3rd/4th degree tears, cervical dilatation on admission or the duration of admission for labour care (see Paper I, p.7).

Adverse outcomes

The risk of adverse outcome is an important aspect in comparison of the quality of the different models of intrapartum care as reflected by the discussion in Paper I. A description of all cases of adverse maternal and perinatal outcome is provided in an additional, online-only table (Paper I, Table C). Table C is appended to Paper I in the article section of this thesis.

Overall, in the restricted sample of low-risk women in the present study, there was one case of adverse maternal outcome (0.6 per 1000) and 12 cases of adverse perinatal outcomes (7.2 per 1000), defined here as a composite outcome including perinatal mortality and proxy variables for morbidity: Apgar score <7/5 minutes and >1 week NICU admittance.

The single incident of severe maternal morbidity (uterine rupture followed by peripartum hysterectomy) occurred in the OU group in a multiparous woman given epidural analgesia and augmentation of labour.

The single incident of perinatal infant death occurred in the FMU group, due to a severe congenital malformation, which had gone undetected in antenatal ultrasound screening. In all other cases of adverse perinatal outcome, the infants were discharged in good health.

There were three cases of neonatal admission to NICU for more than one week. All three children belonged to the FMU group but were born in an OU three, four or twenty hours after transfer. A particularly long NICU stay (36 days) for one of the infants was due to undetected congenital heart disease.

Table C, appended to Paper I, provides further description of all cases of adverse maternal and perinatal outcome.

Clinical outcomes for disadvantaged women and for primiparous women

As discussed in the background section, the present, restricted sample of low-risk women is characterised by a high representation of two potentially vulnerable subgroups that are rarely well represented in studies of out-of-hospital births: socially disadvantaged women and primiparous women.

Paper II investigates the whether the effect of birthplace on birth outcomes differed by level of social disadvantage. The level of disadvantaged was here defined by the woman's level of education; outcomes for women by level of education Paper II, Table 2.

It should be noted that this secondary analysis is based on a conditional logistic regression model; estimates are therefore reported as odds ratios (ORs). The differences between the reported RRs and ORs are negligible, except for one border-significant outcome (maternal readmission to hospital 0-28 days) whose OR is significantly different (0.6;0.4-0.99) but RR is not (0.6;0.4-1.0). While Paper II reports this outcome as significantly different, Paper I does not.

In summary, this specific analysis showed that the results for both groups of women, irrespective of their level of education were similar to those found in the overall study (as reported in Paper II, Table 2).

Clinical effect of birthplace by level of social disadvantage (Paper II)

Perinatal outcomes

Perinatal outcomes showed no overall, significant difference in Apgar score <9/5 min, NICU admission >24 hours or infant readmission to hospital 0-28 days postpartum between women in the FMU group and women in the OU group. The same applied for perinatal outcomes when the two groups of women were compared by level of education. Nor was any significant effect difference between subgroups found.

Maternal birth outcomes

Women in the FMU group were significantly more likely to have an uncomplicated, spontaneous birth with good outcome for both mother and infant (OR 2.6; 2.0-3.4) compared to women in the OU group. This effect was found equally for women with post-secondary education: OR 2.7; 1.9-3.7 and without post-secondary education: OR 2.4; 1.5-3.9 (effect ratio 0.9; 0.5-1.6).

Compared to OU women, FMU women were significantly more likely to have intact perineum (OR 1.3, 1.1-1.6) and to avoid readmission to hospital 0-28 days postpartum for reasons related to childbirth (OR 0.6; 0.4-0.99). In both cases, the effect was estimated slightly smaller for women with than without post-secondary education, but the differences are far from significant. Only for the case of intact perineum among women with post-postsecondary education (OR 1.3; 1.002-1.6); the effect of place of birth was significant in the subgroups. Effect ratio was 1.1; 0.7-1.8.

No difference in the likelihood of 3rd-4th degree tears was detected between the two study groups or in the two subgroups.

Birth interventions

Overall, FMU women compared to OU women were significantly less likely to have a caesarean section (OR 0.5; 0.3-0.9). Similar, but non-significant trends were found both for women with (OR 0.5; 0.3-1.1) and without (OR 0.5; 0.2-1.5) post-secondary education (effect ratio 1.0; 0.3-3.5).

Instrumental delivery (OR 0.4; 0.2-0.6) and augmentation of labour (OR 0.4; 0.3-0.5) were significantly lower for the FMU group compared to the OU group, findings which were confirmed for both education-based subgroupings of FMU women.

In the post-secondary education group: instrumental delivery (OR 0.3; 0.2-0.6) and augmentation of labour (OR 0.3; 0.2-0.5). Women without post-secondary education:

instrumental delivery (OR 0.4; 0.1-1.3) and augmentation of labour (OR 0.4; 0.2-0.7). Effect ratio for instrumental delivery was (OR 1.2; 0.3-4.2) and for augmentation of labour (OR: 1.0; 0.5-2.3).

Pain relief and position for birth

Overall, epidural analgesia (OR 0.3; 0.2-0.5) was significantly less used among FMU women compared to OU women whereas water birth (OR 2.6; 1.9-3.5) and use of an upright position for birth (OR 1.9; 1.4-2.5) were used significantly more frequently.

A significant reduction in use of epidural analgesia was found both for women with post-secondary education (OR 0.3; 0.2-0.6) and for women without post-secondary education (OR 0.3; 0.1-0.7), (effect ratio OR 0.8; 0.3-2.1).

In the case of water birth a significant increase was seen both for women with post-secondary education (OR 2.6; 1.8-3.7), and women without post-secondary education (OR 2.5; 1.3-4.9), (effect ratio OR 1.0; 0.4-2.0).

For the use of an upright position for birth, a significant increase was found in women with post-secondary education (OR 1.9; 1.4-2.7). Similar but insignificant trends were found for women without post-secondary education (OR 1.6; 0.8-3.2).

Clinical effect of birthplace by parity (yet unpublished)

Due to the high rates of transfer among primiparous women, the above analysis was also performed by parity, examining whether the effect of birthplace on birth outcomes differed by level of social disadvantage. These results, presented in Table 7 below are not included in any of the papers presented in this thesis but planned for later publication.

Perinatal outcomes

No significant difference was found for Apgar score <9/5 min, NICU admission >24 hours or infant readmission to hospital 0-28 days postpartum for FMU primiparas or FMU multiparas when compared to OU women with same parity. Nor was any significant effect differences between subgroups found.

Maternal birth outcomes

A significantly increased likelihood of uncomplicated, spontaneous birth with good outcome for both mother and child was confirmed for both primiparous (OR 2.2; 1.4-3.3) and multiparous women (OR 2.9; 2.0-4.2) in the FMU group when compared to the corresponding OU groups. The effect ratio was (OR 0.7; 0.4-1.3).

As for the FMU women in general, a significant reduction in the likelihood of hospital readmission was found for primiparous FMU women (OR 0.3; 0.1-0.9). For multiparous there was no significant effect. Effect ratio was (OR 0.6; 0.2-2.2).

Compared to OU multiparas, multiparous FMU women had significantly increased likelihood of intact perineum (OR 1.3; 1.02-1.7). Same non-significant trend was seen for primiparous women (1.2; 0.9-1.9). The effect ratio was OR 1.0; 0.6-1.6).

For intact perineum and 3rd-4th degree tears, the results were similar to those of the overall study, but results did not reach statistical significance for either primiparous or multiparous women. The effect ratio was OR 1.7; 0.4-6.4).

Birth interventions
The significantly reduced likelihood of caesarean section among FMU women when compared to OU women was confirmed for FMU primiparas (OR 0.4; 0.2-0.9). A similar but non-significant trend was seen for FMU multiparas (OR 0.8; 0.3-2.2). Effect ratio OR 0.6; 0.2-2.1.

The significant reductions in the use of instrumental delivery and augmentation of labour among FMU women were confirmed for both groups: instrumental delivery among primiparas (OR 0.4; 0.2-0.7); among multiparas (OR 0.3; 0.1-0.9). For augmentation of labour among primiparas (OR 0.4; 0.3-0.6); for multiparas (OR 0.3; 0.2-0.5). Effect ratios was OR 1.3; 0.6-2.7 for augmentation and OR 1.5; 0.4-6.2 for instrumental delivery.

Water birth, use of epidural and upright position for birth
The significant reduction in the use of epidural analgesia among FMU women was found for both primiparous (OR 0.4; 0.3-0.8) and multiparous women (OR 1.9; 1.4-2.5). Effect ratio was OR 2.5; 0.9-7.0.

Significant increases in water birth were found for both FMU primiparas (OR 2.4; 1.2-4.6) and FMU multiparas (OR 2.7; 1.9-3.8). The use of upright position for birth was significantly increased in FMU multiparas (OR 1.9; 1.4-2.7); a similar but non-significant trend was seen for FMU primiparas. Effect ratio for water birth was OR 0.9; 0.4-1.9 and for upright position OR 0.8; 0.4-1.7.

Table 7 Effect of birthplace on birth outcomes by parity

Outcomes	FMU / OU*	Primiparas / Multiparas		Interaction
N	839 / 839	215 / 215	624 / 624	
Perinatal outcomes	OR (95 % CI)	OR (95 % CI) / OR (95 % CI)		OR (95 % CI)
Apgar score <9/5 min	0.8 (0.4-1.5)	0.6 (0.2-1.9) / 0.8 (0.4-1.9)		0.8 (0.2-3.0)
NICU admission >24 hours	0.8 (0.4-1.5)	0.8 (0.4-1.9) / 0.7 (0.3-1.8)		1.2 (0.3-4.3)
Infant readmission	0.7 (0.4-1.1)	0.4 (0.1-1.4) / 0.7 (0.4-1.3)		0.6 (0.2-2.2)
Maternal outcomes				
Uncomplicated birth	2.6 (2.0-3.4)	2.2 (1.4-3.3) / 2.9 (2.0-4.2)		0.7 (0.4-1.3)
Intact perineum	1.3 (1.1-1.6)	1.3 (0.9-1.9) / 1.3 (1.02-1.7)		1.0 (0.6-1.6)
3rd-4th degree tear	0.8 (0.4-1.4)	0.9 (0.4-2.0) / 0.6 (0.2-1.7)		1.7 (0.4-6.4)
Maternal readmission	0.6 (0.4-0.99)	0.3 (0.1-0.9) / 0.8 (0.4-1.4)		0.4 (0.1-1.3)
Interventions				
Caesarean section	0.5 (0.3-0.9)	0.4 (0.2-0.9) / 0.8 (0.3-2.2)		0.6 (0.2-2.1)
Instrumental delivery	0.4 (0.2-0.6)	0.4 (0.2-0.7) / 0.3 (0.1-0.9)		1.5 (0.4-6.2)
Augmentation of labour	0.4 (0.3-0.5)	0.4 (0.3-0.6) / 0.3 (0.2-0.5)		1.3 (0.6-2.7)
Other				
Epidural analgesia	0.3 (0.2-0.5)	0.4 (0.3-0.8) / 0.2 (0.1-0.4)		2.5 (0.9-7.0)
Water birth	2.6 (1.9-3.5)	2.4 (1.2-4.6) / 2.7 (1.9-3.8)		0.9 (0.4-1.9)
Upright position for birth	1.9 (1.4-2.5)	1.5 (0.8-3.1) / 1.9 (1.4-2.7)		0.8 (0.4-1.7)

Socio-demographic factors and adverse outcomes

Of the 13 cases of adverse outcome in the study (presented in Paper I, appended Table C), 37.5 % (5 cases) occurred among primiparas and 61.5 % (eight cases) among multiparas. Overall, 25 % of the women in the study were primiparas and 75 % were multiparas.

Of the women with an adverse outcome, 30.8 % (four) had no post-secondary education while 69.2 % (nine) had. Overall, 27.4 % of women in the study had no post-secondary education while 72.6 % had postsecondary education (Paper II, Table 1). Due to the low number of cases, no statistical analysis was undertaken.

Psycho-social outcomes (Paper III)

Primary outcome

The evaluation of the overall experience of childbirth was significantly more positive among women in the FMU group compared to the OU group ($p<0.0000$).

In the FMU group, 57.2 % of women gave their birth experience the best possible evaluation (score 6, "outstanding experience") compared to 35.2 % of women in the OU group (RR 1.6; 1.3-2.0). As seen in Figure 3, data were positively skewed; overall, 91.9 % of women in the FMU group scored their experience of giving birth as "very positive" or "outstanding". The corresponding figure for the OU group was 74.2 % ($p<0.0003$).

The "negative" rating categories were scarcely used by the women. Approximately 1 % of the OU women but none of the FMU women described their birth experience as "Very negative" (score 1); 1 % of FMU women use the "Negative" score 2 versus none of the FMU women. Overall, 3.2 % of the FMU women and 7.4 % of the OU women used one of the three negative responses categories in describing their birth experience ($p<0.1435$).

Figure 3 Childbirth experiences
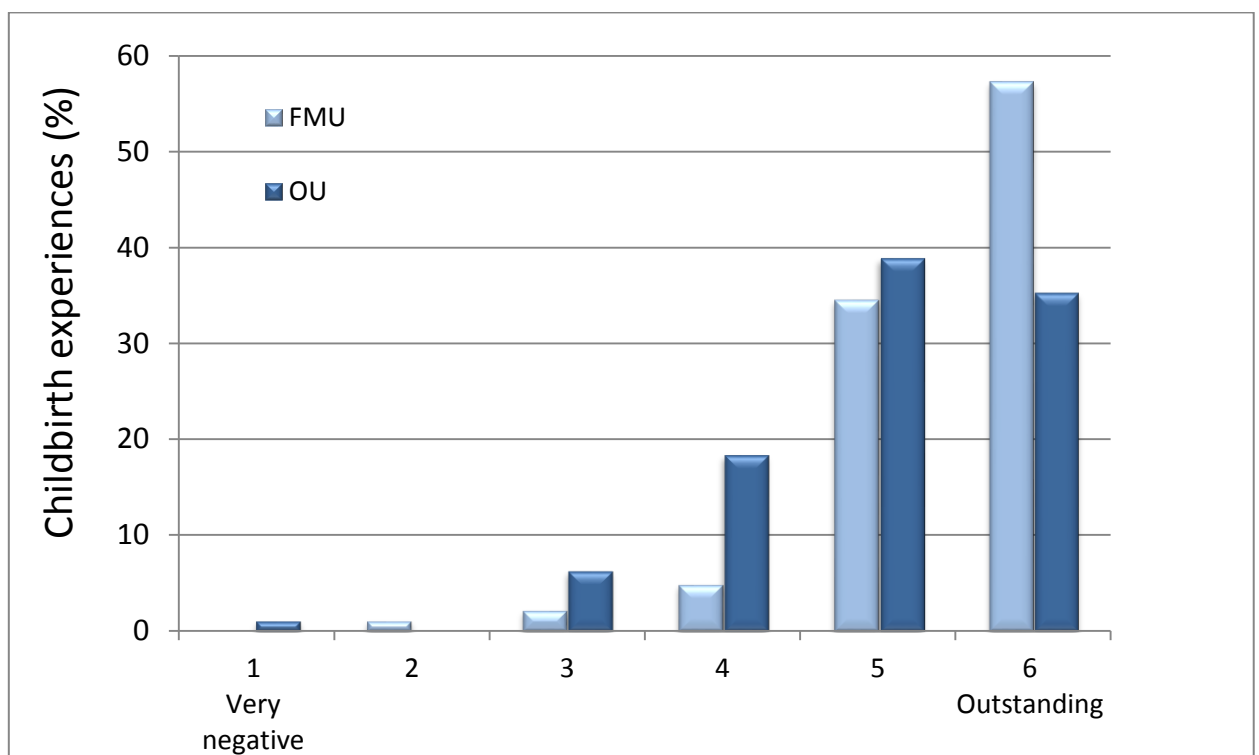
Secondary outcomes: women's perceptions of intrapartum and postpartum care

The women's rating of their satisfaction with care follows the pattern established with birth experience; the FMU women were significantly better satisfied than the OU women (p<0.0000) (Figure 4 below). The best possible rating of care satisfaction ("Extremely satisfied", score 6) was used by 78.4 % of FMU women and 45.8 % of OU women (RR 1.6 (1.4-2.0)).

Again, negative ratings of care satisfaction were extremely rare; only one FMU woman (0.5 %) and seven OU women (3.7 %) used one of the three negative categories (p<0.1250). Score one; the "extremely dissatisfied" category did not occur.

Figure 4 Care satisfaction
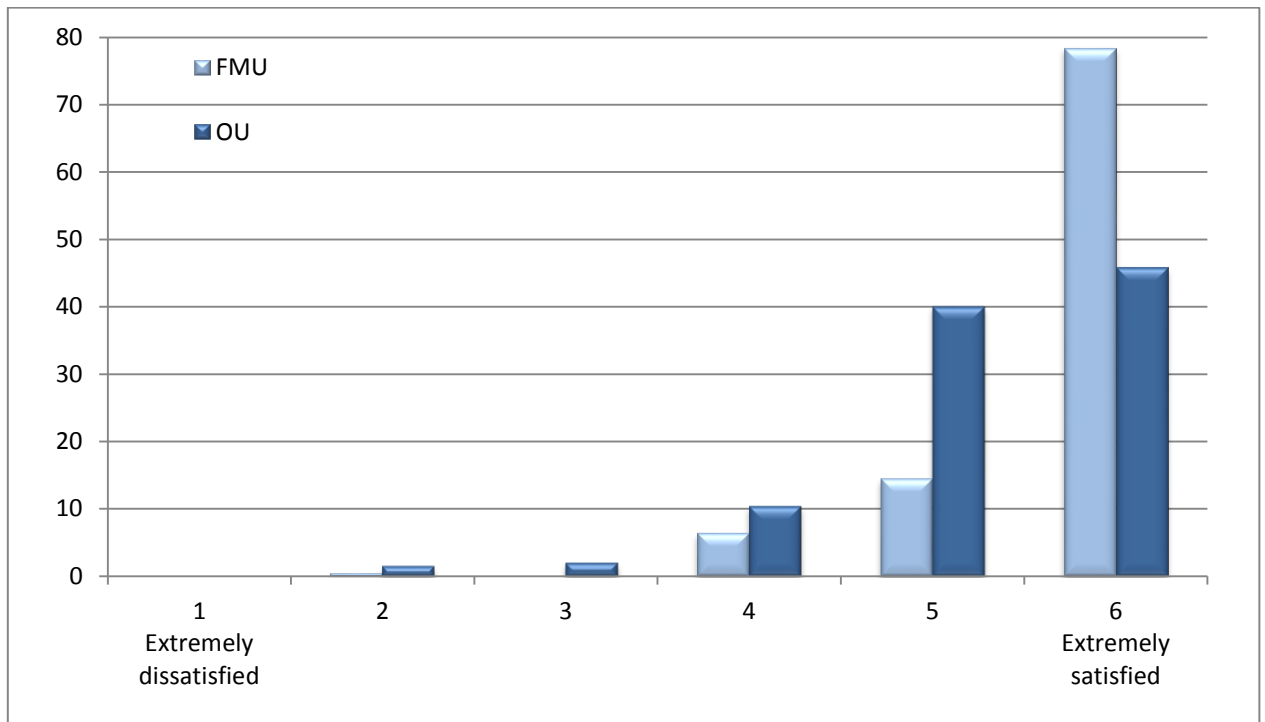
As described in Paper III and as shown in Table 8 on birth experience and perceptions of intrapartum and postpartum care below, FMU women had significantly more positive perceptions of several patient-centred care elements, including midwife support (p<0.0000), having the midwife present when wanted (p<0.0000), ability to participate in decision-making (p<0.0000), staff attentiveness to psychological needs (p<0.0000) and to wishes for birth (p<0.0000), the information provided (p<0.0000), feeling of being listened to (p<0.0000), and staff support for partner (p<0.0013).

There were no significant differences in the two groups of women's perception of loss of neither internal nor external control, the support provided by their partners, the usefulness of

the midwife's suggestions for pain relief, and opportunities for undisturbed contact with the newborn.

The women's perception of postnatal care, care from health visitor after discharge, and feeding of the infant at 28 days were covered by eight items in the questionnaire. The data were not included in Paper III due to the limited space available. For postpartum care, significant differences between groups were found for all six items investigated: staff allocating enough time (p<0.0000), opportunity to rest (p<0.0000), staff care for the needs of the mother (p<0.0000), staff support of parents' care for the infant (p<0.0000), breastfeeding support (p<0.0000), and overall perception of postpartum stay (p<0.0000), all strongly in favour of FMU care. In the FMU group, 2.2 % of the respondents used one of the three negative categories in describing their overall experience of postnatal care versus 11.9 % in the OU group (p<0.0023).

There was no difference in the groups' perceptions of care from health visitor during the neonatal period (0-28 days postpartum) or success in fully breastfeeding infants at day 28. According to women's reports, 81.7 % of infants in the FMU group and 75.3 % of infants in the OU groups were fully breastfed at this time (p<0.0703).

Results after dichotomisation of outcome data

As noted in Paper III, a supplementary analysis was performed, focusing on women's use of the top ratings (score 6) in the two study groups.

The results of McNemar's test on dichotomised data, presented in Table 9, Top ratings in description of birth experience and care perception, show consistency with the results of the imputed primary analysis, thus confirming the robustness of the findings.

Table 8 Birth experience and intrapartum and postpartum care perceptions

	Median		Range (min.-max.)		N	N	N of complete pairs		P-value
							Before imputation	After imputation	
	FMU	OU	FMU	OU	FMU	OU			
Intrapartum care									
Overall birth experience	6	5	4 (2-6)	5 (1-6)	185	190	165	210	0.0000
Care satisfaction	6	5	4 (2-6)	4 (2-6)	185	190	165	210	0.0000
Support from midwife	6	6	4 (2-6)	5 (1-6)	182	190	162	210	0.0000
Midwife present when wanted	6	6	4 (2-6)	5 (1-6)	182	189	161	210	0.0000
Attentiveness psychological needs	6	5	4 (2-6)	5 (1-6)	177	180	149	208	0.0000
Feeling of being listened to	5	5	3 (3-6)	5 (1-6)	180	188	159	209	0.0000
Level of information	6	5	3 (3-6)	4 (2-6)	183	187	162	208	0.0000
Participation in decision-making	6	5	4 (2-6)	5 (1-6)	176	180	148	208	0.0000
Consideration for birth wishes	6	5	5 (1-6)	5 (1-6)	107	120	58	169	0.0000
Suggestions for pain relief	6	5	4 (2-6)	5 (1-6)	106	120	57	169	0.0038
Undisturbed contact with newborn	6	6	3 (3-6)	4 (2-6)	184	188	162	210	0.0026
Staff support for partner	6	5	4 (2-6)	4 (2-6)	174	179	144	209	0.0013
Support provided by partner	5	5	5 (1-6)	4 (2-6)	182	188	160	210	0.3408
Loss of internal control	1	1	4 (0-4)	4 (0-4)	179	190	159	210	0.0310
Loss of external control	0	0	4 (0-4)	4 (0-4)	181	188	159	210	0.0061
Postpartum care									
Staff having enough time	5	4	3 (2-5)	4 (1-5)	138	144	105	177	0.0000
Opportunity to rest	6	4	4 (2-6)	5 (1-6)	140	148	109	179	0.0000
Care for the needs of mother	6	5	3 (3-6)	4 (2-6)	147	140	108	179	0.0000
Support in care for infant	6	5	3 (3-6)	4 (2-6)	138	142	102	178	0.0000
Breastfeeding support	6	5	5 (1-6)	5 (1-6)	135	138	101	172	0.0000
Postpartum stay overall	6	5	4 (2-6)	4 (2-6)	143	140	106	177	0.0000
Care from health visitor 0-28 days	5	5	4 (2-6)	3 (3-6)	190	181	162	209	0.6501

Table 9 Top ratings in description of birth experience and care perception

	FMU/OU N	FMU/OU %	McNemar's test Relative Risk (95 % CI)
Birth experience and intrapartum care			
Outstanding birth experience	106 / 67	57.2 / 35.2	1.6 (1.3-2.0)
Extremely satisfied with care	145 / 84	78.4 / 45.8	1.6 (1.4-2.0)
Optimal support from midwife	146 / 113	80.2 / 54.5	1.3 (1.2-1.5)
Optimal presence of midwife when wanted	158 / 122	86.8 / 64.6	1.3 (1.2-1.5)
Optimal attentiveness to psychological needs	103 / 59	58.2 / 32.8	1.8 (1.4-2.3)
Optimal feeling of being listened to	80 / 39	44.4 / 20.8	2.2 (1.6-3.0)
Optimal level of information	103 / 49	56.3 / 26.2	2.1 (1.7-2.8)
Optimal opportunity to participate in decision-making	97 / 62	55.1 / 34.4	1.6 (1.2-2.1)
Optimal consideration for birth wishes	72 / 36	67.3 / 30.0	2.3 (1.7-3.1)
Optimal suggestions for pain-relief	59 / 38	55.7 / 31.7	1.6 (1.2-2.3)
Optimal opportunity for undisturbed contact with newborn	158 / 139	85.7 / 73.9	1.1 (1.0-1.3)
Optimal support for partner	87 / 59	50.3 / 33.1	1.5 (1.1-2.1)
Unequalled support by partner	80 / 79	44.0 / 42.0	1.1 (0.8-1.3)
Experience of loss of control			
Feeling of control over staff actions lost all through birth	1 / 8	0.6 / 4.3	0.1 (0.0-1.5)
Feeling of control over labour/own reactions lost all through birth	16 / 23	8.7 / 12.1	0.7 (0.8-1.3)
Postpartum care			
Staff having fully enough time	97 /42	70.3 / 29.2	2.5 (1.8-3.5)
Optimal possibility to get rest	103 / 22	73.6 / 14.9	5.1 (3.2-8.1)
Optimal care for the needs of mother	95 / 35	67.9 / 23.8	2.6 (1.9-3.6)
Optimal support in care for infant	89 / 34	64.5 / 23.9	2.3 (1.6-3.2)
Optimal breastfeeding support	72 / 33	53.3 / 23.9	2.0 (1.4-3.0)
Optimal overall perception of postnatal stay	96 / 26	69.1 / 18.2	3.9 (2.6-5.9)
Optimal care from health visitor 0-28 days	104 / 119	57.5 / 62.6	1.1 (0.8-1.4)
Full breastfeeding at 28 days post partum	140 / 143	81.7 / 75.3	1.1 (0.97-1.2)

Correction for influence of medical factors

With birth experience treated as a dichotomous outcome, we performed a supplementary control for medical birth factors that were likely to influence birth experience (Apgar score, transfer to NICU, caesarean section, instrumental delivery, augmentation of labour, amniotomy, labour >12h, epidural analgesia and water birth). A multiple logistic regression model was used. As this analysis was unmatched, we also controlled for social matching factors. The adjustment meant a slight increase in the positive influence of FMU care on women's birth experience (to OR (adjusted):4.0; 2.0-8.2; p<0.0000).

Influence of selected socio-demographic factors on birth experience

An important finding of the research reported in Paper III is the overall, significant, negative effect of no post-secondary education (OR 0.4; 0.2-0.8) and of low-level employment (OR 0.5; 0.3-0.97) on women's birth experience. This effect was found only in the OU group: no post-secondary education (OR 0.35; 0.16-0.8); low-level employment (OR 0.3; 0.1-0.6). For women in the FMU group, a non-significant trend showing a positive effect of having lower-level jobs was seen. The same did not appear to be the case for a low educational level. Age and parity had no significant effect on birth experience.

Impact of education on intrapartum care satisfaction and care perceptions

As shown in Table 10 below (not included in Paper II, but results reported in text), an overall, significant, negative effect of no post-secondary education was found for six items: care satisfaction (OR 0.3;0.2-0.7), midwifery support (OR 0.3;0.2-0.7), presence of midwife when wanted (OR 0.3;0.2-0.7), information (OR 0.3;0.2-0.5), feeling of being listened to (OR 0.3;0.1-0.7), and consideration for birth wishes (OR 0.3;0.1-0.6).

For women in the FMU group, the significant, negative effect was confirmed for two of these outcomes: information (OR 0.3; 0.1-0.5) and the feeling of being listened to (OR 0.3; 0.09-0.9).

In the OU group, the significant, negative effect was consistent across all six items: midwifery support (OR 0.3; 0.09-0.8), information (OR 0.2; 0.1-0.5), feeling of being listened to (OR 0.3; 0.1-0.7), consideration for birth wishes (OR 0.3; 0.1-0.6), presence of midwife when wanted (OR 0.3;0.1-0.8), and overall care satisfaction (OR 0.2; 0.08-0.5) and for staff support for partner (OR 0.3; 0.2-0.7).

No effect was found for participation in decision-making, attentiveness towards psychological needs, suggestions for pain relief, or loss of internal or external control.

Impact of employment level on intrapartum care satisfaction and care perceptions

No significant effect of low-level employment was found for care satisfaction or women's care perceptions in the aggregate group of women or for women in the FMU group. For the following items: care satisfaction, midwifery support, feeling of being listened to, consideration for wishes, participation in decision-making, suggestions for pain relief and loss of control over staff actions, the trends (all non-significant) in the FMU group were reversed towards a positive effect of low-level employment.

For women in the OU group, a significant, negative effect of low-level employment was found for three items: midwifery support (OR 0.3; 0.1-0.8), feeling of being listened to (OR 0.3; 0.1-0.8), consideration for birth wishes (OR 0.4; 0.2-0.9), and staff support for partner (OR 0.4; 0.2-0.7).

Table 10 Influence of socio-demographic factors on care satisfaction and care perceptions

	No post-secondary education OR (95 % CI)			Low-level employment OR (95 % CI)		
Outcomes (dichotomised)	FMU	OU	ALL	FMU	OU	ALL
Birth experience	0.5(0.1-1.4)	0.4(0.2-0.8)	0.4(0.2-0.8)	1.9(0.7-5.6)	0.3(0.1-0.6)	0.5(0.3-0.97)
Care satisfaction	0.8(0.2-3.0)	0.2(0.1-0.5)	0.3(0.2.0.7)	1.4(0.5-4.4)	0.4(0.2-1.1)	0.7(0.3-1.4)
Support from midwife	0.3(0.1-1.3)	0.3(0.1-0.8)	0.3(0.2-0.7)	1.7(0.5-5.9)	0.3(0.1-0.8)	0.5(0.3-1.2)
Midwife present	0.3(0.1-1.1)	0.3(0.1-0.8)	0.3(0.2-0.7)	0.8(0.2-2.7)	0.7(0.3-1.6)	0.7(0.4-1.4)
Psychological needs	0.9(0.3-2.5)	0.7(0.3-1.5)	0.8(0.4-1.5)	0.9(0.4-2.2)	0.7(0.4-1.5)	0.8(0.5-1.4)
Being listened to	0.3(0.1-0.7)	0.3(0.1-0.9)	0.3(0.1-0.6)	1.6(0.5-4.8)	0.3(0.1-0.8)	0.6(0.3-1.2)
Level of information	0.3(0.1-0.8)	0.2(0.1-0.5)	0.3 (0.2-0.8)	0.8(0.3-2.1)	0.6(0.3-1.2)	0.7(0.4-1.1)
Participation in decisions	0.8(0.3-2.7)	0.6(0.3-1.4)	0.7(0.4-1.4)	2.2(0.8-5.9)	0.8(0.4-1.5)	1.1(0.6-1.8)
Birth wishes	0.3(0.1-1.5)	0.3(0.1-0.6)	0.3(0.1-0.6)	1.3(0.3-5.3)	0.4(0.2-0.9)	0.5(0.3-1.1)
Suggestions, pain relief	0.8(0.2-2.7)	0.4(0.2-1.02)	0.6(0.3-1.1)	1.1(0.4-3.3)	0.8(0.4-1.7)	0.9(0.5-1.7)
Undisturbed contact	0.7(0.1-7.2)	0.6(0.2-2.4)	0.7(0.2-2.1)	0.5(0.1-5.1)	0.5(0.1-2.0)	0.5(0.2-1.7)
Staff support for partner	1.6(0.4-5.7)	0.3(0.2-0.7)	0.6(0.3-1.08)	2.0(0.9-5.0)	0.4 (0.2-0.7)	0.7(0.4-1.2)
Support from partner	0.6(0.3-1.4)	0.7(0.3-1.7)	0.6(0.3-1.2)	0.8(0.4-1.7)	0.8(0.3-1.8)	0.8(0.5-1.4)
Loss of internal control	1.7(0.7-3.8)	1.5(0.7-3.3)	1.6(0.9-2.7)	1.8(0.8-3.7)	1.7(0.9-3.2)	1.7(1.0-2.8)
Loss of external control	1.3(0.5-3.2)	1.0(0.4-2.3)	1.1(0.6-2.0)	0.8(0.4-1.8)	1.4(0.7-2.8)	1.2(0.7-1.9)

Transfers

Overall

Close observation of women and timely transfer of women and/or newborns in case of complications or indications of such were key elements of the FMU intrapartum care concept.

Of the 124 FMU women transferred during labour or less than two hours after birth, 13 (10.5 %) were in early labour and chose to use private transport for transfer. The remaining 111 women (89.5 %) were transferred by ambulance: the average transfer time was 42 min from Hobro FMU and 38 min from Frederikshavn FMU. In 85 % of ambulance transfers, the woman was accompanied by an FMU midwife; 47 % were given a tocolytic to stop contractions during transport. Two women (1.6 %) gave birth during ambulance transfer.

One infant with severe congenital malformations died in the FMU before transfer was attempted. In all other cases of adverse outcome in the FMU group, the woman was transferred and admitted to an OU 3-23 hours before giving birth.

In the OUs, to which transfer took place, care for the women was shared by an obstetrician and a midwife. The FMUs aimed for their midwives to stay with the woman after transfer to an OU and continue care under the supervision of an obstetrician; however, this was possible only in 36 % of transfers.

Overall, the rate of transfer during labour or less than two hours postpartum were 14.8 % in the present study. As seen in Figure 5 below, a marked decline in transfer rates from the two FMUs occurred during the study period from overall 18.7 % in 2004 to 9.7 % in 2006. Frederikshavn FMU, which opened in 2004, had the highest transfer rate for that year but its rate declined steadily and ended the study period at a lower level than Hobro FMU. Through 2004-2005 the Hobro FMU transfer rate was stable, at just over 16 %, after which it dropped to 12.2 % in 2006. All transfers and obstetric emergency cases in the FMUs were subsequently audited in regular, multidisciplinary meetings between FMU and OU staff. As Figure 5 also shows there was no indication that the reduction in transfer rates led to more infants being born with low Apgar score or more women experiencing abnormal postpartum bleeding.

Figure 5 Transfer rates during labour or <2 hours after birth
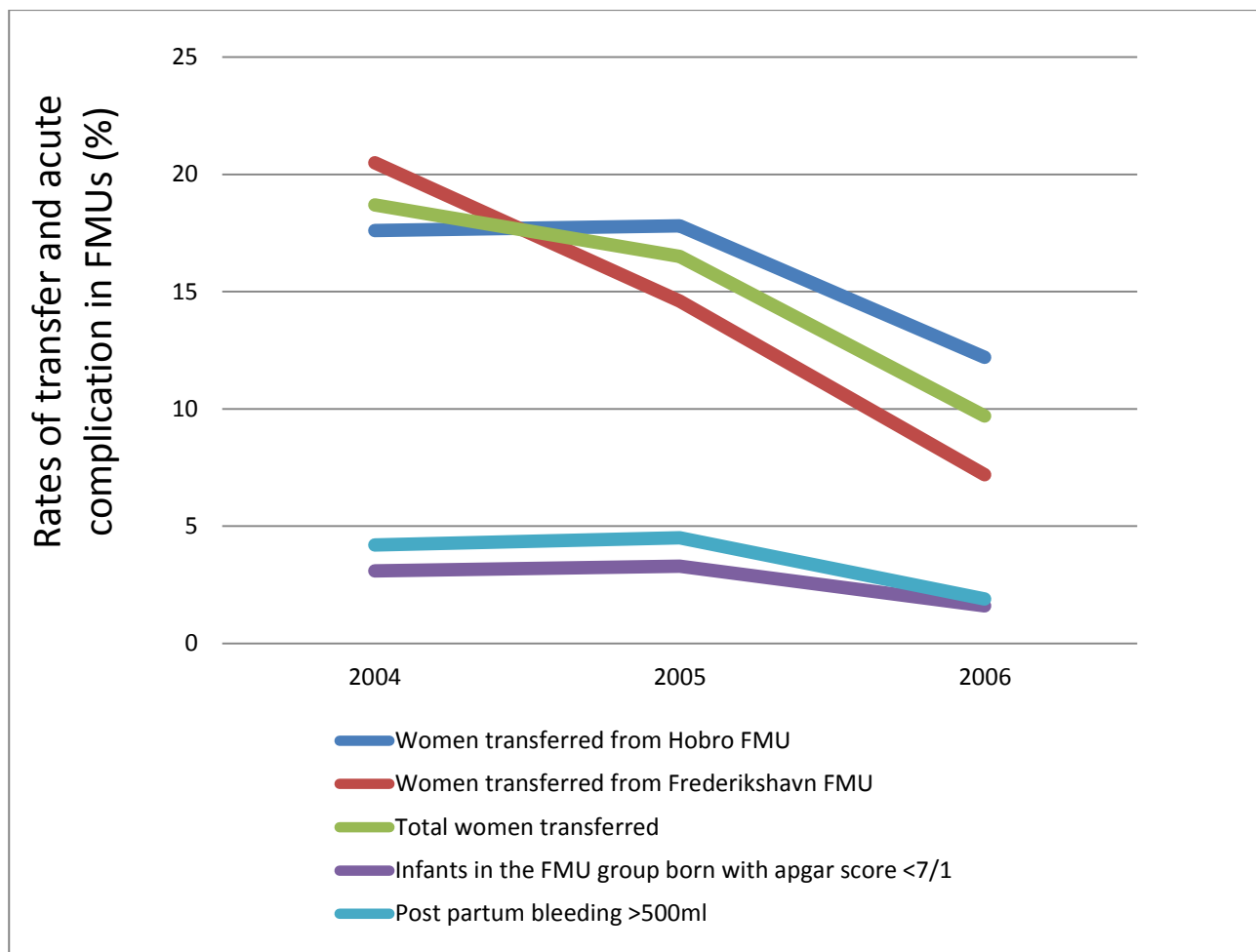
FMUs received feed-back on all transfers, which were later subjected to multidisciplinary audit at regular meetings. Most women were accompanied by midwife during transfer. In 33 % of transfers the FMU midwife continued care in the OU under obstetrician supervision.

Causes for transfer

By far the most common reason for transfer was slow progress of labour. Overall, this was the indication for 44.4 % of transfers but the study period saw declining rates for transfers on this indication (from 50 % in 2004 to 33.3 % in 2006).

Numbers for all other reasons for transfer fluctuated at the level of the mean rate; no decline was seen during the study period. All reasons for transfer are shown in Figure 6.

Figure 6 Reasons for transfer during labour or <2 hours after birth

Legend:
- Slow progress of labour (44%)*
- Perineal trauma (complicated or 3th-4th degree (13%)
- Meconium stained amniotic fluid (11%)
- Postpartum bleeding /retained placentae (9%)
- Fetal heart rate abnormality (8%)
- Prolonged latent phase (6%)**
- Epidural analgesia (5%)
- Abnormal fetal presentation (4%)
- Minor respiratory problem in infant (2%)***
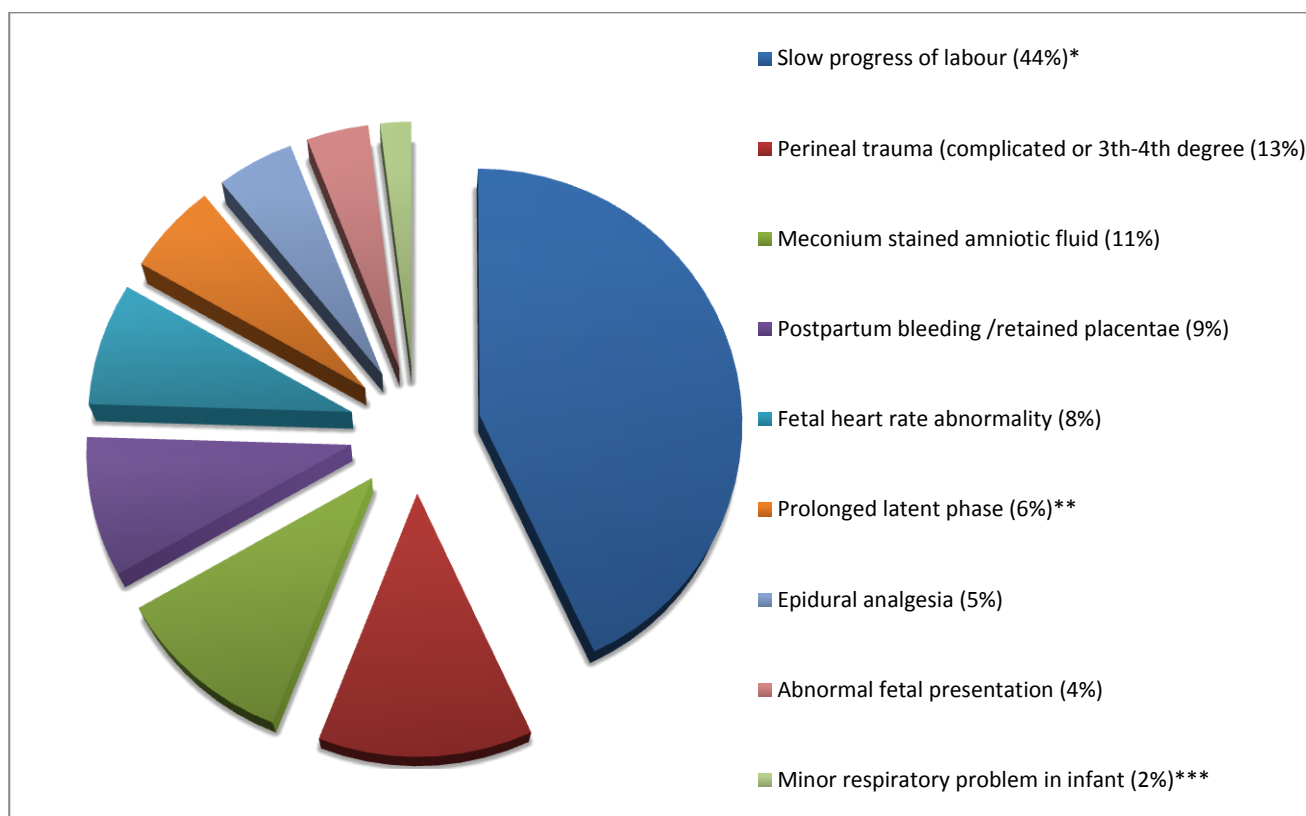
Defined as: 1st stage: no progress for two hours, 2nd stage: primiparas: active pushing >2 hours; multiparas: active pushing >1 hour
**Defined as painful contractions >24 hours and cervical dilatation <3 cm*
*** Intensive neonatal transfer service was available but not used*

Transfer for different subgroups

Primiparous and multiparous women had extremely different transfer rates (36.7 versus 7.2 %). As described in Paper II and illustrated in Figure 7 below, transfer rates did not correlate with women's educational level (post-secondary: 14.9 % versus none: 14.3 %) or their employment level (high: 14.8 % versus low: 14.7 %).

As primiparas with no post-secondary education were expected to be under a double risk factor, the transfer rate was checked separately for this group. No correlation between transfer and educational level was found.

Figure 7 Transfer rates for different subgroups

Subgroup	% transferred
All FMU women transferred	14.8
Primiparas	36.7
Multiparas	7.2
High employment level	14.8
Low employment level	14.7
No post-secondary education	14.3
Post-secondary education	14.9
Primiparas with post-secondary edu	36.3
Primiparas without post-secondary edu	37.9
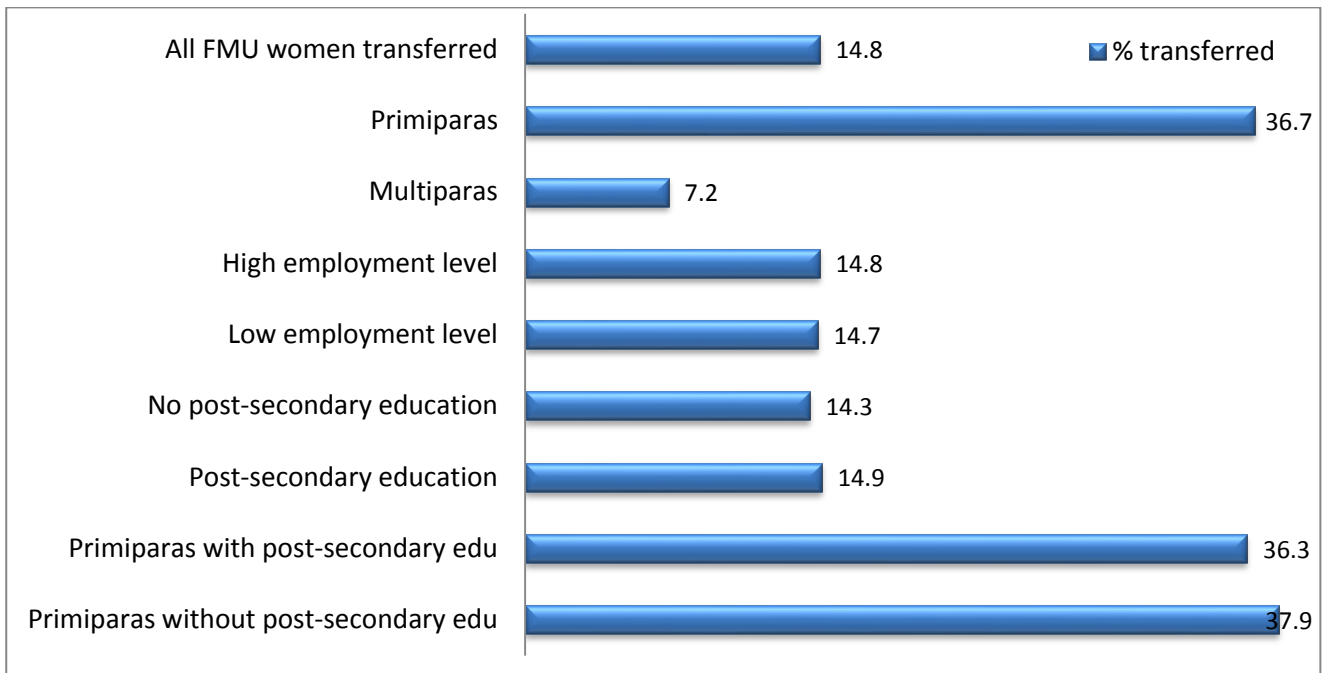
Paper I, II and III all address the issue of transfer. In Paper I, Table 4, all reasons for transfer are presented by parity. The transfer rates for primiparous and multiparous women were very different, with overall 36.7 % of primiparas versus 7.2 % of multiparas being transferred.

As shown in Figure 8 the rate of transfer for multiparas varied little over the study period, while the rate of transfers for primiparas declined from 44.4 % in 2004 to 24.6 % in 2006.

Figure 8 Transfer rates by parity
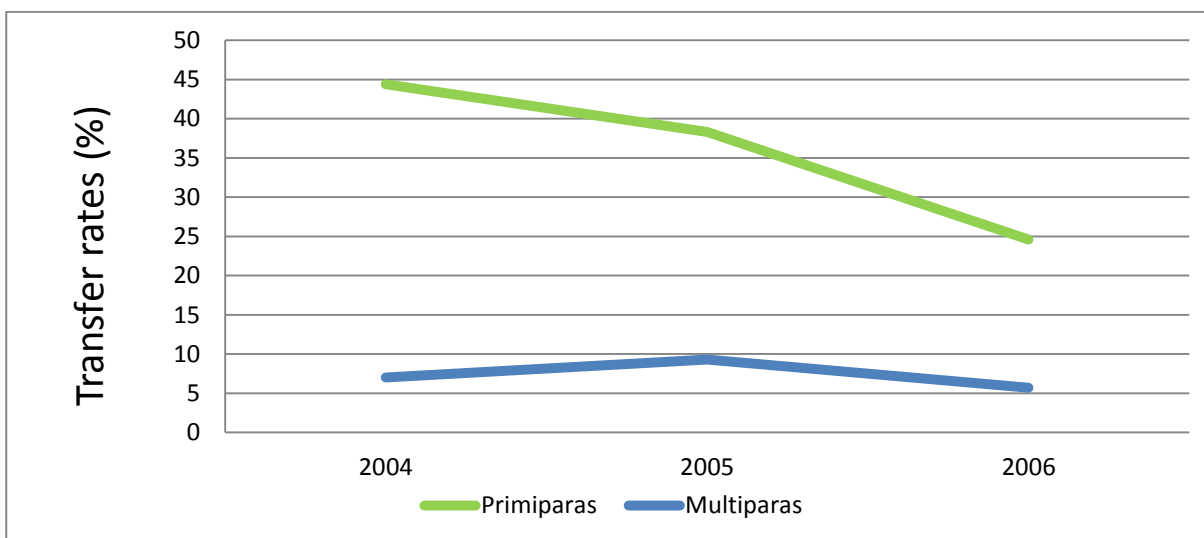
Transferred FMU women's birth experience

In Paper III, the impact of place of birth on women's birth experiences and perception of care is explored with quantitative methods. Statistical analysis of the experiences and perceptions of transferred versus not-transferred women was not possible due to the unexpectedly large decline in the transfer rate (from 20 to 9 %) and a lower response rate among women who experienced transfer (76 %, see Paper III). Ten of the transferred women (62.5 %) gave their birth experience a score of 6 or 5 ("Outstanding/very positive"); three women use the negative scores of 3 or 2 (19 %) (median: 5, range: 4(2-6)), see Figure 9.

Figure 9 Transferred women's birth experiences
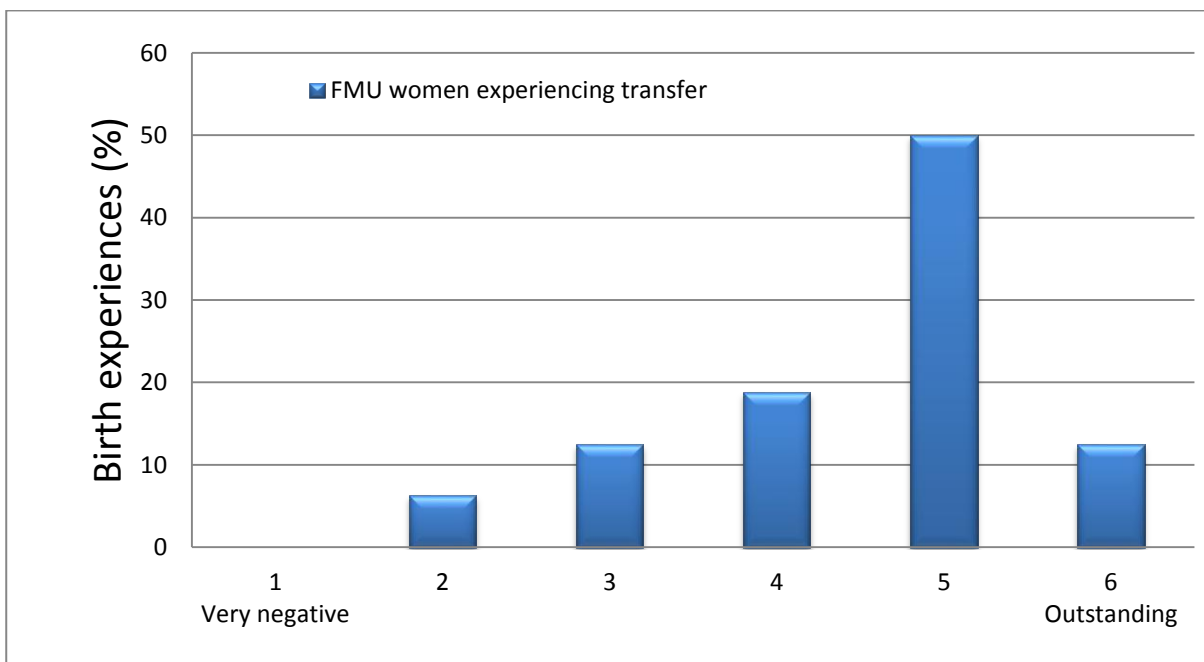
DISCUSSION

This chapter provides a brief summary of the background and context of the study and its main findings, followed by a discussion of strengths and limitations and of findings within the wider body of evidence. That discussion will be structured by the four dimensions of quality that this thesis explores – safety, effectiveness, patient-centredness and equality.

As argued in the introduction, childbirth is not only a significant life event at the personal level for the parents but likewise an important event at the societal level. It is an event that is marked and shaped by beliefs as well as systems. While for centuries, it was an event that took place in the woman's home, the last decades have seen birth to move into hospitals, in most high- and middle-income countries primarily in specialised obstetric units, regardless of the woman's health status or risk of obstetric complication. As an alternative, midwifery units have opened in many countries, offering midwifery-led care to low-risk women.

In Denmark, the peripheral and predominantly rural North Denmark Region took steps in 2001 towards a reorganisation of its maternity care services by introducing freestanding midwifery units as part of mainstream services. The intention was to offer women a choice of care close to home as well as an alternative to OU birth.

The care offered by OUs and FMUs is rooted in two diverging paradigms of childbirth, the technocratic and the holistic paradigms. These paradigms are often seen as contrasting and linked to their different care *providers* (obstetrician versus midwife) and *places of birth* (hospital versus home/midwifery unit). Criticism has been levelled at both models, the technocratic model for being unaccommodating of women's and infant's psycho-social needs and for overuse of birth interventions. The holistic model has been criticised for ignoring medical risk and jeopardising women's and infant's safety.

Over the years a third, "humanistic", paradigm, emphasising patient-centredness and patient autonomy, has emerged from a mediating position between the technocratic and holistic paradigms. "Clearly more loving that the technocratic model, clearly less radical than the holistic model" [74], this model was predicted by Davis-Floyd [70 (p.S10)] to hold the greatest potential for reforming and improving services for childbearing women and families. The humanistic paradigm allows for an open concept of what is good and right; a concept that is as underlined by Wackerhausen [86] ultimately defined by the individual woman. The humanistic approach has gained much support among users and health

professionals as well as policy makers; many FMUs and OUs are therefore working towards a shared goal of providing high-quality, safe, individualised and patient-centred care while their efforts towards achieving such goals may still be fundamentally different.

In the course of the last decades, the rising incidence of medical intervention has caused concern internationally. First-time mothers in particular have high intervention levels. Maternal fear of childbirth and negative birth experiences also present major challenges in maternity care [8, 13, 15, 16, 41, 174-177]. Claims have been made that FMUs provide a responsible response to these challenges [178, 179] but the evidence to support such claims, especially regarding perinatal outcomes, is limited. Assessment, development and improvement of the quality of services are key issues in today's health care systems [99] and the safety and quality of FMUs as a new service should be evaluated and compared to the established care.

In a 2010 Cochrane review comparing AMU and OU outcomes, no differences in perinatal mortality and maternal and perinatal morbidity could be documented, while women intending to give birth in an AMU had significantly fewer interventions and higher care satisfaction. Such data have not yet been obtained for FMU care.

FMU care is primarily chosen by advantaged women and multiparas; the suitability of FMU care for disadvantaged women and primiparas are thus little explored. Transfer rates for primiparous FMU women have repeatedly been found to be high, and the suitability of FMU care for primiparas has been strongly questioned. As there are several reports of more negative birth outcomes among disadvantaged women compared to advantaged women, FMU care for this group of women also raises cause for concern.

The present study of maternity care services explores four elements of quality of care: safety, effectiveness, patient-centredness, and equality [99] in two different models of midwifery care for low-risk women in Denmark.

The objective of the study was to investigate the influence of birthplace on neonatal and maternal morbidity, interventions, pain relief, women's birth experiences and perceptions of care in two FMUs and two OUs in the North Denmark Region and whether the effect of FMU care on clinical and psycho-social birth outcomes differs by level of social disadvantage

Main findings

Clinical outcomes

No significant differences in perinatal morbidity were found between the two study groups, as measured by Apgar scores <7/5 minutes; <9/5 and <7/1 minutes, the total number of NICU admittances, NICU admittance >48 hours, neonatal asphyxia and neonatal readmission to hospital.

FMU women compared to OU women were significantly less likely to experience complications / morbidity such as dystocia, intrapartum fetal-pelvic complications, abnormal fetal heart rate leading to action, occipital-posterior position of the infant at birth, shoulder dystocia, post-partum haemorrhage >500 ml and postpartum mammary complications.

Furthermore, FMU women were significantly less likely to experience major birth interventions, including caesarean section, instrumental delivery, oxytocin augmentation, intrauterine palpation and perineal suturing. They were also less likely to have epidural analgesia but more likely to use water immersion for pain relief.

Overall, an FMU woman had significantly increased likelihood of a spontaneous, uncomplicated birth with good outcome for both herself and the child compared to an OU woman. The likelihood of intact perineum, water birth and use of an upright position for birth was also better for FMU women. Incidences of meconium-stained amniotic fluid, 3rd-4th degree perineal tears, severe postpartum haemorrhage, and use of uterotonics showed no difference between the two study groups.

For the two potentially vulnerable groups in the study, disadvantaged women and primiparas, the effect of birthplace on perinatal outcome did not differ, while the FMU women had a significantly higher likelihood of spontaneous, uncomplicated birth and water birth and a significantly lower likelihood of augmentation of labour and epidural analgesia in comparison to the OU women with the same level of disadvantage or parity. Moreover, for FMU primiparas the likelihood of caesarean section, instrumental delivery and hospital readmission was also significantly lower in comparison.

In all cases, FMU women without post-secondary education had comparable and, in some respects, favourable outcomes when compared to OU women with the same level of education. The findings suggest that the favourable results of FMU care compared to OU care apply for both disadvantaged women and primiparas.

Birth experience and care perceptions

FMU women had significantly better birth experiences and better care satisfaction than did OU women.

Most patient-centred elements, including information, the feeling of being listened to, and the opportunity to participate in decisions about care were rated significantly higher by FMU women than by OU women; moreover, FMU women perceived their midwives as more supportive of themselves and their partners/birth companions and more attentive towards their psychological needs and wishes for birth. The FMU midwives were also likely to be present when wanted and to ensure good information.

There were no significant differences in the women's perception of loss of either internal or external control, the support provided by their partners, the usefulness of the midwife's suggestions for pain relief, and opportunities for undisturbed contact with the newborn.

Among OU women, significant, negative effects of low-level education and low-level employment were found in relation to women's birth experience, and patient-centred care elements such as midwifery support of the woman and her partner, feeling of being listened to, and consideration for birth wishes. OU women with a low level of education also gave significantly more negative ratings for care satisfaction, presence of the midwife when wanted and information.

In the FMU group a significant, negative effect of low education was found for information and the feeling of being listened to. No significant, negative effect of low-level employment was found for any outcome; rather, for several outcomes the direction of the findings was the reverse, with a positive correlation with low-level employment.

No effect of education or employment was found for participation in decision-making, attentiveness towards psychological needs, suggestions for pain relief, or loss of internal or external control.
No effect of parity was found on women's birth experiences.

FMU women had significantly more positive perceptions of their postpartum stay at the unit than OU women and gave significantly more positive accounts of all items measured: the staff's allocation of time for their care, the opportunity to rest, staff care for women's own needs, and staff support of breastfeeding and general care for the infant.

No difference was found between study groups in women's perception of postnatal care from health visitor or infants being fully breastfed when 28 days old.

Study strengths and limitations

The strengths and limitations of the present study are discussed in all three papers, which report different aspects of FMU care. The key points are presented and further discussed below.

Strengths

This study is one of the largest prospective, controlled studies of FMU care ever performed, with adequate power to test for its primary outcomes. The study adds to the very limited body of evidence that concerns both clinical and psycho-social outcomes of FMU care. It gives a major contribution to our knowledge of the reduced maternal morbidity in FMUs and the favourable outcomes of FMU care for disadvantaged women and primiparous women.

Overall, the strengths of the study relate to three aspects of the work, the data, the sample and the settings, and they are thus common for the three papers.

Study data

The application of recent, project-specific data of high quality, relating both to clinical outcomes and socio-economic factors, represents a major strength of our study. It is also noteworthy that few data are missing. Apart from a limited body of FMU data collected in 2004 (discussed below), data from both study groups were collected prospectively. Furthermore, the internal validity of the study is strengthened by the complete inclusion of all eligible women admitted to one of the FMUs during the study period, with no loss to follow-up. There are several reasons for this favourable conditions; foremost are the comprehensive nature of Danish medical records and patient registers, and our liberal legislation on use of patient data for research, allowing inclusion of patient data in purely observational studies*** without informed consent from patients. For comparison, only three thirds of the participating units and trusts in the Birthplace of England study were able to include 85 % or more of the eligible women [182]. In otherwise comparable studies of FMU care, no outcome data were available for 7.3 % [122] and 20.7 % [126] of the eligible women.

*** Denmark has ratified the Helsinki Declaration [180] and international conventions such as the European Council's Declaration on Human Rights and Biomedicine [181]. Thus, in contrast to observational studies, all clinical trials and experiments involving human biological material must be approved by the Danish National Ethics Committee and seek informed consent from participants [171].

Study samples

Although selection criteria may vary between settings, FMU care is generally intended for women at low risk of obstetric complications. However, women with risk factors may also be accepted, or invited, into some FMU settings. The inclusion of women with obstetric risk factors in studies of midwifery units is thus not uncommon [122, 126, 131, 183] although it complicates the interpretation of study findings.

For both groups in the study, women were prospectively defined as being at low risk of obstetric complication at the start of care in labour on the basis of the strictly identical, multidisciplinary criteria applied in the study.

The selection criteria excluded women with obstetric risk factors such as a previous caesarean section, preterm (<37.0 weeks) or post-term (>42.0 weeks) pregnancy, and high blood pressure and thus protected against confounding introduced by differences in risk factors between the two study groups.

The inclusion of women at the start of care in labour allowed for the participation of all eligible women in study, including women who made a late decision on the place of birth. Even more importantly, it minimised the number of cross-overs between study groups that is known to cause underestimation of a true difference [151, 152]. Analysing by *intended* rather than actual place of birth ensured that complications and other conditions leading to transfer from the FMUs were not attributed to the OU groups or units and that risk assessment and safe transfer (key elements of FMU care) were taken into account in the comparison of ratings for quality of care in the two different settings [152, 184, 185]. Identical inclusion principles were applied in the recently published Birthplace of England study [182, 186] , while participants in the two other fully or partly prospective[†††] studies of FMU care were included during pregnancy [122, 126].

Study settings

Of the three existing controlled studies of FMU care, two were conducted in the United States [122, 123] and one in Canada [126]. Rather than a comparison of two established services, the Canadian study was an evaluation of an experiment involving the introduction of midwifery care [187, 188]. As midwifery care is not a fully accepted part of mainstream maternity care services in the USA and Canada, controversies between provider groups are not infrequent [188], and women's ability to pay may influence their access to and choice of intrapartum care. Such conditions increase the risk of poor communication between

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††† Fraser et al included FMU participants prospectively while controls were included retrospectively.

provider groups, lack of teamwork or unclear criteria and pathways for referral and transfer, all of which constitute serious threats to the safety to women and infants [189]. Moreover, as discussed in Paper III , the condition may negatively influence the care and practices of FMU midwifes [95]. The settings of those studies were thus less than optimal.

Taking into account that there are several well-established benefits of midwifery care, as documented in a 2008 Cochrane review, it is essential that FMU care is compared with another model of midwifery care. Comparison with a consultant-led care could induce confounding by difference in care provider. A full exploration of the potential benefits and harms of FMU care can take place only when these factors are taken into account as they are in the present study.

The organisation of maternity services in the North Denmark Region could be seen as a "natural experiment" offering an opportunity to study FMU care in a standardised environment. Not only did midwives lead care for low-risk women in all birth setting, they were also employed by the same regional authority, worked on the basis of the same guidelines for good midwifery practice and participated in the same training programmes to maintain and develop their medical skills. Care provider differences were therefore minimal.

With all low-risk women being offered free choice of birthplace (OU, FMU or home) as well as the same free "packet" of maternity care services, confounding by women's ability-to-pay or differences in antenatal care would be of no concern.

After the carefully planned transformation of the region's two smallest maternity units into FMUs, the region provided an excellent setting for a study of FMUs as part of mainstream services in that it gave an opportunity to disentangle the effect of indented birthplace from the effects of different providers and of different health care models (private / public care).

Limitations

The primary limitations of this study are its non-randomised design and the unexpected closure of the participating FMUs. Each of the two limitations is discussed separately in connection with the study of clinical outcomes and the study of women's experiences. This is followed by a description of other limitations to the work on clinical outcomes and inequity of care. Finally, a specific limitation in relation to the study of women's experiences is discussed.

The study design

As discussed in the introductions to this study overview and in Paper I, it would have been preferable to conduct a randomised, controlled trial (RCT) of care in FMUs versus care in OUs, but was considered unfeasible due to women's strong preferences in the choice of place of birth and the limited number of FMU births. A cohort study was therefore judged to be the most robust study design.

The internal validity of a study, and thus its level of evidence [146], may be defined as the extent to which the observed differences in outcomes between two comparison groups can be attributed to the intervention rather than other factors [151, 152]. As this study was non-randomised, participants were not allocated by chance to the comparison groups. This implies that there may have been factors that determined whether a participant received an intervention which lead to differences in the composition of groups on both measurable and non-measureable factors relating to the outcome.

For the present study, precautions were taken as recommended in the literature to minimise selection bias and confounding: 1) identification of confounding factors through literature study, 2) restriction of the study sample (to low-risk women) and 3) close matching of primary participants and controls on nine important, potentially confounding factors [152-154, 190, 191]. On the basis of this approach, two well-defined and comparable groups of women (cf. Paper II, Table 1 and Paper III, Table 2) were created. As described above, matching was judged to offer benefits over multivariate statistical analysis for this particular study [153]; the successfulness of the matching was confirmed by the results of a supplementary analysis adjusting for the matching factors. However, in a non-randomised study such as this, the possibility of persistent residual confounding or confounding by unknown factors cannot be ruled out. In the perspective of future research, it is pertinent to note that although the effort undertaken in individually matching the 839 primary participants with controls was very worth-while for this cohort study.

FMU closures – impacts on study of clinical outcomes

As described above, the unexpected closure of the two participating FMUs constituted a major challenge to this study by reducing the strength to detect differences between the study groups. A re-calculation of study power nevertheless demonstrated a very limited loss of power after the careful inclusion of 289 eligible FMU women, who had been admitted to one of the FMUs in 2004 (cf. P50). The actual power to detect a difference between study groups is reflected in the confidence intervals reported for all outcomes (Paper I, Tables 2 & 3; Paper II, Table 2 – or the findings section of overview).

As the delayed data collection for these participants posed a risk of introducing bias in the study, the inclusion of 289 FMU participants who had given birth in 2004 was thoroughly considered. On the basis of expert advice it was deemed that the good quality of patient records, the collection of individual and project-specific data, and use of exactly identical inclusion criteria justified the decision. Furthermore the unit's internal statistics were monitored for changes in clinical practices or use of technology and detected none. A subgroup analysis of 2004 data was performed to reveal potential differences between these data and the main body of data, and reassurance was provided by the finding of concordance between the analyses of the two bodies of data.

The inclusion of the 2004 FMU data had the consequence that the performance of the Frederikshavn FMU was evaluated from its opening day. A new service may be somewhat underperforming in a start-up phase, and the inclusion of data from the first day of the FMU may thus show a slightly misleading picture of the quality of the service. In this case it was considered defensible to include the data as the regional authorities and the FMU staff drew heavily on the knowledge and experience obtained during the start-up of the region's first FMU in Hobro. The midwives at the new FMU were experienced staff who had been employed at the former unit and were well prepared for the challenges they were to meet. Additionally, there was close cooperation with the midwives at the nearest OU. The underperformance may be reflected in the transfer rate from Frederikshavn FMU. As seen in Figure 5 the transfer rate for its first year was high and showed a steady decline during the study period. The inclusion of 2004 data in the FMU group is thus unlikely to have caused any bias in favour of the FMU group.

FMU closures – impacts on study of women's experiences
The sub-study on women's birth experiences was the study that was most severely affected by the unexpected reduction of the study sample caused by the FMU closures. It meant a cut in the projected sample size of this study from 830 to 217 women in each group. As this was the first controlled study of Danish women's birth experiences and care perceptions by place of birth, the estimates used for calculation of the appropriate sample size for the questionnaire survey had to be based on regional reports [158, 192] and literature study. The estimates used were conservative; with the originally planned sample size of 830 women, the study had power to detect minor changes of a magnitude of 3-5 percentage points between study groups. This was done to take into account the uncertainty about what response rate could be achieved and the fact that, in this study, differences between women's experiences in two midwifery-led care models which shared the aim of providing individualised, patient-

centred care would possibly be smaller than in prior studies that had compared a midwifery-led care model to consultant-led care [139, 193].

As is evident from the reported P-values in Paper III, Table 3, and the quite narrow confidence intervals accompanying the estimates on dichotomized data (in this overview presented in Table 9) the study retained adequate power to detect clinically relevant differences between study groups despite the dramatic sample size reduction caused by the FMU closure.

Overall, the lack of power to detect rare outcomes is an important limitation of this study that is related to the fact that perineal mortality and severe perinatal morbidity is very rare in a sample of well-selected low-risk women as this. In the present study both groups had even fewer infants than estimated with an Apgar score <7/5. As a consequence, the confidence intervals for this primary outcome are the widest in the study; all other confidence intervals are fairly narrow. To aid the interpretation of this important outcome, several additional perinatal outcomes are reported in Paper I (Table 2); Figure 2 in this overview gives a visual presentation. Furthermore, a presentation of all cases of adverse outcome is provided in Paper I, appended Table C.

Limitations – clinical outcomes and social inequity study (papers I & II)

It is an overall limitation of the study of clinical outcomes and social inequity that it was inadequately powered to detect rare outcomes. This is precluded by the rarity of such events in a low-risk population. Apart from documenting that the rate of adverse perinatal and maternal outcome was low, this study provides no answers to questions regarding perinatal mortality, severe neonatal morbidity such as encephalopathy, maternal mortality and cases of severe maternal morbidity such as intrauterine rupture or severe postpartum haemorrhage. Although the Birthplace in England study [182] provides important insights into these questions, not even this study with its more than 65,000 low-risk women have been fully able to answer such questions.

In the present study, the proxies used for perinatal/neonatal morbidity (Apgar score, admission to NICU and neonatal readmission) are exposed to measurement subjectivity. The chosen outcomes are, however, commonly used as clinical quality indicators in studies of perinatal outcomes.

The study was powered to detect all primary as well as several secondary outcomes; in general, the confidence intervals for the outcomes reported are relatively narrow. However, due to a slight underestimation of the incidence of the rarest outcome, Apgar score <7/5, confidence intervals for this

important outcome are quite wide. To aid the interpretation of the key result, eight additional perinatal outcomes were reported in Paper I, Table 2. As mentioned, most of these are presented in Figure 2 in this overview, furthermore, a description of cases of adverse outcome was provided in Paper I, appended Table C. Paper I also discusses the uncertainty of outcomes stemming from two incidents in the FMUs: 1) the performance of a caesarean section against protocol, and 2) the birth of an infant with severe congenital malformation.

In the elaborative analyses of the impact of social position and parity, confidence intervals were relatively wide for Apgar score <9/5 min, infant readmission and water birth.

Strengths and limitations – the questionnaire survey (Paper III)

This work is one of the few existing studies of women's birth experiences and care perceptions in FMUs which use a controlled design and prospective inclusion of participants. It is solidly based on previous qualitative studies of FMU care and the wider evidence base of both qualitative and quantitative studies of women's birth experiences and the quality of care (cf. Paper III). Still, the choice of a quantitative design for the investigation of highly personal, complex phenomena can be contested [168]. The chosen design allows for quantification and aggregation of women's experiences and for statistical comparison of the evaluation of different models of care while it does not provide insight into the complex priorities underlying women's choice of either FMU or OU care that may influence their birth experiences and perceptions of care.

In 2005, when the sub-study on women's experiences was planned, a validated questionnaire that fitted the study aim to investigate birth experience, care satisfaction and patient-centred care elements was not found. As discussed in Paper III, a questionnaire that has not previously been validated may produce less reliable information than a questionnaire that has already been tested in different settings. Comparison of findings between studies is also more difficult.

The construction of a questionnaire, on the other hand, had its advantages as the process provided the opportunity to ensure a close fit with the study sample and enabled a further development for use on a wider scale among Danish women (or other populations). After a rigorous study of the methodological literature and literature on women's experiences, the questionnaire was developed and validated by use of both qualitative and quantitative techniques. Our statistical analyses indicated that high internal

content consistency and reliability were achieved. The questionnaire was generally very well received by the women, which was attested by the high response rate (86 %).

The response rates for women with Danish as their second language and for single mothers were, however, far lower than expected, and the under-representation of the two groups of potentially vulnerable women is a limitation of the study. This is a recognised factor in studies collecting data by the use of postal questionnaires [46, 167]; the problem is typically eliminated by excluding non-native speakers from the study [162]. In this study where medical data on all eligible women were available, it was found appropriate to give all women the opportunity to evaluate their experiences and the care received. Translation of the questionnaire was outside the limits of the study as the represented range of first languages was very wide. Our data furthermore indicate that we may in general have overestimated these women's Danish skills. Seen in retrospect, more support, especially of women with Danish as their second language and single mothers (e.g. home visits by a survey interviewer) may have secured a more balanced participation in the study.

FMU care contributions to low-risk intrapartum care safety and quality

Below, the study findings and their contribution to our knowledge are discussed within the overall framework of the definition of quality in health care services on which this study is based[99]. For the purposes of this overview, the definition is adapted to the requirements of the present study and in the following focus will be on the four dimensions found to be most relevant to this study: safety, effectiveness, patient-centredness and equity.

Safety

Safety is a key issue for those receiving and providing care in FMUs, and this is reflected by the debates over FMU care. Care in FMUs should be based on safe procedures that support midwives in the identification of women for referral or transfer to OU care, facilitate smooth and timely transfer without loss of important information, ensure continuity of care, and enable midwives to deal adequately with obstetric emergencies. Furthermore, FMU care depends on OUs/NICUs to have safe systems for receiving transferred women/infants, ensuring continuity of care end avoiding any delays of necessary treatment.

Results concerning the safety of FMU care are presented and discussed in Paper I and II. Overall, the incidence of adverse perinatal outcome is low in both settings under comparison and the results show no indication of FMU posing a safety risk to infants. For all primary and secondary perinatal outcomes

measured, no difference in perinatal morbidity was found for infants of mothers intending to give birth in an FMU compared to women intending to give birth in an OU. The same result was found for infants of disadvantaged women and primiparas. The findings are in full agreement with those of other studies of FMU care [122, 123, 125, 127-129, 194-200], including the findings of the Birthplace of England-study[182], which recently confirmed the safety of FMU birth for primiparas and their infants as well as for low-risk women in general.

Comparing FMU and OU women, the former were significantly more likely to have an uncomplicated, spontaneous birth with good outcomes for mother and infant and to avoid perineal tearing. Furthermore, the likelihood of birth complications such as dystocia, intrapartum fetal-pelvic complication, occipital-posterior position of the infant at birth, shoulder dystocia and postpartum haemorrhage < 500ml and postpartum mammary complications was significantly reduced. Severe maternal morbidity was very rare; one incident occurred in the OU group.

Birth complications are seldom among the variables measured in studies of the impact of place of birth. This study gives an important contribution to our knowledge of clinical outcomes of FMUs by reporting outcomes for several birth complications and the finding of a significant reduction of fetal-pelvic complication, abnormal fetal heart rate, fetal occipital-posterior position at birth, shoulder dystocia and postpartum mammary complications among FMU women.

Safety-supporting systems in FMUs

It is widely acknowledged that women with a high risk of complications should be recommended OU birth [104, 115, 201, 202]. The difficulty then lies in defining who is at low and who is at high risk [203-205]. Guidelines for referral and transfer vary greatly, a 2010 study of English FMUs found that the general quality of clinical transfer guidelines was poor [206]. As primiparous women have higher complication rates and higher transfer rates than do multiparous women, FMU care for this low-risk group is particularly controversial. Not all FMUs accept primiparous women [117].

In 2003 Mahmood et al.'s evaluation of an FMU in Scotland documented that 22 % of the women were transferred and that in 9 % of births neonatal resuscitation was required, which lead the authors to call for a higher level of medical services in FMUs, as they found the present antenatal criteria unable to determine who will remain at low risk throughout pregnancy [203].

As the evaluation was uncontrolled, any firm conclusions as to the safety of the evaluated service are precluded. It cannot be contested, however, that Mahmood and his co-authors are right: even with strict and evidence-based selection criteria as those outlined in the NICE Intrapartum Guidelines [201] and applied in this study, unexpected complications are not unlikely to arise in low-risk births. But as documented in the present and other studies, this does not mean that women who are defined as low-risk and who intend to give birth in an FMU care have poorer outcomes when they are compared to women with the same low risk status who intend to give birth in OU care. But what is all-important is the ability of FMU carers to detect complications and signs of such and to respond adequately.

The overall transfer rate of 14.8 % found in this study is comparable to transfer rates reported by other FMU studies [116], which have ranged between 5 and 22 %. However, our result masks a large difference in the transfer rates recorded for primiparous and multiparous women and a decline over the study period from 18.7 % to 9.7 % (cf. Figure 8) This result is attributable mainly to the development in primiparous women's transfer rates.

As part of quality assessment and development[207], all cases of obstetric emergency occurring in the FMUs and all FMU transfers were routinely subjected to multidisciplinary audit. Feed-back to the FMUs was given by the OUs, and in many cases also by the women themselves as re-transfer to the FMU for postpartum care was not unusual. Widely used in Danish obstetrics since the 1990s, audits have proved to be a valuable tool for quality assessment and development [207]. In the North Denmark Region they have stimulated communication and multidisciplinary discussion between care providers and units to support continuous professional development as well as to streamline transfer procedures. Both these factors seem very likely to have contributed to the safety of women and infants in the FMUs and to be associated with the substantial drop in transfer rates, with no increase in adverse events that occurred during the study period.

Except for the infant with severe congenital malformation, all FMU infants with an adverse outcome were born in an OU after timely transfer. However, it is concerning that all three cases of NICU admission >7 days occurred in the FMU group (born 3-7 hours after OU admission). As the safety procedures described above demonstrate the strong focus on transfer criteria and transfer procedures from FMUs and collaborators, the finding indicates a potential for improvement of patient safety in relation to the hand-over of FMU women. In unison with other studies who have pointed out transfers and hand-overs as potential risk situations [183], we strongly advocate further study in this field.

With the establishment of FMUs in sparsely populated areas, concerns has been expressed that midwives whose jobs involve working alone and caring only for a small number of women may have difficulty maintaining and developing their competences. A recent study from Scotland found that rurally based midwives' perception of their own competence was at the same level as that of urban midwives and that they were more motivated for continuing professional development but they felt their decisions to be under scrutiny by urban colleagues [208].

To meet these challenges and ensure their ability to identify and take adequate action in emergency cases, all FMU midwives were required to have a minimum of two years of practice experience and to undergo continuing multidisciplinary mannequin training in dealing with obstetric emergencies, including ventouse delivery. Their skill maintenance was also supported by factors such as their escort of transferred women to the OUs and (if possible) and the continued care under supervision of an obstetrician. Their obligation to assist the nearest OU in cases when staff and occupancy made this opportune also played a part in supporting relations and teamwork between FMU and OU midwives and had the effect of precluding against stereotyping and marginalisation of the FMU midwives. These activities must be considered crucial for the FMU midwives' attention giving to the maintenance and development of midwifery skills and the cooperation and relationship between FMU and OU midwives to the safety of care in the regional FMUs. The data give no indication that the safety of either infants or women in the FMU group was compromised by inadequate response to obstetric emergencies by FMU midwives. Paper I, discusses the one incident where safety procedures were not followed and presents a sensitivity analysis on the assumption that the infant would have had an Apgar score of <7/5 had a caesarean section not been carried out against protocol on the community hospital hosting the FMU. The analysis showed no difference between study groups, and the overall finding was thus not affected. It is therefore concluded that the FMU care concept investigated in this study appears to offer good safety.

Effectiveness

Effective care is based on systematically acquired evidence and it requires health professionals to provide care based on scientific knowledge to all who may benefit from it and avoid care that is more likely to harm than help. Effective care is closely linked to an evidence-based practice that integrates clinical expertise with the best available research evidence and takes into account patients' values[99]. However, determining what effective care is may be is less straightforward than it would seem.

In childbirth perinatal and maternal morbidity are key measurement of effectiveness as well as safety. As a result of the medicalisation critique and the summarised debates over childbirth, also the use of interventions has become a key measurement. Concern for adverse events is inherent in the technocratic paradigm and its pathogenic perspective on childbirth and prompts confidence in the feasibility of improving maternal and perinatal outcomes through intervention [70]. Although even the strongest proponent of holistic childbirth is likely to appreciate the possibility of caesarean section when the life of a women or infant is clearly at stake, the use of preventive interventions such as caesarean section for "humane" reasons and routine episiotomy/forceps delivery to reduce asphyxia/perinatal death [209, 210] are apt to cause controversy between two very different perspectives on high-quality care.

As discussed earlier and also in Paper III, "technocratic" childbirth and the choice of for example induction of labour or a caesarean section may be perceived as empowering or liberating by some women. While this may cast some light on why the proportion of women accepting interventions is rising[43] it may also be seen as a negative expression of what Illich would call cultural iatrogenesis that lead women to lose their ability to deal with childbirth and therefore accept health care "designed on an engineering model" [67]. As discussed in the theory section, a post-structuralist perspective may also imply a perspective on the women as passively influenced by a disciplinary power, providing guidelines on how she should understand and think about childbirth, but instead of trying to look for someone to blame for this development such as the medical profession, we would have to focus on "the myriad complex factors" [211] that have permitted this positive attitude to childbirth technology to occur – and why and how some women may benefit from it while others do not.

While the post-structuralist perspective is helpful in informing our understanding of women's childbearing experiences and priorities, its inherent relativism and rejection of "objective" knowledge, lack of moral norms and thus reluctance to, in the words of Annandale "evaluate the nature of the effect of power upon the body" [211] (p.41) is troublesome for those trying to answer concrete questions on health care: for example do one treatment offer advantages over another, and what services or treatments should be offered, to whom and why - or why not?

The major contribution to of the third wave, post-structualist inspired childbirth critique was an increased acknowledgement of women's experiences of childbirth as complex and diverse; some find a technological approach to birth empowering, other adapt a compliant role in the attempt to achieve

other ideals and desires[212], while others associate it with a higher risk of negative birth experience, postpartum distress or depression, thus making them wary of future childbirth [18, 41, 213]. The following discussion of the quality of FMU care returns to the field of evidence-based medicine.

The use of interventions and pain relief as measurement of quality

As argued in the background section, birth interventions have benefits as well as harms, also from a medical perspective. Interventions undoubtedly reduce maternal and perinatal mortality, it is however controversial to what extent interventions should be used in that side effects are unavoidable and may induce further important risks. For example, caesarean section increases the risk of hysterectomy due to postpartum haemorrhage, cardiac arrest and the incidence of NICU admission [214]. Instrumental delivery increases the risk of severe perineal trauma, fetal facial and scalp injuries and cephalhematoma [215, 216]. It could be added that evidence is conflicting for a variety of other outcomes as the general level of evidence is low.

As birth interventions are most frequent in connection with complicated labour, it is difficult to distinguish the effects of an intervention from the condition that prompted its use. The use of interventions is therefore an area in which it has proven difficult to provide good evidence for the guidance of practice, as Searle notes [217]. Low intervention rates should be accompanied by low rates of perinatal and maternal morbidity.

Epidural analgesia, the most widely used form of medical pain relief in high- and middle-income countries, is an equally complex measurement as its use is associated with complicated labour as well as with childbirth interventions. As documented in a Cochrane review, epidural analgesia is associated with lengthening in the duration of births, and the incidence of oxytocin augmentation and instrumental delivery. Effects on minor instances of maternal morbidity such as fever and low blood pressure are also noted while no effect has been documented for perinatal outcomes [218]. Women may feel dissatisfied if a preferred method of pain relief is not available [219] or report their birth experiences as more satisfactory when experiencing low pain levels [84, 159, 220], which has led some to argue that effective pain relief is essential to a positive birth experience [221], but no evidence of a positive association between epidural analgesia and birth experience has been found [218]. Adherents of a holistic model of childbirth have made a strong claim that labour pain is meaningful, a claim which is supported by evidence to the effect that having coped with pain is a rewarding experience for women that leads to a feeling of accomplishment and a higher level of self-esteem [43, 222].

On the basis of this evidence, frequent use of epidural analgesia in low-risk childbirth may be considered non-effective care, as proponents of holistic childbirth certainly do. On the other hand, pain being an extremely complex and subjective phenomenon, the mentioned harms should be balanced against the woman's individual needs and her request for effective pain relief. Evidence does, however, suggest that administration of epidural analgesia is strongly related to place of birth and the cultural norms among staff [223]. This fact lends support to including epidural analgesia among outcome measures.

In a way that mirrors the severe criticism of the frequent use of interventions and epidural analgesia in low-risk childbirth, fierce opposition and controversy has surrounded the use of low-technology procedures such as use of upright positions for labour and birth, immersion in water for pain relief during labour and, in particular, water birth [224, 225]. As with many medical interventions and procedures, the use of water and upright position for birth were advocated by women and care providers long before their effectiveness was tested in RCTs. They were believed to reduce pain, shorten labour and increase women's sense of control. While water immersion during the first stage of labour and upright position for birth have later been documented in Cochrane reviews to provide more benefit than harm [45, 226, 227], more evidence is needed to judge the harms and benefits, and thus the effectiveness, of water birth, especially for the infant [45]. Although water birth can thus not be deemed effective care, it nevertheless continues to be popular among many women and care providers. In Denmark, the National Board of Health makes no mention of it in recommendations on intrapartum care [202], still in the majority of maternity units, including all the participating units in this study, water birth is an option for low-risk women. Differences in user-influenced outcomes such as water birth, epidural analgesia, water immersion, and upright position for birth may be a reflection of women's preferences but also of their opportunity to exercise an informed choice about care aspects that are formally open to them, but are in practice regulated or restricted by care providers, including midwives [142].

The present study shows that FMU care compared to OU care significantly increased the likelihood of the ultimately desired outcome: uncomplicated, spontaneous birth with a good health outcome for mother and infant of women. Internationally, the category "vaginal, spontaneous birth", which is typically easier to extract from routine birth data, is often reported as an expression of positive birth outcome. This is the reason that this outcome is presented in Paper I. Furthermore, FMU care was associated with significantly lower incidences of all major interventions, including caesarean section. These findings show good correspondence with the findings of the two largest of the existing controlled studies of FMU birth [122, 126], of which one compared prospectively included FMU women with

a control group of retrospectively matched OU women. Other studies of FMU care are also supported by the present [123, 127-130, 196, 199, 200, 228]. While all studies of FMU care have focused on perinatal outcome, interventions and maternal morbidity, e.g. perineal tears and postpartum bleeding >500ml, few have made a comparison of the incidence of intrapartum complications. In the present study, these complications were also found to be significantly reduced (abnormal fetal heart rate, dystocia, intrapartum fetal-pelvic complications, shoulder dystocia, occipital posterior position at birth).

After the main clinical result of the present study were published (in Paper I), the results were confirmed by the landmark Birthplace in England study [229], which included 11,280 FMU women in its extremely large prospective cohort study. Significant decreases in admissions to higher-level care (a proxy for serious maternal morbidity) (OR 0.32; 0.13-0.84) and in the number of caesarean sections (OR 0.32; 0.24-0.42) among FMU women compared to OU women were also reported there. Also in agreement with the finding of the present study, the Birthplace in England study found no difference in perinatal outcomes (perinatal mortality/severe morbidity OR 1.22; 0.76-1.96). The present study and the larger English study were comparable by their inclusion of women at the start of care in labour, the rigorous criteria excluding all but women at low risk of complication (NICE Guidelines on Intrapartum Care [201]) and by basing analysis on an intention-to-treat principle. Denmark and England have comparable systems of public health care in which all frontline intrapartum care is provided my midwives. The results of the two studies are judged to be highly generalisable.

In the present study, immersion in water, water birth and upright position for birth were used significantly more often in the FMUs than in the OUs, while perinatal morbidity was not increased and perineal first/second degree tearing was significantly lower (no difference for third/fourth degree tears). On the basis of the above discussion, the model of FMU care provided in the present study must be judged to provide highly effective care compared to OU care.

Patient-centredness

As described in the background section the philosophy of patient-centred care is informed by insights originating from within the field of medical anthropology but health psychology and medical sociology have also contributed to this line of thinking. Patient-centred care focuses on patients' experience of illness and health care and on how organisations meet, or fail to meet, the needs of the individual patient [99], or birthing woman. The importance of empathy, compassion and responsiveness to the patient's or woman's needs, values and preferences has gained widespread recognition, lately also within the field of evidence-based medicine, where consideration of the "patient's unique values and

circumstances" [146] now forms part of the definition of evidence based medicine, thus underlining that patients should be involved in determining what care is best suited to meet their individual needs [230].

While the philosophy of patient-centredness can be seen as a reflective response to the medicalisation critique and a strategy for focusing on the "humanisation" of care, the recipient of care is still seen as a patient with needs. An important ideal it that of shared decision-making, that decisions should be guided by the individual patient's values and preferences as well as professional's knowledge of "means and consequence", to use Wackerhausen's term [86]. Investigation of patients care perceptions are relevant from this perspective, because they evaluate how well patient's needs are met. In this tradition, the "target" population of the questionnaire tool should be involved in its development, and the evaluation of patients' perspectives is seen as essential in order to assess and develop the quality of care and real patient influence on care as well as what aspect of care that should be evaluated [98, 99].

The present study of psycho-social outcomes of care, reported in Paper III, places itself primarily within this tradition. Many of the items in the questionnaire tool relate to key aspects of patient-centred care as defined by Gertis et al. [98]: respect for the patient's values, preferences and expressed needs, emotional support and physical comfort, information and communication and the involvement of relatives in care. The concern for such aspects is reflected in questions regarding the perceived supportiveness of the midwife, opportunity to receive support from her when needed, attentiveness towards the woman's psychological needs, the feeling of being listened to, the support provided by staff for the woman's birth companion, etc. (Cf. Table 6, listing questions in the questionnaire tool.)

The autonomy of patients are even more strongly emphasised where concepts of health consumerism are supported by market theory, which have their stronghold in countries where private health care systems are dominant. But the inspiration of health consumerism is now apparent in publicly financed health care systems where they were introduced to improve efficiency and quality through increased competition between hospitals and providers [231]. In Danish health care, increased consumerism was introduced in an 1992 act giving patients a free choice of hospital [231]. While the choice of place of birth is a key issue in the British public health care system [103, 114], Danish maternity services have been moving towards 100 % OU births since this goal was introduced by the childbirth reform in the 1970s that was described earlier. In the Danish debate over childbirth, concern for women's choice and control has been voiced primarily in the "third wave" of childbirth critique, mainly as arguments for increased

access to epidural analgesia and caesarean section without medical indication and joined forces with individualist feminist claims over women's rights not to have labour pain enforced on them [232].

The health consumerist perspective marks a contrast to the view of the patient as someone who is dependent and passive, a view implied in the medicalisation critique. Instead the patient is positioned as an autonomous, active consumer of services who gains influence, if not control, over services through her choices. Critics have argued that patients can never obtain full autonomy over their situation because of the anxiety, pain and uncertainty inherent in their condition. The ability of patients to obtain sufficient information and knowledge to actually be able to make informed decisions is also questioned. The role of active consumer may as a result be accessible for only the most resourceful patients [233, 234], which may explain the fact that the non-mainstream choice of home or FMU birth is typically made by well-educated, middle-class women [235]. Several studies have, however, shown that "consumerist" issues (e.g. women's choice and control over birth) are important to birthing women [7, 79, 80], and that some women are in a position to act as active health consumers [25, 236]. As the recipient of care in this tradition is seen as a buyer or use of services, many evaluation of patient perspective in this tradition emphasise the concept of patient satisfaction, the availability of choice and control over care. Influence from a consumerist approach to patient perspectives is evident in several questions in this study's questionnaire's, e.g. on loss of control (especially of control over staff actions and things that were done), consideration for birth wishes and opportunity to participate in decision-making.

The survey questionnaire tool in the present study was developed to focus on women's birth experience, women's perception of care elements that may have important impact on their experience as well as satisfaction with care. An important critique against the consumerist approach is that it diverts focus away from care towards the needs of women by directing it towards their opportunity to exercise choice and to feel in control. If active consumerism is expected or even required, it leaves women in a bad position if they are not capable, ready or willing to assume the role of an active consumer. What has also been lost, Lupton notes, is the possibility of surrendering control to care providers [87].

Where childbirth is concerned it may should be seen as a quality of care that the woman can trust the care provider to take over control in the most intense phases of labour, (trust her) to respond to her needs, and, as noted by Wackerhausen, act on the basis of an understanding of the woman's "genuine long term values and goals" [86]. The patient-centred philosophy allows for the patient to occupy a more

passive role in which care providers should try to tailor care to the specific needs and circumstances of the individual [98, 99]. In this perspective, it is acknowledged that patients "differ in their view about how active they wish to be in decision making", and that the individual's preferences may change from one situation to the next.

As discussed in Paper III, the findings of this study provide strong support for FMU care, also when compared to another model of midwifery-led care. It should be noted, however, that comparison with similar controlled studies is limited due to the large gap in knowledge in this field. Of the two cost-effectiveness studies investing patient perspectives, the small American study by Stone (1997) also found significantly better satisfaction with the childbirth experience when comparing the views of 69 FMU women versus 77 OU women [123]. Similar findings are reported in Reinharz et al.'s study from 2000, which reported increased feeling of control over delivery and higher rating of the quality of intrapartum care among women receiving FMU care compared to women receiving OU care [139]. The findings of this study are however also in consistence with a 2010 Cochrane review of AMU versus OU care, which reported a significantly higher number of women in the AMU group to give "very positive" ratings of their perceptions of care [121].

Four studies focusing exclusively on the perspectives of women who had received FMU care have produced very positive accounts of FMU care. Rook's large-scale American study from 1992 reported that 94 % of the women indicated that they would use the FMU for a future birth [131], while a smaller English study of the Edgware birth centre found that 96 % of women would recommend the FMU to a friend and 88 % agreed that FMU care offered advantages over OU care [128]. In their combined qualitative and quantitative study, Watts et al. [137] reported 90 % of the women to be "satisfied with care" and that 66 % "would not change anything". Satisfaction score in the present study was even higher with less than 1 % using negative satisfaction scores. Moreover, in Walker et al.'s study [136] the women said that they felt that FMU care offered a good balance between support and personal control and that they were given relevant choices and were well informed. These results show good correspondence with the results of the patient-centred outcomes measured in the present study.

As a category, transferred women report less positive experiences. Watts et al. found that all the ten women transferred were dissatisfied with aspects of their care [137]; Walker et al. underlined that such women are in a vulnerable situation and need a higher level of continuity than that which they are typically offered [237].

By 2006 when work on the survey of the present study was undertaken, the transfer rate among FMU women had dropped to 9.7 %, an unexpectedly low figure. This fact, combined with the reduction in the planned study sample due the FMU closures, means that the study offers little information on the perspective of transferred women. Despite the complications indicated by their transfer and the inconvenience of transfer itself, ten of the 16 (65 %) transferred women rated their birth experience as very positive or outstanding while 19 % gave negative scores (Cf. Figure 9).

The present study offers new and important insights into patient-centred elements of the two care models being compared. Of the 12 psycho-social care elements compared, eight key aspects of patient-centred care elements were rated significantly more positively by FMU women (e.g. midwife support, availability of support when needed, attentiveness to psychological needs and wishes for birth, feeling of being listened to, and information).

The findings suggest that FMU midwives focused their attention on psychological dimensions of childbirth, good communication and involvement of the women and her partner, thus offering patient-centred, individualised and supportive care. Furthermore, the study showed that women strongly favoured the family-oriented care that the FMU concept of postpartum care offers in comparison to standard post partum care in OUs.

No studies of FMU postpartum care could be identified, but a Swedish study of AMU versus OU care has found no differences between AMU and OU postpartum care but more minor problems relating to breastfeeding among the AMU women. In the present study this picture was reversed, women in the present study were significantly more satisfied with all elements of their care, including the support received for breastfeeding and significantly more post partum mammary complications among OU women compared to FMU women was found in the clinical outcome-part of this study. The excellent results recorded her may have been due to the training in 'baby-friendly' postpartum care received by the FMU staff in connection with the WHO/UNICEF accreditation. The results were achieved in spite of the limited day time opening hours of the FMUs' postnatal wards, which were supplemented by a midwife on 24-hour duty. In contrast, the OU postnatal wards were staffed 24 hours a day.

The tendency of patient questionnaire surveys to elicit very positive responses among the respondents is one of the most important challenges in this field of research [46, 164, 165]. In this respect, the present study is no exception although the questionnaire's sensitivity is indicated by the fact that women's

assessment of care elements and their birth experiences reveal highly significant differences between the FMU and OU groups while outcomes related to aspects with no relation to the type of care provided (e.g. care from the woman's partner and the post partum health visitor) do not show such differences.

As a high number of tests were performed, protection against the risk of significant P-values occurring by chance was sought through Bonferroni correction, which represents a conservative approach to this problem. Although it provides good protection against Type I errors, Bonferroni correction leaves the study slightly more vulnerable to Type II errors, i.e., the risk of underestimating a true difference. This may have been the case in the present study, where for all other patient-centred care outcomes, strong non-significant trends towards more positive results in the FMU group was found.

The comparison of FMU care and OU care shows that the former offered important psycho-social benefits for birthing women and was associated with significantly better birth experiences and higher satisfaction with care. Specific care elements, including information, the feeling of being listened and the opportunity to participate in decisions about care were rated significantly higher by FMU women than by OU women. Moreover, FMU women perceived their midwives as more supportive and more attentive towards their psychological needs and wishes for birth. On this basis, the FMUs studied here are found to have provided higher quality of care as measured by the women's experiences, care satisfaction and perception of patient-centred care elements.

FMU care is a highly complex intervention and present study allowed no further exploration of either FMU culture, the characteristics of the midwives working in the compared settings, or the underlying mechanisms behind their excellent results in helping women to have good birth experiences. The design of the study did not permit us to take into account potentially important factors that may have influenced women's birth experiences, most importantly their expectations of birth and personality-related issues such as antepartum level of anxiety, social support.

In addition to the superior clinical outcomes of FMU care, increased levels of continuity, including greater availability of one-to-one care and continuous support is related to improved birth experiences [27]. Such factors seem to play an important role in the high quality of FMU care documented here. It has been suggested that care providers' job satisfaction and motivation may be important factors for the quality of care [238, 239]. The team model and, as suggested by Walsh [240], the general organisational

characteristic of FMUs may also have contributed to creating an environment in which meaningful and caring relationships between midwives and the women and their families could develop.

Equity

The aim of maternity care services in Denmark is to lend strength to empower and assist the woman and her partner/family in connection with pregnancy, delivery and childbirth so that mother and child will experience the best possible birth process. A further aim is to give support to ensure that the period is experienced as a coherent and natural life process offering opportunities for personal development as well as security [202].

Equity is emphasised as an element of patient-centred care to secure these benefits for all women, infants and families. Health care services should improve the health status of the population in a manner that reduces social inequality in health [99] and thus takes into account socio-economic conditions that, in Raphael's definition, establish the extent to which a person possesses the physical, social and personal resources to identify and achieve personal aspirations, satisfy needs and cope with the environment [241]. Furthermore, equality in care is concerned with securing universal access to health services and ensure that the quality of care offered is independent of individual characteristics such as gender, age, ethnicity, education and location of residence [99].

The overall structure and organisation of health care systems is instrumental in determining how care is provided. It follows that the influence of cultural mores and preferences on professional practises and thinking about care may be easily overlooked. Thus, Annandale and Clark argue that the proponents of holistic childbirth, in promoting home birth, were in effect enforcing a middle class cultural universalism and ignored that many women were not in a position to avail themselves of "alternative" care models, should they have wanted to [62]. But the authors themselves overlook several structural and organisational factors that supported this notion as well as their own universalist assumptions and the fact that they were basing their arguments cultural norms that made access to health care an individual responsibility and consultant-led birth care a tradition.

Equity in health is a normative concept that may find broadest support in countries with comprehensive welfare systems such as the Nordic welfare states [242]. In countries with predominantly private health care systems, debates over equity is often linked to question of universal access to care, in public health care systems the question of access concerns 1) geography and centralisation of care – how to ensuring

people in sparsely populated areas access to relevant services and 2) inequity in the use of services and the quality provided for different social groups.

FMU care take a variety of forms, have different settings but all FMUs offer decentralised, low-technology care on the basis of a humanistic philosophy [179, 240]. When established in sparsely populated areas, as those studied here, they address the issue of equality in care provision by offering care to women in their local area closer to home. The quality of this offer is examined in the present work. Social inequity in birth outcomes is an acknowledged problem in Denmark although it has a comprehensive welfare system and offers extensive free health care services, with the result that it is among the countries with the highest degree of social equality [242]. The levels of perinatal and maternal mortality and morbidity are also among the lowest in the world [243, 244]. In contrast to its neighbouring country, Sweden, Denmark has been unable to narrow the inequality gap in birth outcomes. Rather than diminishing social difference, Denmark has seen rising inequity in outcomes such as birth weight and infant mortality [245, 246].

The FMUs in the North Denmark Region were opened in areas characterised by what are, for Denmark, low levels of education and income and high levels of unemployment. Disadvantaged women are consistently reported to suffer increased morbidity and mortality during childbirth [243, 247] when compared to advantaged women, and their infants have higher perinatal and neonatal morbidity and mortality, especially due to low birth weight and preterm birth [247-257]. Furthermore, some studies report that underprivileged women have more negative psycho-social outcomes of birth [18, 19], receive a lower quality of care [23, 24, 140]. When this study was initiated only a few studies had examined birth outcomes for disadvantaged women fulfilling low-risk criteria at term. It was therefore relevant to study the extent to which the effect of birthplace on psycho-social as well as clinical birth outcomes differs by women's level of social disadvantage. Paper II reports the findings of an elaborative analysis of the effect of birthplace on birth outcomes by women's level of disadvantage while Paper III explores the influence of socio-economic factors as part of the overall study of women's birth experiences and care perceptions.

The choice of education as proxy for women's social position is discussed in Paper II. No single measurement is likely to be able to capture the full complexity and meaning of a person's social position but the association between education and birth outcomes is well documented [245, 249, 251-253, 258-260] and believed to be mediated through e.g. employment, economic circumstances and psycho-social resources and constraints [261]. The links between education and women's ability to obtain, understand

and transform knowledge into actions, choices and/or power over own care is of particular importance to this study.

Overall, Paper II documents that the effect of birthplace on birth outcomes does not differ with women's level of education. When women without post-secondary education were compared according to their choice of birthplace, the FMU women were found to have a significantly higher likelihood of a spontaneous, uncomplicated birth and water birth, and a significantly lower likelihood of augmentation of labour and epidural analgesia than the OU women. No differences in perinatal outcomes were detected.

In this restricted sample of healthy low-risk women with spontaneous onset of labour at term after an uncomplicated pregnancy, the positive results of FMU care as compared to OU care were found to hold for women with post-secondary education as well as the potentially vulnerable group of FMU women with no post-secondary education. This finding is an important contribution to the existing knowledge of FMU care, and corroborates the results of a German register study of FMU care [133]. Furthermore, Jackson has reported good overall outcomes of FMU care compared to OU care in a population of low-income women in the USA.

The strict risk assessment criteria used in the study proved useful in defining a group of women with low risk of obstetric complication [201]. As both perinatal and maternal outcomes for women with no post-secondary education intending to give birth in an FMU were similar to or favourable in comparison with the outcomes for a similar group women intending to give birth in an OU, FMU care can be considered to be as appropriate a choice for this group of women as for other women with low risk of obstetric complication.

For the study of psycho-social outcomes, reported in Paper III an unmatched approach to the elaborative investigation was chosen. Women's experiences and care perceptions were explored by their level of education and employment. Overall, significant, negative effects of low education and employment level were identified, but this finding was isolated to the OU group. This group of women reported significantly more negative scores for care satisfaction and their perception of most patient-centred care elements, with the most negative responses given by the most vulnerable group of women with no post-secondary education.

For the women in the FMU group there was no significant, negative effect of a low-level employment on their care satisfaction or patient-centred care elements; on the contrary, non-significant trends in a positive direction were observed. However, for two patient-centred care elements, information and the feeling of being listened to, a significant, negative effect of no post-secondary education was found. This may be taken as indication that there is room for improvement, also in FMU care. Overall, these findings do however indicate a promising potential of FMU care to alleviate the effect of social disadvantage on women's birth experience. It seems that this organisation of care is a promising aspect of public health care, and one which should be further investigated. The potential of FMU care to improve the birth experiences of disadvantaged women has likewise been identified by an study of an impoverished American inner-city FMU [145]. Otherwise this issue is relatively unexplored.

In the present study, a very high percentage of the women who chose FMU care had little or no education (27.4 %) and/or employment (63.8 %). Data on women's educational level are not routinely recorded in the Danish birth register [262] and no examination of the relationship between the choice of FMU care and the women's level of education was possible; still it is evident that the choice of care closer to home and based on a FMU model of humanistic, patient-centred care had appeal for a broader category than the advantaged, well-educated women.

A 2003 WHO report on social determinants of care states that:

> "Life contains a series of critical transitions: emotional and material changes in early childhood, the move from primary to secondary education, starting work, leaving home and starting a family (…). Each of these changes can affect health by pushing people onto a more or less advantaged path. Because people who have been disadvantaged in the past are at the greatest risk in each subsequent transition, welfare policies need to provide not only safety nets but also springboards to offset earlier disadvantage" [263 (p.10)].

Giving birth and forming a family can be seen as one of such important transitions. For advantaged as well as disadvantaged women of low risk of obstetric complications, the findings of this study suggest that FMU care offers important benefits in terms of improved maternal health, improved birth experience and care satisfaction without posing additional perinatal risks. Furthermore, FMU care may have potential to mitigate the effect of social disadvantage on birth experience, and for some women, it may offer such a springboard onto a more positive path.

CONCLUSION

This research has taken a close look at a small maternity care service in a peripheral region of a relatively small country. It would be relevant to ask what knowledge can be generated and to what extent generalisation can take place from such research. De Vries asked himself this question in his study of the Dutch maternity care system, and I concur with his view that such studies allow us to:

> " (…) discover that culture forms and re-forms health practices, a discovery that not only offers a new way of thinking about the organisation of health systems, but also presents policymakers with the possibility of a fresh approach to the development and promotion of innovative health policies" [2] (p.233).

Maternity care services in Denmark are rarely the subject of international discussions, yet the attempt by the health authorities of the North Denmark Region to develop and innovate its services may serve as an inspiration to others. Its focus on how high-quality maternity services contribute to the way that childbirth experienced in a way that recognises the social aspects of birth and important role that a positive birth outcome and experience play in future health and wellbeing of women and families.

In providing an environment where important factors such as care provider, clinical practice, women's access to care, and their ability to pay were fully comparable, the North Denmark Region has offered a rare opportunity to investigate the effect of place of birth.

Implications of study

The findings of this study of FMU versus OU care with midwives as lead caregivers in a public health care system suggest a range of implications that should be relevant to the diverse groups of stakeholders within the field: authorities' policies, professionals' practices, the users of services and the multidisciplinary group of researchers.

Overall, the study showed that the risk of adverse maternal and perinatal outcomes in low risk births in the North Denmark Regions was low and outcomes were generally very good.

Low risk women intending to give birth in an FMU had a significantly increased likelihood of uncomplicated, spontaneous birth with good outcome for mother and infant compared to low risk women intending to give birth in an OU. Infants of women intending to give birth in an FMU appeared

to have the comparable perinatal morbidity to infants of women intending to give birth in an OU while for women intended FMU birth is associated with reduced maternal morbidity, reduced likelihood of childbirth complications, and fewer birth interventions, including about a halving of caesarean sections. The effect of FMU care did not appear to differ with women's level of social disadvantage or parity.

For multiparous women intending birth in an FMU, the risk of transfer to an OU was at a stable 6-9 % all through the study period. For primiparous women, there was an overall risk of transfer at 37 %; this figure did however cover an initial transfer rate of 44.4 % in 2004 that by 2006 had declined to 24.6 % and showed tendency of further decline.

FMU care offered important psycho-social benefits for birthing women and was associated with a significantly better birth experiences and high satisfaction with care, compared to OU care. Specific care elements such as information, the feeling of being listened to, the opportunity to participate in decisions about care were also rated significantly higher by FMU women than by OU women; moreover, FMU women perceived the midwife as more supportive and more attentive towards their psychological needs and wishes for birth.

The location of the FMUs at community hospital in predominantly rural areas offered women in a local area a choice of low-technological, patient-centred care close to home. This offer was accepted by women from a far wider range of social backgrounds than seen in most studies of out-of-OU birth. In assessing this aspect of the study, it is noteworthy that women with a low level of education did not constitute a minority.

Exploration of the women's birth experiences and care perceptions revealed that FMU care has potential to mitigate the effects of social disadvantage on women's birth experience. A similar effect of FMU care was not found where clinical birth outcomes were concerned; advantaged and disadvantaged women found to be benefit equally well from FMU and OU care. The same was true for primiparous and multiparous women, both in terms of birth experience and clinical outcomes.

Overall, the findings of this study that are in line with the results of the Birthplace of England and other well conducted, controlled studies of FMU care, supports a policy of offering women choice of place of birth.

There is need to address the higher intervention rates in the OUs, and this study offers lessons on the quality of FMU care that should be brought to bear on the development of OU care for low-risk women.

In a public health perspective, FMU care holds great potential for the improvement of maternal health and well-being in populations of low-risk women. The strict risk assessment criteria used in the study proved useful in defining a group of women with low risk of obstetric complication and FMU care may thus be considered an adequate alternative to OU care for low-risk women within a network of supporting OUs. It is therefore suggested that FMU care is made available to low-risk women regardless of their social position and parity and that all women and their partners are provided adequate information about different care models and their benefits and harms in order to support them in making an informed decision about their preferred place of birth.

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IMPLICATIONS FOR FUTURE RESEARCH

There are several areas in which the impact of FMU care can be further explored; both in terms of the health and well-being for mother and child in the ante, intra- and post partum period, and how the support of such goals can contribute to the formation of families in modern society.

Important topics that have been identified though this study include:

- What are the underlying mechanisms of FMU care that lead to improved birth experience and decreased maternal morbidity?

- What are the underlying mechanisms of the FMUs mitigating effect on social disadvantage on women's birth experience?

- What is the role of different forms of continuity in FMU care and how do they contribute to the quality of FMU care?

- Can increased continuity of care or carer contribute to safer transfer and hand-over situations?

- To what extend to women's views of the world or their expectations of birth differ by their chosen place of birth and are women's world views and expectations associated with their birth outcomes?

- How can social inequity in women's choice of birthplace be reduced?

- How can unnecessary interventions in low risk births in OUs be reduced?

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DANSK RESUMÉ

Baggrund

Organiseringen af fødselshjælp og kvaliteten af den professionelle omsorg, som ydes i forbindelse med graviditet og fødsel, har væsentlig samfundsmæssig betydning, da de kliniske og psykosociale følger af graviditet, fødslen og barsel har såvel kort- som langsigtede konsekvenser for både barnets, kvindens og familiens helbred og velbefindende. Opfattelsen af, hvad der er godt og rigtigt i fødselsomsorg, er imidlertid stærkt påvirket af såvel kulturelt betingede anskuelser som historiske og sociale forhold og strukturer, hvilket indgår som et underliggende tema i denne undersøgelse af to forskellige modeller for fødselshjælp for lavrisikogravide.

I løbet af de seneste årtier er der sket en stigende centralisering og specialisering af fødselsomsorgen. I de fleste høj- og mellem-indkomstlande, er det i dag normen, at fødsler foregår på en specialiseret fødeafdeling, uanset hvilken risiko den enkelte kvinde har for fødselskomplikationer. Denne udvikling er drevet af et medicinsk og teknologisk perspektiv på fødsler, men de stigende frekvenser af indgreb i fødsler samt de obstetriske specialafdelinger evne, mulighed og vilje til at tilgodese kvindens og familiens individuelle ønsker og psykosociale behov har været stærkt debatteret. Den globale debat har ledt til et generelt øget fokus på fødende kvinders autonomi og "humanisering" af fødselsomsorgen, og på lokalsygehuse og sundhedscentre er der i en række lande, herunder i Danmark, opstået en ny og endnu ikke fuldt evalueret fødestedstype - fritstående fødeklinikker. Fritstående fødeklinikker udgør sammen med hjemmefødsel et decentralt alternativt til fødsel på specialafdeling for kvinder i lavrisikogruppen, der tilbydes en lavteknologisk, individualiseret og patient-centreret omsorg, typisk i nærheden af kvindens hjem.

Formål

Studiet havde til formål:

- at sammenligne perinatal og maternel morbiditet, fødselskomplikationer, indgreb, brug af smertelindring såvel som kvinders fødselsoplevelse, tilfredshed med og oplevelse af omsorgen på to fritstående fødeklinikker og to obstetriske fødeafdelinger i Nordjylland, der alle stræbte efter at virkeliggøre et ideal om høj kvalitet, humanistisk og patientcentreret omsorg

- at undersøge hvorvidt fødestedet indflydelse på perinatal og maternel morbiditet, fødselskomplikationer, fødselsinterventioner og lindring af smerter hænger sammen med kvinders sociale position, som defineret ift. deres uddannelsesniveau

- at undersøge hvilken indflydelse social position har på kvinders fødselsoplevelse og oplevelser af omsorgen

Design

Overordnet, er studiet designet som et kohortestudie med en matchet kontrolgruppe og det omfatter 1678 kvinder, 839 lavrisikokvinder, som ønskede at føde på fritstående fødeklinik samt en kontrolgruppe af 839 lavrisikokvinder, som ønskede at føde på specialafdeling i Nordjyllands Amt.

Studiet foretaget mellem marts 2004 og oktober 2008 og kvinderne, som blev modtaget til fødsel på klinik blev individuelt og fremadrettet matchet ift. 9 udvalgte obstetriske/socio-demografiske faktorer med 839 lavrisiko kvinder som blev modtaget til fødsel på specialafdeling. En undergruppe bestående af 218 kvinder, som blev indlagt til fødsel på klinik i perioden januar-oktober 2006, samt deres 218 matchede kontrolpersoner, blev inviteret til at deltage i spørgeskemaundersøgelsen.

Uddannelsesniveauet blev valgt som primær erstatning for social position. Analysen blev foretaget i henhold til intention-to-treat-princippet.

Resultater

Der kunne ikke registreres nogen signifikant forskel i perinatal morbiditet mellem grupperne (Apgar-score <7 / 5, <9 / 5 eller <7 / 1, indlæggelse på neonatal afdeling, asfyksi eller genindlæggelse). I begge grupper forekom der enkelte dårlige udfald hos barn og/eller mor men forekomsten heraf var generelt lav.

Kvinder som ønskede at føde på klinik havde i sammenligning med kvinder som ønskede at føde på specialafdeling en signifikant lavere tendens til unormal hjertefrekvens hos fostret (Relativ Risiko (RR) 0,3; 95 % confidensinterval: 0,2-0,5), forekomst af mekanisk misforhold mellem barnet hoved og kvindens bækken (0,2; 0,05-0,6), fastsiddende skuldre (0,3; 0,1-0,9), uregelmæssig baghovedpræsentation (0,5; 0,3-0,9) og blødning efter fødslen > 500ml (0,4; 0,3-0,6).

Markant færre kvinder i klinikgruppen fik foretaget kejsersnit (0,6; 0,3-0,9) og instrumentel forløsning (0,4; 0,3-0,6) og modtog vestimulation (0,5; 0,3-0,6) og epidural analgesi (0,4; 0,3-0,6).

Overflytning under fødslen eller <2 timer efter fødslen skete i 14,8 % af alle klinikfødsler, med større hyppighed for førstegangs- end for flergangsfødende kvinder (36,7 % mod 7,2 %). Hvor

overflytningsraten for flergangsfødende var stabil over studieperioden, sås der for førstegangsfødende et stærkt fald fra 44,4 % til 24.6 %.

Der indkom besvarelser fra 375 af de 436 kvinder, der blev inviteret til at deltage i spørgeskemaundersøgelsen (86 %). Fødselsoplevelsen og tilfredshed med omsorgen blev vurderet markant mere positivt af kvinderne i klinikgruppen end af kvinderne i specialafdelingsgruppen.

Også for forskellige patientcentrerede omsorgselementer (psykosocial støtte under fødslen, inddragelse i beslutningsproces, opmærksomhed over for psykologiske behov samt fødselsønsker, information, og kvindens oplevelse af at blive lyttet til) gav kvinderne i klinikgruppen signifikant mere positive tilbagemeldinger end kvinderne i specialafdelingsgruppen.

Klinikkernes placering ved lokalsygehuse i hovedbyerne for overvejende landlige områder gav kvinderne mulighed for at vælge et lokalt alternativ til specialafdelingsfødsel; et tilbud, der endvidere var baseret på en bevidst humanistisk, patient-centreret omsorgsfilosofi. Dette tilbud tog kvinder fra en langt bredere vifte af sociale baggrunde imod, end man hidtil har set i internationale studier af fødsler, der finder sted uden for obstetriske fødeafdelinger.

En undergruppeanalyse viste, at lav uddannelse og dét at have ufaglært eller faglært arbejde er associeret med en signifikant mere negativ fødselsoplevelse. Denne effekt blev imidlertid udelukkende konstateret i blandt kvinder i specialafdelingsgruppen, hvorimod fødeklinikker ser ud til at have et væsentligt potentiale for at afbøde virkningerne af mindre gunstige sociale omstændigheder på kvinders fødselsoplevelse.

Forholdet mellem fødested og kliniske fødselsresultater var ikke på samme måde forskellig ift. kvinders uddannelsesniveau. Således så højt og lavt uddannede kvinder ud til i lige grad at nyde godt af den positive effekt of fødselsomsorgen på klinik. I alle tilfælde havde lavt uddannede kvinder i klinikgruppen sammenlignelige og i nogle henseender gunstigere resultater i ift. lavt uddannede kvinder, som havde valgt at føde på obstetrisk fødeafdeling.

Effekten af fødestedet på fødselsresultaterne ift. kvinders paritet blev undersøgt på tilsvarende måde, og også her sås, at førstegangsfødende og flergangsfødende havde lige god effekt af klinikomsorg, samt at førstegangsfødende i klinikgruppen - på trods af det høje antal overflytninger - havde

sammenlignelige og i nogle henseender gunstigere resultater end førstegangfødende, som havde valgt at føde på obstetrisk fødeafdeling.

Konklusion

Samlet set yder det foreliggende studie stærk støtte til fritstående fødeklinikker som koncept, selv i et område, hvor al primæromsorgen ydes af jordemødre, og hvor alle fødesteder stræber efter at levere patientcentreret omsorg af høj kvalitet, som det var tilfældet i Nordjyllands Amt.

Studiet indikerer, at valg af fødsel på klinik indebærer væsentlige sundhedsmæssige og psykosociale fordele for den fødende uden at øge risikoen for barnet. Resultaterne er i tråd med andre internationale studier af fødsel på fritstående klinik.

I et folkesundhedsperspektiv har klinikomsorg et stort potentiale for at bidrage til et vigtigt løft af fødendes/nybagte mødres sundhed og trivsel, og det må overvejes om muligheden for fødsel på fødeklinik, som aktuelt er særdeles begrænset i Danmark, bør forbedres. Alle kvinder, uanset uddannelse og paritet, bør sikres fyldestgørende oplysning om de forskellige fødestedstyper og deres fordele og ulemper samt støttes i på et oplyst grundlag at træffe deres egen beslutning om valg af fødested. Den genererede viden om centrale kvaliteter ved klinikomsorg kan desuden med fordel anvendes til at udvikle og forbedre omsorgen for kvinder, der føder på specialafdeling.

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THESIS' PAPERS

In the following section the three thesis' papers are presented:

Paper I   **Freestanding midwifery unit versus obstetric unit: a matched cohort study of outcomes in low-risk women.**
Overgaard C, Møller AM, Fenger-Grøn M, Knudsen LB, Sandall J.
BMJ Open 2011;2:e000262.doi:10.1136/bmjopen-2011-000262
(Published version)

Paper II   **Freestanding midwifery units versus obstetric units: does the effect of place of birth differ with level of social disadvantage?** Findings of a matched cohort study of two different models of intrapartum care for low risk women.
Overgaard C, Fenger-Grøn M, Sandall J.
BMC Public Health 2012, 12:478 doi:10.1186/1471-2458-12-478
(Provisional Pdf)

Paper III   **The impact of birthplace on women's birth experiences and perceptions of care.**
Overgaard C, Fenger-Grøn M, Sandall J. Social Science & Medicine 2012; 74: 973 -981.
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Freestanding midwifery unit versus obstetric unit: a matched cohort study of outcomes in low-risk women

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ABSTRACT

Objective: To compare perinatal and maternal morbidity and birth interventions in low-risk women giving birth in two freestanding midwifery units (FMUs) and two obstetric units (OUs).

Design: A cohort study with a matched control group.

Setting: The region of North Jutland, Denmark.

Participants: 839 low-risk women intending FMU birth and a matched control group of 839 low-risk women intending OU birth were included at the start of care in labour. OU women were individually chosen to match selected obstetric/socio-economic characteristics of FMU women. Analysis was by intention to treat.

Main outcome measures: Perinatal and maternal morbidity and interventions.

Results: No significant differences in perinatal morbidity were observed between groups (Apgar scores <7/5, <9/5 or <7/1, admittance to neonatal unit, asphyxia or readmission). Adverse outcomes were rare and occurred in both groups. FMU women were significantly less likely to experience an abnormal fetal heart rate (RR: 0.3, 95% CI 0.2 to 0.5), fetal—pelvic complications (0.2, 0.05 to 0.6), shoulder dystocia (0.3, 0.1 to 0.9), occipital—posterior presentation (0.5, 0.3 to 0.9) and postpartum haemorrhage >500 ml (0.4, 0.3 to 0.6) compared with OU women. Significant reductions were found for the FMU group's use of caesarean section (0.6, 0.3 to 0.9), instrumental delivery (0.4, 0.3 to 0.6), and oxytocin augmentation (0.5, 0.3 to 0.6) and epidural analgesia (0.4, 0.3 to 0.6). Transfer during or <2 h after birth occurred in 14.8% of all FMU births but more frequently in primiparas than in multiparas (36.7% vs 7.2%).

Conclusion: Comparing FMU and OU groups, there was no increase in perinatal morbidity, but there were significantly reduced incidences of maternal morbidity, birth interventions including caesarean section, and increased likelihood of spontaneous vaginal birth. FMU care may be considered as an adequate alternative to OU care for low-risk women. Pregnant prospective mothers should be given an informed choice of place of birth, including information on transfer.

ARTICLE SUMMARY

Article focus
- The safety of birth in free-standing midwifery units (FMUs) is strongly debated, as acute complications may arise in a spite of a careful risk assessment of women.
- Prior studies suggest that FMU care for low-risk women is related to low perinatal and maternal morbidity, fewer interventions and a decreased use of medical pain relief compared with care from obstetric units (OUs) care, but some are limited by, for example, the inclusion of high-risk women, low number of participants, and inadequate control of bias and confounding.
- The present study aims to compare perinatal and maternal morbidity, birth interventions, and pain relief in low-risk women giving birth in two freestanding midwifery-led units and two obstetric units (OUs) in Denmark.

Key messages
- No difference in perinatal morbidity was found among infants of low-risk women who intended birth in an FMU compared with infants of low-risk women who intended birth in an OU. More studies on rare adverse outcomes are needed.
- FMU care had important benefits such as reduced maternal morbidity, reduced use of birth interventions including caesarean sections and increased likelihood of spontaneous vaginal birth compared with OU care. However, 37% of primiparas and 7% of multiparas transferred during or <2 h after birth.
- Care in FMUs may be considered as an adequate alternative to OU care for low-risk women, and women should be given an informed choice of place of birth, including information on transfer.

INTRODUCTION

In most industrialised countries, obstetric units (OU) have become the primary setting for birth with the safety of other birth settings strongly debated.[1–5] The primary concern regarding birth outside an OU relates to the anticipation of adverse perinatal outcomes. However, steadily increasing birth intervention rates and studies of women's

ARTICLE SUMMARY

Strengths and limitations of this study

- The study compares processes and outcomes from women who have been rigorously and prospectively judged to be at low obstetric risk in two well-defined and carefully established settings in the same region.
- Data are complete, as all eligible women planning to give birth in the FMU settings were included, and full follow-up on all participants was obtained.
- Although the study groups were matched, and adjustment for the matching factors revealed no residual confounding, the risk of confounding by unknown factors related to women's choice of care in labour persists.

perceptions of childbirth indicate that OUs may not always provide optimal conditions for low-risk childbirth or satisfy women's individual needs.[6–14] In many countries, the introduction of midwifery units has given women more choice of place of birth. A midwifery unit is a clinical location offering care to women with straightforward pregnancies during labour and birth in which midwives take primary professional responsibility for care. It may be in the site of a hospital with an obstetric unit, hence termed an 'alongside' midwifery unit, or be a physically separated, freestanding unit where obstetric, neonatal and anaesthetic care requires ambulance transfer.[15]

A Cochrane review concerning alongside midwifery units (AMU) found no significant differences in perinatal mortality or perinatal and maternal morbidity. It also documented significantly fewer medical interventions and increased maternal satisfaction.[12] However, this evidence cannot be generalised to freestanding midwifery units (FMU). Concern has been expressed that acute intrapartum and postpartum complications may arise in spite of careful assessment of low-risk women and that transfer delays may affect lifesaving medical interventions such as caesarean section or advanced neonatal resuscitation.

Two prospective, controlled cohort studies of FMUs[16 17] both report low perinatal and maternal morbidity, fewer interventions and decreased use of medical pain relief. The results are supported by a wide range of retrospective, uncontrolled and/or population-based studies,[6 10 18–30] but the evidence is conflicting, as two of these studies found significantly lower 1 min Apgar scores[28] and an increased need for neonatal ventilation[10] in FMUs. Because of greatly varying criteria for low-risk categorisation, care standards, midwives' training, cooperation between FMUs and OUs, etc, considerable caution must be observed when generalising findings to other settings and countries. Furthermore, the level of evidence was weak.[31] The applicability/validity of many studies is limited by factors such as small sample size, inclusion of high-risk women, limited control of bias and confounding, and inadequate descriptions of inclusion and exclusion criteria, medical assistance (if any) and transfer criteria.

There is a need for further research, but the rarity of adverse outcomes in a low-risk population, the limited number of FMU births and women's strong preference for choice of birthplace[32 33] converge to form serious barriers for the investigation of perinatal mortality in large, adequately powered, randomised controlled trials. This increases the need for evidence from carefully planned cohort studies.

OBJECTIVES

The present study compared labouring processes, perinatal and maternal morbidity, and birth interventions in low-risk women intending to give birth in two FMUs and two OUs in Denmark. The study is reported in accordance with 'Strengthening the Reporting of Observational Studies in Epidemiology' requirements.[34 35]

STUDY HYPOTHESES

On the basis of previous research, we hypothesised that FMU care, with its emphasis on the physiological birth process and psycho-social well-being during childbirth, would entail a number of positive effects for the women, such as a higher rate of spontaneous vaginal birth, intact perineum, and use of non-pharmacological pain relief. FMU women were hypothesised to experience fewer interventions (including caesarean section) and require less use of pharmacological pain relief compared with OU women. No differences in perinatal or maternal morbidity were predicted.

METHODS

Design

A matched cohort study.

Setting

The study was conducted in North Jutland, a relatively sparsely populated region of Denmark where the local health authorities in 2001 had decided to transform two of the region's four maternity units into FMUs, opening in 2001 and 2004. The FMUs offered midwifery-led care during pregnancy and intrapartum and postnatal periods to low-risk women.

Data collection

In a 3.5-year period between 2004 and 2008, data on socio-demographic factors, previous pregnancies and births, current pregnancy and birth, infants, FMU transfers, and maternal/neonatal readmissions 0–28 days postpartum were collected from patient records and the North Jutland Patient Administration System. The data collection was carried out by project staff with comprehensive professional knowledge of the field on basis of written instructions.

Data security and ethics

The project was approved by the Danish Data Protection Agency (reference number: 2005-41-5352) and the regional health authorities of North Jutland. Data were

handled in strict confidentiality and in accordance with Danish law requiring neither approval from an ethics committee nor informed consent from patients for observational studies involving no risk or inconvenience to patients.[36]

Characteristics of the freestanding midwifery units

In Denmark care for low-risk women is midwifery-led in all birth settings. Both FMUs were located in community hospitals with an intensive care unit but without an obstetric service. The annual numbers of births in the FMUs were approximately 170 (Hobro) and 130 (Frederikshavn). Women transferred to OUs by ambulance using multidisciplinary regional criteria and continued care with an FMU or OU midwife under the supervision of an obstetrician. FMU midwives had at least 2 years' experience and training in obstetric emergencies, including ventouse delivery. FMU midwives provided antenatal care and out-of-hours postpartum care for all women in the area booked for both OU and FMU birth. FMU midwives also assisted at the nearest OU, if FMU not busy, and had 40−70 births a year. Additional contextual information is available in online table A.

Characteristics of the obstetric maternity units

Aalborg University Hospital is a one of five highly specialised Danish hospitals with a specialist OU who saw approximately 3500 births a year. Vendsyssel Hospital is a provincial hospital with 10 clinical specialities, including an OU providing care for low-risk and most high-risk pregnancies and a generalised paediatric ward. The annual number of births was approximately 1400. Mothers and infants with severe illness were transferred to Aalborg University Hospital or one of the other four, highly specialised hospitals in Denmark, depending on the condition (additional contextual information is available in online table B).

Participants

The study population was composed of an intervention group of 839 low-risk women from two FMU in Hobro and Frederikshavn, and a control group of 839 low-risk women, matched for key factors, who received routine care from the specialist obstetric unit at Aalborg University Hospital and the obstetric unit at Vendsyssel Hospital, Hjørring.

Inclusion criteria

All labouring women admitted to the FMUs by their midwives on the basis of multidisciplinary, regional admission criteria were included in the study. As informed consent of participation was not required due to Danish legislation, all eligible women were included.

Women in the control group were eligible for inclusion only if they represented an individual match to the obstetric and social characteristics of a woman in the FMU group.

Women in both study groups were thus rigorously judged to be at low-risk and fulfil criteria for FMU birth, and included at the start of care in labour.

Exclusion criteria

Excluded from the study were three women admitted to an FMU for emergency treatment without satisfying the criteria for FMU care; an event occurring very rarely.

Matching process

Confounding is a main concern in cohort studies. The matched design was chosen because it potentially increases the statistical precision in a cohort study and effectively eliminates the association between the exposure (place of birth) and the matching variables, given a perfect balance of data is obtained on matched variables between groups.[34 37 38] Matching is especially relevant in situations with non-linearity and intercorrelation between variables or where a substantial difference in the distribution of confounders between groups is expected.[39] This was the case in the present study whose participants were recruited from areas characterised by varying degrees of urbanisation and heterogeneity in socio-demographic characteristics.[40 41]

Women in the control group were selected from the region's patient administration system which carries detailed information on the region's pregnant women. For each participant included in the FMU group, a control participant from the nearest OU was identified among the admitted low-risk women. The selection of matched control participants was conducted in accordance with strict guidelines by project staff that were blinded to the identity and the birth outcomes of women in the FMU group. The matching result was blinded until the selected control participants had given birth.

Matching was done prospectively on criteria with an established influence on birth outcomes[42−45]: low-risk status, parity, smoking, body mass index (BMI), age, ethnicity, education, occupation and cohabitation status. A 100% match was carried out on: low-risk status, parity and smoking status. BMI and age were matched with a range of ±5; meaning that BMI/age scores of 22 were matchable with scores between 17 and 27. Socio-demographic characteristics such as ethnicity, education level, occupation and cohabitation status were matched within groups as shown in table 1.

Definition of low risk

Women were judged to be at low risk if they were healthy, presented in spontaneous labour between 37+0 and 41+6 days of gestation and had an uncomplicated pregnancy and no medical/obstetric history or conditions increasing obstetric risk as outlined in the UK NICE intrapartum care guidelines.[46] However, we considered healthy multiparous women as low-risk regardless of their age and BMI if their previous pregnancies and deliveries had been uncomplicated.

Variables and data measurement

The primary outcomes were Apgar score <7/5 min and caesarean section.

Secondary outcomes were as follows: (infant) Apgar score <9/5 min, <7/1 min; neonatal asphyxia; admittance

Table 1 Matching characteristics

Characteristics	Freestanding midwifery unit (%)	Obstetric unit (%)
Complete match retained in all cases		
Obstetric risk status		
Low risk	839 (100)	839 (100)
Parity		
Primiparous	215 (25.6)	215 (25.6)
Multiparous	624 (74.4)	624 (74.4)
Smoking status		
Non-smoker	684 (81.5)	684 (81.5)
1−9 cigarettes	59 (7.0)	59 (7.0)
10 or more cigarettes	96 (11.5)	96 (11.5)
Individuals matched within ranges/groups		
BMI		
<18	17 (2.1)	22 (2.6)
18−24.9	528 (62.9)	530 (63.2)
25−29.9	226 (26.9)	219 (26.1)
>30	68 (8.1)	68 (8.1)
Age		
16−20	24 (2.9)	25 (3.0)
21−35	731 (87.1)	716 (85.3)
>35	84 (10.0)	98 (11.7)
Ethnicity		
Nordic or Western European	805 (96.0)	809 (96.4)
Eastern European or Asian	27 (3.2)	22 (2.6)
Arab or African	7 (0.8)	8 (1.0)
Education level*		
No training/education qualifying for the labour market	216 (25.7)	217 (25.9)
Skilled training	255 (30.4)	255 (30.4)
1−2½ years of postsecondary education	84 (10.0)	81 (9.6)
3−4 years of postsecondary education	254 (30.3)	256 (30.5)
5−6 years of postsecondary education	30 (3.6)	30 (3.6)
Occupation		
No paid work	160 (19.1)	131 (15.6)
Unskilled work	107 (12.7)	119 (14.2)
Skilled work†	542 (64.6)	557 (66.4)
Academic work/manager or senior official	30 (3.6)	32 (3.8)
Cohabitation status		
Living with partner	815 (97.1)	819 (97.6)
Not living with partner	24 (2.9)	20 (2.4)

*Students and trainees were classified along with the educational level for which they were being trained.
†All non-academic/non-managerial vocations requiring 1−4 years of postsecondary education/training.

to neonatal intensive care unit (NICU); admittance to NICU >48 h; neonatal readmission 0−28 days postpartum; (maternal) spontaneous vaginal birth; intact perineum; epidural analgesia; use of water tub for pain relief; abnormal fetal heart rate leading to action; dystocia; shoulder dystocia; instrumental vaginal delivery; postpartum haemorrhage >500 ml; first-/second-degree tear; third-/fourth-degree tear; maternal readmission 0−28 days postpartum. These outcomes were, along with a range of additional outcomes, defined prior to the initiation of the study, and reported as well as all cases of perinatal mortality and severe perinatal and maternal morbidity. Unfortunately, data on umbilical blood gas could not be obtained.

The intended birthplace at the start of care in labour was considered the exposure. The study did not aim to examine differences in maternal or perinatal mortality,

since their low occurrence in the Danish low-risk population (0.065‰ and 3‰, respectively) would require an extremely large and therefore unrealistic number of participants.

The data were recorded in accordance with the National Birth Register and the North Jutland Birth Register, standards and guidelines applying to all four units and with which all midwives and doctors in the region were familiar. A stop watch was used when measuring Apgar scores. Postpartum haemorrhage was routinely estimated rather than measured.

Power calculation, sample size and changes in study protocol

Clinically important differences were defined, and power calculations performed for all the above-mentioned

clinical endpoints. The frequencies used in the calculations originate in the North Jutland Birth Register and the international literature. Estimations of sample sizes were based on power calculation for the primary outcomes: Apgar score <7/5 min and caesarean section. The limited number of FMU births, at 300−350 per year, was also taken into account. The study was originally planned to include data on 1027 FMU participants and 1027 control participants over a period of 3.5 years, starting 1 January 2005; however, in October 2006, the local authorities unexpectedly announced the closure of its two FMUs. The National Board of Health expressed concern that the local authorities had introduced a new model of care that had not been subjected to adequate evaluation. The power to detect differences between our two study groups was consequently reduced, and a thorough revision of the study protocol was required. At the time of the FMU closures, 550 FMU participants had been included, and in order to obtain the largest possible sample of FMU participants, we included all of the 289 eligible women who had been admitted to the FMUs since the opening of the second FMU (1 March 2004). These women were prospectively matched with women from the nearest OU, thus ensuring total samples of 839 women in each group.

After the FMU closures, power calculations were rerun. The results showed that with a sample of 839 women in each group, the study sustained the power to detect clinically relevant differences between groups on all primary and secondary outcomes. For the two primary outcomes, the revised sample provided power (5% significance level, 80% power) to detect an increase in Apgar score <7/5 min from expected 1.07% in the OU group to 3.1% in the FMU group and a reduction in the incidence rate of caesarean section from 8.8% in the OU group to 5.5% in the FMU group.

Statistical analysis of data

Analyses were based on the intention-to-treat principle and carried out using STATA software, V.11.

The two groups (matched 1:1) were compared by paired tests on all measures, the McNemar' test for paired binary data (medical data on the birth process) and the Wilcoxon signed-rank test for paired continuous data (eg, birth weight). As we were concerned that residual confounding might remain, a supplementary regression analysis adjusting for the matching characteristics was performed using both continuous and grouped variables.[47 48] For ease of interpretation (eg, calculation of confidence bands), ordinal outcomes were dichotomised, but we controlled for conclusive agreement with test results based on the original data.

The analysis for occipital posterior position was performed after excluding caesarean deliveries. For all comparisons, relative risks with 95% CIs were calculated. All reported p values were two-sided, and the level of statistical significance 5%. To check for bias introduced by the inclusion of FMU women giving birth in 2004, supplementary subgroup analyses were performed on 2004 data and main data, respectively.

Participants

A low-risk match was prospectively identified for all 839 women admitted to an FMU, and full follow-up was

Figure 1 Study flow chart.

Women included in the study at beginning of care in labour

* Birth occuring unplanned at home or during transport was included if the woman <24 hours before had consulted a midwife and been advised to stay at home longer / return to her home
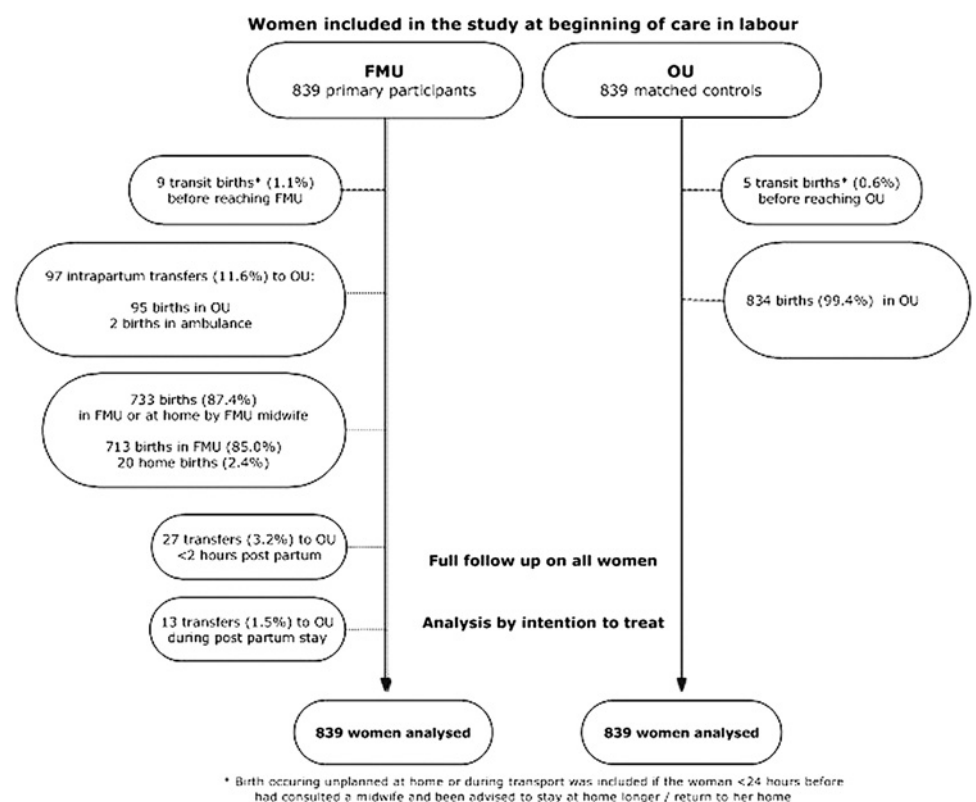
obtained for all 1678 women. Of the 839 FMU women, 733 (87.4%) gave birth as planned in the FMU or at home, assisted by a FMU midwife (cf. figure 1). Transit births were included in the few cases where the woman had consulted a midwife <24 h before giving birth and had been advised to stay at home longer or return home.

Ninety-seven FMU women (11.6%) were transferred intrapartum; among these, two gave birth in the ambulance. Eleven, who were in early labour, were transported in their own vehicle. Twenty-seven transfers (3.2%) took place <2 h after birth, another 13 (1.5%) during the postnatal stay. The total number of transfers was 137 (16.4%).

As shown in table 1, the matching produced two fully comparable groups in terms of key medical and socio-demographic factors. The FMU women's background details reflected the life conditions of the local population in general.[40 49] With Aalborg and Hjørring munic-ipalities as exceptions, the educational and income levels in North Jutland rank as the lowest in Denmark. In the FMUs' predominantly rural catchment areas, unem-ployment rates are high, which is reflected in a slightly higher rate of FMU women without employment outside the home.

MAIN RESULTS
Primary outcomes
No statistically significant differences between the two study groups in the rate of infants with an Apgar score of <7/5 were found (RR: 1; 95% CI 0.3 to 3.4). The use of caesarean section (0.6, 0.3 to 0.9) was significantly reduced among FMU women compared with OU women (see table 2).

Secondary perinatal outcomes
No significant differences were found in perinatal outcome such as an Apgar score of <7/1 at 1 min and <9 at 5 min; neonatal asphyxia; neonatal admittance to NICU; neonatal stay in NICU >48 h or neonatal read-mission to hospital 0–28 days postpartum (see table 2).

One infant was delivered by caesarean section owing to umbilical-cord prolapse in the hospital where an FMU was co-located. As a result, a sensitivity analysis was conducted on the hypothesis that, had the women been transferred, the infant would have had an Apgar score of <7/5 min. Analysis showed no difference between groups (1.25, 0.3 to 4.6) and did not affect overall findings. Full case details are given in online table C on adverse outcomes.

Table 2 Outcomes

	Freestanding midwifery unit (%)	Obstetric unit (%)	RR (95% CI)	p Value
Primary outcomes				
Apgar score <7 after 5 min	5 (0.6)	5 (0.6)	1 (0.3 to 3.4)	1.0000
Caesarean section	19 (2.3)	34 (4.0)	0.6 (0.3 to 0.9)	0.0400
Secondary perinatal outcomes				
Apgar score <9 after 5 min	15 (1.8)	20 (2.4)	0.8 (0.4 to 1.5)	0.4996
Apgar score <7 after 1 min	22 (2.6)	25 (3.0)	0.9 (0.5 to 1.6)	0.7709
Neonatal asphyxia	27 (3.2)	41 (4.9)	0.7 (0.4 to 1.1)	0.1143
Neonatal admittance to NICU	28 (3.3)	42 (5.0)	0.7 (0.4 to 1.1)	0.1143
Neonatal stay in NICU >48 h	14 (1.7)	15 (1.8)	0.9 (0.5 to 1.9)	1.0000
Neonatal readmission hospital 0–28 days postpartum	26 (3.1)	35 (4.2)	0.7 (0.4 to 1.1)	0.1480
Child live-born	839 (100)	839 (100)		
Perinatal/neonatal death	1*	0		
Secondary maternal outcomes				
Abnormal fetal heart rate leading to action	34 (4.1)	98 (11.7)	0.3 (0.2 to 0.5)	0.0000
Dystocia in labour	88 (10.5)	234 (27.9)	0.4 (0.3 to 0.5)	0.0000
Intrapartum fetal–pelvic complications†	3 (0.4)	16 (1.9)	0.2 (0.05 to 0.6)	0.0044
Shoulder dystocia	3 (0.4)	12 (1.4)	0.3 (0.1 to 0.9)	0.0352
Meconium-stained amniotic fluid	136 (16.2)	148 (17.6)	0.9 (0.7 to 1.1)	0.4004
Occipital posterior presentation at birth‡	13 (1.6)	28 (3.3)	0.5 (0.3 to 0.9)	0.0201
Postpartum haemorrhage >500 ml	29 (3.5)	68 (8.1)	0.4 (0.3 to 0.7)	0.0001
Postpartum haemorrhage >1000 ml	11 (1.3)	14 (1.7)	0.8 (0.4 to 1.7)	0.6900
Intact perineum	514 (61.3)	466 (55.5)	1.1 (1.02 to 1.2)	0.0142
First-/second-degree tear	290 (34.6)	337 (40.2)	0.9 (0.8 to 0.97)	0.0154
Third-/fourth-degree tears	19 (2.3)	24 (2.9)	0.8 (0.4 to 1.4)	0.5224
Readmission /outpatient visit 0–28 days postpartum	24 (2.9)	40 (4.8)	0.6 (0.4 to 1.0)	0.0599
Discharge <6 h postpartum	106 (12.6)	191 (22.8)	0.6 (0.5 to 0.7)	0.0000
Severe maternal morbidity	0	1§		

*The infant was born with severe diaphramic hernia, not detected by ultrasound screening at 19.4 weeks.
†Including diagnosis for: abnormal maternal pelvis, cephalopelvic disproportion and failed ventouse delivery.
‡Deliveries by caesarean section excluded from this analysis.
§Uterine rupture followed by peripartum hysterectomy in a multipara having epidural analgesia and oxytocin augmentation.

Table 3 Birth interventions and pain relief

Outcome	Freestanding midwifery unit (n)	Obstetric unit (n)	RR (95% CI)	p Value
Birth interventions and pain relief				
Spontaneous vaginal birth	796 (94.9)	751 (89.5)	1.06 (1.03 to 1.09)	0.0000
Instrumental delivery*	25 (3.0)	61 (7.8)	0.4 (0.3 to 0.6)	0.0000
Oxytocin augmentation of labour	69 (8.2)	154 (18.6)	0.5 (0.3 to 0.6)	0.0000
Treatment for shoulder dystocia	1 (0.1)	10 (1.2)	0.1 (0.01 to 0.8)	0.0117
One or more uterotonics	675 (80.5)	672 (80.1)	1.0 (0.9 to 1.0)	0.9070
Perineal suturing	294 (35.0)	366 (43.6)	0.8 (0.7 to 0.9)	0.0002
Intrauterine palpation	5 (0.6)	16 (1.9)	0.3 (0.1 to 0.9)	0.0266
Pain relief				
Epidural analgesia	35 (4.2)	86 (10.3)	0.4 (0.3 to 0.6)	0.0000
Water tub for pain relief	269 (32.1)	197 (23.5)	1.4 (1.2 to 1.6)	0.0001
Other				
Non recumbent position for birth	188 (22.4)	158 (18.3)	1.2 (0.98 to 1.4)	0.0964

*Freestanding midwifery unit midwives had extended authorisation to perform ventouse deliveries in case of acute fetal distress in the second stage of labour (ventouse delivery is included in the International Confederation of Midwives Essential Competencies for Midwifery Practice, and midwives in many different settings and countries have acquired the necessary skills). This was used only once, in a case of acute bradycardia. Apgar score 2/1, 8/5, 10/10.

Secondary maternal outcomes

As shown in table 2, compared with OU women, FMU women were significantly less likely to experience: abnormal fetal heart rate leading to action (0.3, 0.2 to 0.5); dystocia in labour (0.4, 0.3 to 0.5); intrapartum fetal−pelvic complications (0.2, 0.05 to 0.6); shoulder dystocia (0.3, 0.1 to 0.9); occipital posterior presentation at birth (0.5, 0.3 to 0.9); postpartum haemorrhage >500 ml (0.4, 0.3 to 0.7) and 1st/2nd degree tear (0.9, 0.8 to 0.97).

Moreover, compared with OU women, FMU women were significantly more likely to experience: intact perineum (1.1, 1.02 to 1.2) and discharge <6 h postpartum (0.6, 0.5 to 0.7).

No significant differences were found in meconium-stained amniotic fluid; postpartum haemorrhage >1000 ml; third- and fourth-degree tear; maternal readmission/outpatient visit 0−28 days postpartum and severe maternal morbidity.

In addition, infant birth weight (mean: 3.636 kg (FMU) and 3.641 kg (OU), cervical dilatation on admission (mean: 4.4 cm (FMU) and 4.3 cm (OU)) and duration of admission for labour care (mean: 5.3 h

Table 4 Causes of freestanding midwifery unit to obstetric unit transfer

	Primipara (%)	Multipara (%)	All (%)
Total no of transfers intrapartum or <2 h after birth	79/215 (36.7)	45/624 (7.2)	124/839 (14.8)
Causes for intrapartum transfers			
Failure to progress (cervical dilation >3 cm or during second stage)*	42 (53.2)	13 (44.8)	55 (44.4)
Meconium-stained amniotic fluid	9 (11.4)	5 (11.1)	14 (11.3)
Fetal heart rate abnormality	5 (6.3)	5 (11.1)	10 (8.1)
Prolonged latent phase†/rupture of membranes >24 h (+ birth not imminent)	3 (3.8)	4 (8.9)	7 (5.6)
Request for epidural analgesia	5 (6.3)	1 (2.2)	6 (4.8)
Abnormal fetal presentation (cephalic or caudal presentation)	4 (5.1)	1 (2.2)	5 (4.0)
Causes for transfers after birth but <2 h postpartum			
Perineal trauma (complicated/third-/fourth-degree tear)	10 (12.7)	6 (13.3)	16 (12.9)
Retained placenta/postpartum haemorrhage <500 ml	1 (1.3)	8 (17.8)	9 (7.3)
Minor respiratory problem (infant)	0 (−)	2 (4.4)	2 (1.6)
Total no of transfers intrapartum or <2 h after birth	79 (100)	45 (100)	124 (100)
Causes for transfers >2 h after birth/during postpartum stay			
Neonatal cause (light for date, minor respiratory problem, hypoglycaemia, jaundice)	6 (85.7)	5 (83.3)	11 (84.6)
Maternal cause (postpartum bleeding, infection)	1 (14.3)	1 (16.7)	2 (15.3)
Total no of postpartum transfers	7 (100)	6 (100)	13 (100)

*Delay in the first stage of labour was defined as no progress for 2 h and delay in the second stage as a duration of active second stage of >2 h for primiparas and >1 h for multiparas.
†If painful contractions >24 h and a cervical dilatation <3 cm (or before, if preferred by the woman).

(FMU) and 5.6 h (OU)) were no different between the two study groups.

Birth interventions

As shown in table 3, compared with OU women, FMU women were significantly less likely to experience: instrumental delivery (0.4, 0.3 to 0.6), oxytocin augmentation in labour (0.5, 0.3 to 0.6), treatment for shoulder dystocia (0.1, 0.01 to 0.8), perineal suturing (0.8, 0.7 to 0.9), intrauterine palpation (0.3, 0.1 to 0.9) and epidural analgesia (0.4, 0.3 to 0.6).

Moreover, compared with OU women, FMU women were significantly more likely to experience spontaneous vaginal birth (1.06, 1.03 to 1.09) and the use of a water tub for pain relief (1.4, 1.2 to 1.6).

No significant differences between groups were found for one or more uterotonics, and non-recumbent position for birth.

Other analyses

A regression analysis adjusting for the matching characteristics showed coinciding results with the match analysis, thus confirming the robustness of our results and matching. A subgroup analysis comparing the late collected data on 2004-FMU participants with the main, prospectively collected data detected no systematic differences or deviation of results between the two bodies of data.

Transfer

All reasons for transfer are tabulated in table 4. Overall intrapartum transfer rates (up to 2 h postpartum) were 14.8% but different for primiparous and multiparous women (36.7 vs 7.2%). The most common reason for transfer for all women was slow progress of labour. Ambulance transfers from the two FMUs averaged 42/38 min (range: 20–60).

After transfer, women had shared care between an obstetrician and a midwife, and 36% of transferred women continued to be cared for by the FMU midwife under the supervision of an obstetrician.

Adverse outcomes were defined as severe maternal morbidity, perinatal mortality, Apgar score <7/5 min and >1 week NICU admittance. One incident of severe maternal morbidity (uterine rupture) occurred among the OU women. In the FMU group, one perinatal/neonatal death occurred owing to an undetected, severe congenital malformation. Nine infants were born with 5 min Apgar scores of 4–6; three belonged to the FMU group but were born in an OU following intrapartum transferral. Eight of the nine infants were admitted to NICU; all were later discharged well.

Three infants from the FMU group, who were born in an OU after transfer, had NICU stays exceeding 1 week. One infant with a 5/5 Apgar score had a stay of 36 days, but this was due primarily to an undetected congenital heart disease.

One adverse perinatal event was dealt with in an FMU shortly after its opening. Owing to an umbilical-cord prolapse, an emergency caesarean section was carried out by a gynaecologist, employed at the unit before its transformation into a FMU and summoned against protocol. The Apgar scores were 10/1, 10/5. Supplementary information on all adverse events is provided in online table C.

DISCUSSION
Key results

This study was powered to compare two primary maternal and infant outcomes for women at low risk who intended to give birth in FMU or OU settings. We found no significant differences in Apgar score <7/5 min, and women in the FMU group were less likely to have experienced a caesarean section.

Looking at secondary outcomes, there were no significant differences between Apgar scores <9/5, <7/1 min; total number of NICU admittances; NICU admittance >48 h; neonatal asphyxia; or neonatal readmission to hospital. Among this population of low-risk women, women in the FMU group compared with the OU group were significantly less likely to experience dystocia, intrapartum fetal–pelvic complications, occipital–posterior position of the infant at birth, shoulder dystocia, oxytocin augmentation, instrumental delivery and postpartum haemorrhage >500 ml. Moreover, women in the FMU group were significantly more likely to experience spontaneous vaginal birth and intact perineum.

Limitations

The limitations of our study stem partly from its observational design, and partly from the sudden closure of the two FMUs. A non-randomised study design precludes elimination of all potential confounding factors; only known confounders can be adjusted for, and only as far as they can be accurately measured. Despite our close matching of study groups and adjustment for matching factors, residual confounding and confounding by unknown factors related to women's choice of care in labour may persist. In addition, bias linked to the delayed data collection for 289 FMU participants from 2004 cannot be ruled out, but we were somewhat reassured to find that the 2004 data were in conformity with the later data. Our contention that such a risk is limited is also supported by the fact that no interventions were performed in the study, participants were included on the same principles, individual and project-specific data collections were performed for all participants, patient records were of good quality, and all control participants were prospectively included. The obstetric quality indicators, which were compiled annually by the units, were closely followed to detect any changes in practices or technology use; no systematic changes occurred during the study period. No new technology was introduced, and no major changes in obstetrical practices were implemented.

Furthermore, some outcomes (Apgar scores, postpartum haemorrhage) were exposed to measurement subjectivity, others were proxies for morbidity, although

globally used quality indicators/research outcomes, and the number of events in some analyses was low. It is also uncertain whether the outcomes would have been different for the two FMU infants had (1) a caesarean section not been performed and (2) the infant with severe congenital malformation been born in the alternative setting. Ideally, the results should be confirmed (or refuted) in a large randomised controlled trial, but as the recruitment of an adequately large number of women willing to be randomised to place of birth would be logistically challenging, the most robust design seems to be a large prospective cohort study.

Strengths

We present findings from the second-largest prospectively controlled study of FMU care so far. A major strength of our study is that it compares processes and outcomes from women who have been prospectively judged to be at low obstetric risk in two well-defined and carefully established settings in the same region and that care for women in both groups is provided by midwives. Also, contrary to several earlier studies,[10 16 29] the data are complete, as all eligible women planning to give birth in the FMU settings were included, and a full follow-up on all participants was carried out.

Interpretation

We found no differences in perinatal morbidity between groups, and our results agree with the results of most studies of FMU versus OU care.[6 11 18−30] Although women were transferred to the OU without delay (3−23 h before giving birth), it is a concern that the three NICU stays exceeding 1 week occurred in the FMU group. Further study of rare adverse outcomes and optimisation of care for transferred women is needed.

The study findings also agree with other studies of FMU care[6 10 18 24 26 28 29] that have all reported a reduced incidence of birth interventions while the caesarean section rate is seldom found to be affected, something which may stem from inadequacies in the power or robustness of their design. In this respect, our study forms an important exception in finding a significant reduction in caesarean section in women in the FMU group. In addition, the present study is the first to report that FMU women were significantly less likely to experience fetal−pelvic complications, occipital−posterior position of the infant at birth and shoulder dystocia compared with OU women.

FMU care is a complex intervention, and although the study does not enable us to be specific about the individual mechanisms or elements of FMU care leading to decreases in the incidence of birth complications and birth interventions, including caesarean section, we would indicate as influencing factors the greater availability of continuous support during labour, the encouragement of women to ambulate and adopt a different position during labour, and the spacious and calm FMU facilities. Continuous support during labour has been proved to reduce birth interventions and the need for pharmaceutical pain relief.[50] Mobilisation and the practice of the hand−knee position have furthermore been shown to support fetal rotation into an occipital anterior position and to reduce the duration of labour.[51 52] In contrast, the use of epidural analgesia and oxytocin augmentation in OU care both require CTG monitoring and are likely to restrict mobility[53] and thus use of different labour positions. Furthermore, oxytocin augmentation can cause uterine hyperstimulation leading to fetal heart-rate abnormality and oxygen desaturation.[54]

The overall rate of transfers intrapartum and <2 h after birth at 14.8% is comparable[18] or slightly lower than that found in some studies of FMU care[21 22 24 26] (18−24%), though one study[6] reported a slightly lower rate of 12%. Few studies report transfer rates for primiparas and multiparas separately, but a large American study also finds a transfer rate of 7% for multiparas but a lower rate of 29% for primiparas.[24] In all studies, slow progress of labour was one of the most common reasons for transfer, depending on the strictness of transfer guidelines. These findings provide information upon which women, professionals and policy makers can make decisions. However, these will vary depending upon individual preferences and trade-offs.

We suggest that the assessment of the risk of rare adverse outcomes in low-risk FMU births be balanced against our findings that infant morbidity was not affected, and women intending to give birth in a FMU are less likely to suffer complications or undergo caesarean section and other birth interventions when compared with women intending to give birth in an OU.

Generalisability

Data were collected between 2004 and 2006, but there has been no change in the background characteristics of participants at that time compared with latest national data in Denmark.[41 55]

Any generalisation of our findings must consider the full public funding of all maternity services in Denmark. The FMU midwives were skilled in dealing with obstetric emergencies, cooperation between FMUs and OUs was excellent, and the local implementation of multidisciplinary guidelines for referral and transfer was based on the best evidence available, thus improving the reliability of care provided. Furthermore, the FMUs were located in community hospitals that offered life-supporting assistance in emergencies. Generalising to other countries offering different conditions should be made with caution.

Compared with most other countries, Denmark is culturally less diverse and characterised by less social inequality, with high standards of health and one of the lowest perinatal mortalities in the world (6.6 per 1000 in 2004).[56] However, the FMU women in this study had higher-than-average BMIs and a lower educational and occupational status than Danish women in general,[49 55] characteristics that reflect the life conditions and health status of women in the FMUs' peripheral catchment area. We take this as an indication that positive outcomes for

women choosing FMU care are not necessarily restricted to women privileged by high socio-economic status or excellent health, an assumption that is in line with the findings of the largest study so far of FMU care.[16]

The distances between the four units studied were 35–55 km; FMU and OU care was thus not equally accessible to all women. Taking into account the characteristics of women in the study and the finding of convenience/proximity as the most important factor in North Jutland women's choice of birthplace,[57] we hypothesise that philosophies/ideas about childbirth play a minor role in our study in comparison with studies involving women whose choices are not affected by geography.

Further work should examine the potential influence of birth expectations and perceptions on women's choice between FMU and OU care to determine any impact of world views or philosophies on birth outcomes. Additional aims would be to elucidate the underlying elements of FMU care and their influence on outcomes, and to explore the potential differences between alongside midwifery units care and FMU care. Operational efficiency, cost-effectiveness and rare outcomes also present areas for further work, the latter through a rigorous review of controlled studies of FMU.

Conclusion

In conclusion, the present study found no increase in perinatal morbidity among infants of low-risk women intending to give birth in an FMU compared with infants of women intending to give birth in an OU. Among the FMU women, it found reduced maternal morbidity, fewer caesarean sections and other birth interventions, along with an increased likelihood of spontaneous vaginal birth. Further study of rare adverse outcomes is needed.

Care in FMUs may be considered an adequate alternative to OU care for low-risk women within a network of supporting OUs. Pregnant women should thus be given an informed basis for their choice of birthing place, with information on key maternal and infant outcomes, and transfer rates for multiparous and primiparous women. FMU care seems to offer important lessons that should also be brought to bear on the development of OU care for low-risk women.

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Freestanding midwifery unit versus obstetric unit: a matched cohort study of outcomes in low-risk women

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Appending information to paper I

Table A: Characteristics of freestanding midwifery units

	Hobro FMU	Frederikshavn FMU
Geographical setting	District/community hospital, southern town in region (11 000 inhabitants)	District/community hospital, northern town in region (24 000 inhabitants)
Obstetrical assistance	Not available No epidurals or argumentation	Not available No epidurals or argumentation
Assistance for maternal and neonatal emergencies *	24-hour emergency assistance on site from anaesthesiologist (day) / resuscitation-capable specialist nurse (evening + night).	24-hour emergency assistance on site from anaesthesiologist (day) / resuscitation-capable specialist nurse (evening + night).
Midwifery staff and training	Experienced local midwives whose employment predated unit's conversion into FMU, working in 24 hour shifts in an economically sustainable, team care model Multidisciplinary mannequin training in obstetrical emergencies, including ventouse delivery$^{\pm}$ FMU midwives provided antenatal care and out-of-hours post partum care for all women in the area booked for both OU and FMU birth. FMU midwives also assisted at the nearest OU, if FMU not busy.	Experienced local midwives whose employment predated unit's conversion into FMU, working in 24 hour shifts in a economically sustainable, team care model Multidisciplinary mannequin training in obstetrical emergencies, including ventouse delivery$^{\pm}$ FMU midwives provided antenatal care and out-of-hours post partum care for all women in the area booked for both OU and FMU birth. FMU midwives also assisted at the nearest OU, if FMU not busy.
Minimum transfer time	35 minutes If possible, FMU midwives accompanied women who were transferred to an OU and continued care, supervised by an obstetrician.	25 minutes If possible, FMU midwives accompanied women who were transferred to an OU and continued care, supervised by an obstetrician.
Women transferred to	OU, Aalborg Hospital	OU, Vendsyssel Hospital
Some women may choose transfer to:	OU, Randers Hospital or OU, Viborg Hospital (out-of-region hospitals)	OU, Aalborg Hospital

Number of birthing rooms	2	2
Birthing facilities	Conventional birthing rooms with easy access to birthing pool and shower. Other facilities such as resting room, living room, corridor and kitchen were also used	Large birthing rooms with birthing pool, shower and both double bed and obstetric bed. Other facilities such as living room, corridor and kitchen were also used
Care characteristics	One-to-one care and continuous support in labour most often available. Mobility and use of different labour positions encouraged. Music used for relaxation	One-to-one care and continuous support in labour most often available. Mobility and use of different labour positions encouraged. Music used for relaxation
Cardiotocography (CTG)	Admission CTG offered to all women. Transfer performed if CTG indicated	Admission CTG offered to all women. Transfer performed if CTG indicated
Early labour assessment	Home visits occasionally offered	Home visits occasionally offered (10-20%)
Homebirth[‡]	Offered as part of service	Offered as part of service
Postnatal care	3-4 days in family rooms, family friendly environment, always possible for partner to stay. No postnatal staff during night. Full 'baby-friendly' WHO/UNICEF accreditation. Women with no post partum complications who had given birth in the OUs could be transferred to the FMUs for post partum care	3-4 days in 2-bed postnatal rooms, family friendly environment, always possible for partner to stay. No postnatal staff during night. Full 'baby-friendly' WHO/UNICEF accreditation. Women with no post partum complications who had given birth in the OUs could be transferred to the FMUs for post partum care
Antenatal care	The region's 'standard package' of antenatal care offered by FMU midwives	The region's 'standard package' of antenatal care offered by FMU midwives

* Only for emergencies such as maternal collapse, severe postpartum haemorrhage or need for neonatal resuscitation.

[±]Ventouse delivery is included in the ICM Essential Competencies for Midwifery Practice and midwives in many different settings and countries (including FMUs in e.g. the UK, Norway and Denmark) have acquired the necessary skills

[‡] As selection criteria for home birth and FMU were identical, both home birth and FMU birth were offered to all low-risk women by FMU midwives. Women could change their decision about place of birth at any time, also during labour.

Table B: Characteristics of obstetric units

Characteristics	Aalborg OU	Vendsyssel OU
Geographical setting	Specialist, university hospital, located in main city of the region (120.000 inhabitants)	Provincial hospital, centrally placed in the North of the region (25.000 inhabitants)
Facilities	Neonatal intensive care unit Neonatal surgical Adult intensive care	Generalised paediatric unit with neonatal beds Adult intensive care unit
Consultant obstetrician	24-hour service on site	On site during daytime
Consultant paediatrician	24-hour service on site	On site during daytime
Consultant anaesthesiologist	24-hour service on site	On site during daytime (resuscitation-capable specialist nurse on site during night)
Midwifery staff	Mixed level of experience Most OU midwives also provided antenatal care for both high and low risk women in the area 24-hour consultant midwife on site	Mixed level of experience Most OU midwives also provided antenatal care for both high and low risk women in the area Consultant midwife on site during daytime
Number of labour rooms	12	5
Birthing facilities	Conventional birthing rooms. 1 room with birthing pool, access to two labour pools Most women stay in birthing room during labour	Conventional birthing rooms, two rooms with birthing pool Most women stay in birthing room during labour
Care characteristics	One-to-one care and continuous support in labour typically not available	One-to-one care and continuous support in labour typically not available
CTG	No admission CTG Auscultation used in low-risk labour (continuous CTG used in case of oxytocin augmentation and epidural analgesia)	No admission CTG Auscultation used in low-risk labour (continuous CTG used in case of oxytocin augmentation and epidural analgesia)
Early labour assessment	Home visits not offered	Home visits not offered
Postnatal care (complicated birth)	Conventional postnatal ward (nurse staff) 2-4 postnatal beds per room	Conventional postnatal ward (nurse staff) 2-4 postnatal beds per room

Postnatal care (underline) (uncomplicated birth)	3-4 days on midwifery ward 2-4 postnatal beds per room Rarely possible for partner to stay Postnatal staff on ward 24 hours a day	3-4 days in same conventional postnatal ward as women with complicated birth Rarely possible for partner to stay Postnatal staff on ward 24 hours a day
Antenatal care	The region's 'standard package' of antenatal care offered by OU midwives	The region's 'standard package' of antenatal care offered by OU midwives

Table C: Adverse outcomes: maternal morbidity, perinatal death, 5 min Apgar score<7, >1 week NICU stay

Cases	Apgar score	Birth description	Place of birth	Days in NICU	Neonatal events
Freestanding Midwifery Unit					
Case 1	3/5	**The only case of perinatal/neonatal mortality in the study** Multipara FMU in active labour, normal admission CTG, clear amniotic fluid, spontaneous vaginal birth. Respiratory failure 2-3 minutes after birth. Anaesthesiological assistance called, immediate **advanced resuscitation attempted but the infant did not response**. The rare and severe condition of the infant was not detected by antenatal ultrasound screening at 19.4 weeks. Had the mother not chosen FMU care, this infant would most likely have been born in the nearest OU, here located in a provincial hospital with a generalised paediatric unit (consultant paediatrician, obstetrician and anaesthesiologist on call outside daytime). Transfer required to specialised unit (305 km away).	FMU	0	**Infant dead** **Severe congenital malformation** (diaphragmatic hernia). Occurrence 1:2500-1:5000, approx. 40% of infants have additional malformations. Total mortality (Danish population): 43% Advanced resuscitation on site
Case 2	4/5	Primipara Primary rupture of membranes, FMU 20 hours later, 1 cm cervical dilatation, normal admission CTG. Transferred to OU 6 hours later (3 cm dilatation) due to slow progress of labour and request for epidural. In OU: shared care (OU midwife and obstetrician). Epidural, augmentation of labour, pathological CTG pattern. Pyrexia, meconium-stained fluid, fetal blood sampling, episiotomy, instrumental delivery of infant 7 hours after transfer	OU	36 *	Ventilation Admitted to NICU shortly after birth, treated for sepsis and asphyxia. Continuous positive airway pressure (CPAP) and antibiotics. **Severe congenital heart disease,** surgery at 6 months Discharged well
Case 3	5/5	Primipara Primary rupture of membranes, presents at FMU 10 hours later, clear amniotic fluid, latent phase. Returns home after 6 hours, transferred to OU 24 hours after rupture of membranes. In OU: shared care (OU midwife and obstetrician). Cervical dilatation 1 cm, augmentation of labour, no antibiotics, meconium-stained fluid. Spontaneous vaginal birth 6.5 hours after transfer.	OU	5.7	No ventilation, short intubation for trachea suction. Admitted to NICU shortly after birth due to asphyxia and meconium aspiration CPAP, antibiotics Discharged well
Case 4	5/5	Primipara FMU during latent phase, 1 cm cervical dilatation. Normal admission CTG. After 9 hours, cervix dilated 3 cm, transferred to OU due to protracted latent phase In OU: shared care (OU midwife and obstetrician). Amniotomy, augmentation of labour, epidural, CTG. Occipital posterior position, clear amniotic fluid. After 23 hours in OU, spontaneous vaginal birth	OU	0	No ventilation Child not admitted to NICU Discharged well

Case 5	**6/5**	Multipara FMU at 2 cm cervical dilatation. Normal admission CTG. Transferred to OU 8 hours later because of no progress In OU: shared care (FMU midwife and obstetrician). Augmentation of labour, epidural. Pyrexia, antibiotics. Clear amniotic fluid. Caesarean section 5 hours after transfer because of pathological CTG	OU	0.6	Ventilation, no chest compressions. Birth weight low for gestational age (2554 g). Child admitted to NICU for 14 hours, observation only Discharged well
Case 6	(7/5)	Multipara FMU at 2 cm cervical dilatation, frequent painful contractions. **Admission CTG with pathological pattern, emergency transferred to OU** 1 hour after admittance. Tocolytic given for transfer, CTG pattern improves In OU: shared care (FMU midwife and obstetrician). CTG, Caesarean section 4 hours after transfer due to fetal distress. Abruptio placentae	OU	**12.5 ****	Ventilation, no chest compressions. Admitted to NICU shortly after birth. CPAP and antibiotics. 2 days later, acute apnoea: Intubation, ventilation and transfer Discharged well
Case 7	(7/5)	Primipara FMU at 1 cm cervical dilatation. Normal admission CTG. Transferred to OU 10 hours later at 7 cm cervical dilatation because of slow progress of labour In OU: shared care (OU midwife and obstetrician). Augmentation of labour, CTG, spontaneous vaginal birth 3 hours after transfer	OU	**11 *****	No ventilation Admitted to NICU shortly after birth for respiratory problems. CPAP Discharged well
Case 8	10/5	**Adverse event with potential adverse outcome** Multipara: Umbilical cord prolapse in multipara after spontaneous rupture of membranes. Local gynaecologist is summoned against protocol and an emergency caesarean section performed. Had guidelines been followed, the woman would have had a tocolytic, pelvic elevation, and the infant would have been pushed up vaginally while an emergency transfer was carried out (minimum duration 20 min.). The women would have been taken directly to the operating theatre where an obstetrician would decide on the further action. **(case included in sensitivity analysis)**	FMU	**0**	The event happened less than two months after the maternity unit had been turned into a FMU. The staff involved had previously worked closely together and chose not to follow the regional guidelines for emergency transfer from FMUs. Apgar score 10/1, 10/5. Infant and mother discharged well
Obstetric Unit					
Case 9	**4/5**	Multipara OU at 10 cm cervical dilatation, fast labour. No CTG. Meconium-stained amniotic fluid just before spontaneous vaginal birth	OU	0.4	Ventilation, chest compression. Admitted to NICU for 9 hours, CPAP Discharged well
Case 10	**6/5**	**The only case of severe maternal morbidity in the study (The incident also lead to neonatal morbidity).** Multipara OU at 5 cm cervical dilatation. Epidural, augmentation of labour, continuous CTG. Meconium-stained amniotic fluid, fetal distress leading to caesarean section. **Uterine rupture** discovered. Postpartum haemorrhage>2500 ml. **Peripartum hysterectomy.**	OU	5	Oxygen mask, no ventilation Admitted to NICU shortly after birth, hypertonia and respiratory problems. CPAP Discharged well
Case 11	**6/5**	Primipara OU at 5 cm dilatation. No dilatation for two hours: Augmentation of labour, CTG, meconium-stained fluid. Spinal analgesia (saddle block), followed by short fetal bradycardia. Ventouse delivery 7.5 hours after admission	OU	4.6	No ventilation Admitted to NICU shortly after birth for respiratory problems. CPAP, antibiotics Discharged well

Case 12	**6/5**	Multipara OU at 5 cm cervical dilation. Augmentation of labour, meconium-stained labour, continuous CTG, spontaneous vaginal birth	OU	3.7	No ventilation Admitted to NICU, hypertonia and respiratory problems. CPAP, treatment for seizures. Discharged well
Case 13	**6/5**	Multipara OU at 10 cm cervical dilation. No CTG, fast labour, clear amniotic fluid, spontaneous vaginal birth	OU	1.5	No ventilation Admitted to NICU for respiratory problems CPAP. Discharged well

*Longest NICU stay in study   **Second longest NICU stay   ***Third longest NICU stay

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Freestanding midwifery units versus obstetric units: does the effect of place of birth differ with level of social disadvantage?

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Freestanding midwifery units versus obstetric units: does the effect of place of birth differ with level of social disadvantage?

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Abstract

Background

Social inequity in perinatal and maternal health is a well-documented health problem even in countries with a high level of social equality. We aimed to study whether the effect of birthplace on perinatal and maternal morbidity, birth interventions and use of pain relief among low risk women intending to give birth in two freestanding midwifery units (FMU) versus two obstetric units in Denmark differed by level of social disadvantage

Methods

The study was designed as a cohort study with a matched control group. It included 839 low-risk women intending to give birth in an FMU, who were prospectively and individually matched on nine selected obstetric/socio-economic factors to 839 low-risk women intending OU birth. Educational level was chosen as a proxy for social position. Analysis was by intention-to-treat.

Results

Women intending to give birth in an FMU had a significantly higher likelihood of uncomplicated, spontaneous birth with good outcomes for mother and infant compared to women intending to give birth in an OU. The likelihood of intact perineum, use of upright position for birth and water birth was also higher. No difference was found in perinatal morbidity or third/fourth degree tears, while birth interventions including caesarean section

and epidural analgesia were significantly less frequent among women intending to give birth in an FMU.

In our sample of healthy low-risk women with spontaneous onset of labour at term after an uncomplicated pregnancy, the positive results of intending to give birth in an FMU as compared to an OU were found to hold for both women with post-secondary education and the potentially vulnerable group of FMU women without post-secondary education.

In all cases, women without post-secondary education intending to give birth in an FMU had comparable and, in some respects, more favourable outcomes when compared to women with the same level of education intending to give birth in an OU.

In this sample of low-risk women, we found that the effect of intended place on birth outcomes did not differ with women's level of education.

Conclusion

FMU care appears to offer important benefits for birthing women with no additional risk to the infant. Both for women with and without post-secondary education, intending to give birth in an FMU significantly increased the likelihood of a spontaneous, uncomplicated birth with good outcomes for mother and infant compared to women intending to give birth in an OU. All women should be provided with adequate information about different care models and supported in making an informed decision about the place of birth.

Keywords

Background

Social inequity in perinatal and maternal health is a well-documented health problem [1] affecting women the world over. Systematic disparities in health associated with social determinants [2] are still seen in societies with high levels of social equality. Even in the Nordic countries with their comprehensive public health care and welfare systems, social factors exert a strong influence on both maternal and perinatal birth outcomes [1,3].

Socially disadvantaged women, as defined by factors such as low levels of education, employment, income, or residence in a deprived area, suffer increased morbidity and mortality during childbirth [1,4] when compared to women from socially advantaged backgrounds. Their infants have higher perinatal and neonatal morbidity and mortality [3-9] and are more often born preterm [10-13], with lower Apgar scores and birth weight [4,9,14-16] and are overrepresented [17,18] in neonatal units.

The incidence of epidural analgesia [19,20], use of an upright birth position [21], caesarean section and other birth interventions have also been suggested as being affected by social inequality, but results on caesarean section are conflicting with some studies finding a higher [22,23] and others a lower likelihood among disadvantaged women [24-29]. It is unclear whether this inconsistency in findings for caesarean section and epidural is due to differences

in the organisation of maternity care services (private/public) [25,28-30], hospital specialisation level [31], and the type of lead caregiver (obstetrician/midwife) [32]. It may be noted, though, that the use of birth interventions is more widespread in societies with high levels of hospitalisation and specialisation and where private health services are prevalent [25,28-31].

It has been argued that disadvantaged pregnant women perceive themselves as having little knowledge and little choice, and that they have considerable faith in medical "experts" [33], and are more positive towards interventions and use of medical pain relief compared to advantaged women [34]. In this perspective, disparities in the use of intervention, pain relief and birth position are seen to reflect different preferences between the two groups of women. However, Green et al. [35,36] have contested this perception while Lazarus has argued that insufficient attention is given to how social restraints and conditions impact on women's expectations and experiences [37]. We find it likely, as argued by de Jorge [21], that some care options are offered less frequently to disadvantaged women while health professionals tend to offer more positive responses to the wishes and demands of advantaged, confident and articulate women [28,38]. They may also generally receive a higher level of continuity of care [39], higher quality care and be prioritised over disadvantaged women [40].

The complex relationship between social disadvantage and birth outcomes is confounded by the influence of several factors such as stressful life conditions, life style, health behaviours and their accompanying/underlying medical conditions [41]. Despite an overall increased risk of complications, the majority of disadvantaged women enter spontaneous labour at term without having developed maternal or perinatal complications and are thus categorised as being at low risk of intrapartum complications. As population-based studies generally are not able to take into account differences in women's obstetric risk factors [1,3-10,13,14,16-18], it is unclear whether social inequality persists among these women.

Obstetric units (OU) have today become the primary setting for birth in most middle- and high-income countries, often with all frontline care being provided by midwives. However, alternative birth settings such as freestanding midwifery units (FMUs) are also offered in several countries, including New Zealand [42], the United Kingdom [43], Canada [44], the United States [45], Italy [46], Germany [47], the Republic of South Africa [48], Brazil [49], Norway [50], in some of which childbirth policies aim to provide women with a choice of birthplace [51,52].

Generally, FMUs are based on a woman/family-centred philosophy and aim to provide supportive, individualised care and encourage spontaneous, vaginal birth [53]. They provide low-risk women with a choice among different models of intrapartum care. In sparsely populated areas, FMUs offer care closer to home (to low-risk women) [50], while in low-income countries they may provide women with affordable and accessible care [54,55].

The primary professional responsibility for care in FMUs is in the hands of midwives. All need for obstetrical, neonatal, and anaesthetic care requires ambulance transfer of the women and /or

infant to an OU [56]. As acute perinatal and maternal complications may arise in spite of careful risk assessment of women, safety of FMU care has been a concern and until recently limited evidence has been available [57].

In 2011 the Birthplace in England Research Programme, an extremely large, prospective cohort study found no significant differences in perinatal outcome between women intending to give birth in a FMU and women intending to give birth in an OU while the use of medical interventions and medical pain relief were significantly reduced among women receiving care from FMUs [58]. In our own recent study of FMU versus OU care in Denmark, we compared perinatal outcomes for low-risk women intending to give birth in an FMU and low-risk women intending to give birth in an OU. We also found no difference for perinatal outcomes while women in the FMU group had reduced maternal morbidity and fewer birth interventions [59]

Several studies document that the women rate their experience of care in terms of psycho-social outcomes more positively in midwifery units compared to OUs [43,44,60-63]. In our study of FMU care, we also found that the effect of FMU care on women's birth experiences differed by women's level of social disadvantage and that FMU care had a mitigating effect on the effect of social disadvantage on birth experience [63]. With this increased evidence on the safety and quality of care in midwifery units [64], it seems likely that more low-risk women will choose FMU settings for birth if they are available.

In general, non-OU settings for birth have been found to be the choice of the group of more mature, better-educated, middle-class women of socially privileged backgrounds [44,58,65-67]. However, proximity is also seen to exert a strong influence on women's choice of birthplace [68-70]. With increasing distance between maternity units as a result of centralisation, the social characteristics of women choosing a non-OU service may become more mixed [68].

There is limited evidence concerning birth outcomes of FMU versus OU care for disadvantaged women. A systematic literature search identified only one study on perinatal and maternal outcomes in FMUs, which explored the interaction between birthplace and perinatal and maternal birth outcome. This study concluded that outcomes did not differ by women's level of social disadvantages [71]. Our study of two FMUs located in community hospitals in peripheral, low education and low income areas, provides a rare opportunity to investigate the outcomes and suitability of FMU care for socially disadvantaged women.

Objectives

The aim was to study the whether the effect of intended birthplace on perinatal and maternal morbidity, birth interventions and use of pain relief and upright position for birth among low risk women intending to give birth in two FMU versus two OU in Denmark differed by level of social disadvantage.

The study is reported in accordance with the STROBE requirements for observational studies [72,73].

Study hypotheses

Our study of the literature led us to hypothesise that in the present sample of low risk women where all frontline care in both groups are provided by midwives in the context of a public health system, the effect of birthplace on perinatal and maternal morbidity would not differ by women's level of education

For disadvantaged women we hypothesised that FMU care, with its focus on social support, individualised care and shared decision-making, would support the likelihood of spontaneous, uncomplicated birth, water birth and use of water tub and upright position for birth when compared to disadvantaged women intending to give birth in an OU.

Methods

Design

The study was a cohort study with a matched control group. Data were sampled during a 3.5-year period between 2004 and 2008

Setting

The study was conducted in the peripheral and relatively sparsely populated North Denmark Region, which provided low-risk women with a free choice of birthplace between two FMUs and two OUs. All four units were publicly financed and cooperated closely on referral and transfer on the basis of multi-disciplinary guidelines.

In Denmark, pregnant women have shared antenatal care provided by a general practitioner and a midwife who are both responsible for screening of pregnant women for risk factors and referral to a higher level of care in case of complications or indications of such. The lines of referral follow regional, multi-diciplinary guidelines. In the North Denmark Region low risk women had the choice of intrapartum care from any of the two FMUs and two OU in the region or a home birth (1%) and they were able to change their decision at any time, including during labour. Proximity/ accessibility has been found to be an important factor for women's choice of birthplace in the region.

Freestanding maternity units

The two FMUs were located in the vicinity of two community hospitals, staffed by 4–8 midwives who provided antenatal, intrapartum and postpartum care in a team care model. No on-site obstetrical service was available in the two FMUs, who saw approximately 170 (Hobro FMU) and 130 (Frederikshavn FMU) births a year.

The two units were characterised by one-to-one care and continuous support throughout labour and active encouragement of women to ambulate and use water and music for pain relief and relaxation.

Following the Region's multidisciplinary guidelines for referral and transfer, all FMU women were offered a 20 minute cardiotocography test as a screening for fetal well-being. Midwives and obstetrician agreed on this practice although not fully evidence based as it lowered some medical concerns over perinatal safety and offered increased documentation of fetal well-being at the start of care in labour.

The midwives employed at the FMUs had at least two years of practice experience and multidisciplinary mannequin training in obstetrical emergencies, including ventouse delivery. In case of complications or any indication of them, the women and/or infants were transferred to the nearest OU/ Neonatal Intensive Care Unit (NICU) 25 to 35 minutes away. If possible,

FMU midwives accompanied women during transfer and continued care under supervision of an obstetrician in the OU. Please see Table 1 for further information.

Table 1 Characteristics of the participation FMUs and OUs

	The Freestanding Midwifery Units	The Obstetric Units
Referral to place of birth	Risk assessment by midwife and general practitioner at all antenatal visits	Risk assessment by midwife and general practitioner at all antenatal visits
	Low risk women self-referred to preferred place of birth (home, FMU, OU). Decision could be changed at any time	Low risk women self-referred to preferred place of birth (home, FMU, OU). Decision could be changed at any time
Primary intrapartum care provider	Midwife	Midwife
	In case of transfer, the FMU midwife would accompany the women to an OU and if possible, continued care, supervised by an obstetrician.	In case of complications, the OU midwife would continue care, supervised by an obstetrician.
Midwifery staff	Midwives with >2 years of training, working in a team care model. When needed the FMU midwives would assist at the nearest OU if the FMU was not busy.	Midwives with different levels of experience, supervised by consultant midwife. No team care.
	All FMU midwives provided antenatal care one day a week for high and low risk women in the area, regardless of the woman's choice of birthplace	Most OU midwives provided antenatal care one day a week for high and low risk women in the area
	The FMU midwives provided intrapartum and out-of-hours post partum care in 24-hour, on-call shifts.	OU midwives worked in a combination of 8-hour shifts and 24-hour (on-call) shifts.
	1–2 FMU midwives provided only antenatal and postnatal care (all women in the area with low risk of post partum complications could be admitted to the postnatal ward).	No OU midwives provided post partum care
Care concept	Priority was given to one-to-one care and continuous support in labour. Most women would be cared for by 1(−2) different midwifes during labour.	One-to-one care and continuous support in labour typically not available. Most women would be cared for by 2–3 different midwives during labour
	Active encouragement of ambulation, use of different labour positions and use of water and music for pain relief and relaxation.	Ambulation, use of different labour positions, use of water and music for pain relief and relaxation possible but not routinely encouraged.

	Amniotomy (<5 cm dilatation) and episiotomy could be performed if considered relevant by the midwife	Amniotomy (>5 cm dilatation) and episiotomy could be performed if considered relevant by the midwife as well as oxytocin augmentation of labour (the latter only on basis of local guidelines).
Cardiotocography (CTG)	Auscultation. Admission CTG offered to all women. Transfer performed if CTG indicated	Auscultation. No Admission CTG. CTG only used on indication (including epidural analgesia and oxytocin augmentation)
Assistance for emergencies *	The FMUs were hosted by regional hospitals providing 24-hour emergency, on site assistance from anaesthesiologist (day) / resuscitation-capable specialist nurse (evening + night). All obstetric and paediatric assistance required transfer	Assistance of obstetrician, anaesthesiologist and paediatrician available 24-hour on site / on site during daytime
Transfer	Ante- and intrapartum referral/transfer to OU on basis of regional, multi-disciplinary guidelines. The FMUs, OUs and ambulance service had well-established routines for ambulance transfer of mother and infant.	OU midwife / consultant midwife/ obstetrician and/or paediatrician would always be contacted by FMU midwife before transfer in order to prepare the admission of the patient.

Obstetric maternity units

Aalborg University Hospital, located in the regional capital, is a highly specialised hospital offering a specialist OU 24-hour on-site service with approximately 3500 births a year. The unit was staffed by consultant obstetricians, paediatricians, anaesthesiologists and midwives. Vendsyssel Hospital, located in the main town of a municipality of Hjørring, has ten clinical specialities including a generalised paediatric ward and an obstetric unit that provides care for low-risk and most high-risk women (appr

The birthing rooms at both OUs were conventionally equipped with a labour bed as the central feature. Electronic fetal monitoring was not routinely used in births in low risk women. As in the FMUs, birthing pools were available and used both for pain relief and water birth, but one-to-one care and continuous support in labour was typically not available until late in the first stage of labour. Epidural analgesia was available 24 hours a day (used in 10-15% of all births during the study period). In Denmark, midwives are the lead carer for all low risk women including those giving birth in obstetric units.

Participants

The study included 839 low-risk women intending to give birth in Hobro or Frederikshavn FMUs and a matched control group of 839 low-risk women intending to give birth in the one of the obstetric units at Aalborg University Hospital or Vendsyssel Hospital.

The study included all women admitted in labour to the FMUs on the basis of the regional, multidisciplinary admission criteria during the study period and their individually matched controls, identified among low-risk women intending to give birth in the nearest OU.

Definition of low risk

Women in the study were categorised as low-risk if they were healthy, had presented in spontaneous labour between $37 + 0$ and $41 + 6$ weeks of gestation and had no obstetric risk-increasing conditions as outlined in the NICE Intrapartum Care Guidelines [74]. Women with fetal growth retardation in an earlier or in current pregnancy and severe social problems such as substance or drug abuse or a history of child neglect were not eligible for FMU care.

The matching process

For each participant included in the FMU study group, a data form containing anonymised information on matching data was sent to the project staff at the nearest OU. Control participants were selected from the region's patient administration system which contains detailed information on all pregnant women in the region. All controls were prospectively identified among the low-risk women admitted to the nearest OU. Matching was performed at the start of care in labour on the following criteria: low-risk status, parity and smoking status, Body Mass Index (BMI), first language, education level, occupation level, and cohabitation status.

Variables and data measurement

In our overall study of FMU care, Apgar score of <7 at 5 min and caesarean section was defined as primary outcomes to allow for comparison with other studies. An important secondary outcome was spontaneous vaginal birth. These outcomes are reported in [59].

This study compares two models of care for low risk women, both striving to achieve the best perinatal and maternal birth outcome. In this analysis, we focused on the optimum outcome of birth: *a spontaneous, uncomplicated birth leaving both mother and infant in good condition"* as the primary outcome. This outcome was defined as birth following spontaneous onset of labour in 37th to 42nd gestational week leading to spontaneous birth of an infant with a minimum Apgar score of 9 or 10 at 5 minutes and no need of NICU admission. The analysis was based on the intention-to-treat principle and women were excluded if experiencing: shoulder dystocia, third-fourth degree perineal tear, uterine rupture, caesarean section, instrumental delivery, medical augmentation of labour, episiotomy, retained placenta, and bleeding exceeding 500 ml. Participants who during labour had epidural analgesia, CTG monitoring and amniotomy were included if they did not experiencing the mentioned complications or interventions but had a spontaneous vaginal birth with good maternal and perinatal outcome.

Apgar score of <9 at 5 min was chosen as another primary outcome. A 5 min Apgar score of <9 cannot be classified as a poor outcome but in this specific study of freestanding midwifery units, located 50 km (25–35 min of ambulance transfer) away from the nearest obstetric unit, it is an undesirable outcome that would prompt action from the midwife both in term of care for the infant and call for assistance. In some cases immediate transfer to NICU would be needed, in other cases the infant would be kept under increased observation, at least for some hours after birth. Depending on the infant's 1 and 10 min Apgar Score and general condition, the midwife would have to assess the infant's risk of e.g. neonatal hypoglycaemia and hypothermia and maybe seek pediatric advice (e.g. via telephone). Furthermore, the routine postnatal care regime for low risk women (discharge few hours after birth or admission to the postnatal ward with only on-call staff between 8 pm and 8 am) may not be considered safe.

Other outcomes related to the infants were: NICU admission <24 h, readmission 0–28 days postpartum, while outcomes related to the mothers were: caesarean section, instrumental delivery, augmentation of labour, intact perineum, third or fourth degree tear, maternal readmission 0–28 days postpartum, epidural analgesia, water birth and upright position for birth.

The intended place of birth at the start of care in labour was considered the exposure.

A number of socio-economic factors have traditionally been used as indicators for women's social position in society, including length of education, income, occupation, unemployment and level of area deprivation. Our choice of education as explanatory variable was based on both international and Danish findings [3,7,9-11,14,75,76] which have established a clear association between a low level of education and numerous negative health outcomes such a low birth weight and preterm birth.

In Denmark education is free and compulsory from the age of seven to 16 (9 year program). In 2008, 56% of students continued to complete upper-secondary education after 12 or 13 years. Students aiming to continue into a vocational education program (35%) often chose the comprehensive school's optional 10th year [77]. This provided the basis for dichotomising the women's school qualifications into "No post-secondary" versus "All types of post-secondary education". Women with 9–13 years of schooling were categorised into the group "No post-secondary education" if they had not completed or were not undertaking any official training or educational program qualifying for the labour market. Post-secondary education was used as cut-off point, as the absence of labour market qualification increases the risk of unemployment or employment involving manual, physically demanding and/or, unfulfilling labour with low pay.

Statistical analysis of data

The present study is a secondary analysis, and power calculations are thus not performed. The study strength is however reflected in the confidence intervals.

For the overall study, power calculations and thus sample size was estimated on basis of a number of clinical endpoints in relation to maternal and perinatal morbidity, birth complications and interventions. Due to unexpected closure of the two participating FMU during the data collection period, the study sample size was reduced from the originally planned 1027 women to 839 women in each group. To achieve the highest possible number of women in the FMU group, 289 women that had been admitted to the FMUs between

01.03.2004 and the original study start 01.01.2005 were included in the study and prospectively matched with control participants. This decision was made after thorough revision of the study protocol and only possible because of the highly detailed patient records that were of very good quality. The study implication is discussed later and also in Overgaard et al. 2011[59] (open-access publication of the overall study).

The reduced sample provided power (5% significance level, 80% power) to detect an increase in Apgar score <7 at 5 min from the expected 1.07% in the OU standard care group to 3.1% in the FMU group and a reduction in the incidence rate of caesarean section from 8.8% in the OU group to 5.5% in the FMU group.

The data analysis was carried out by use of STATA statistical software, version 11. Two groups of women with fully comparable obstetric and socio-demographic characteristics were matched on the basis of their intentions regarding birthplace. Women opting for an FMU were matched 1:1 with women who preferred an OU. The analysis was based on an intention-to-treat principle.

For all outcomes a conditional logistic regression grouped on match-pairs was applied to estimate and test the effect of birthplace overall and in education-induced subgroups as well for assessing effect differences between subgroups. For all comparisons, odds ratios with 95% confidence intervals were calculated. All reported P-values were two-sided with a statistical significance level of 5%.

Data security and ethics

The project was approved by the Danish Data Protection Agency (reference number: 2005-41-5352) and data were treated in strict accordance with Danish legislation on the use of patient data in research [78]. According to this legislation, ethical approval from authorities or participants' consent is not required for an observational study of this kind.

Participant characteristics

Each of the two study groups comprised 839 low-risk women, none of whom were lost to follow up (see Figure 1, flow chart).

Figure 1 Flow chart

As shown in Table 2, the matching produced two fully comparable groups in terms of key medical and socio-demographic factors. Almost all women had as their first language a Nordic or West European language (FMU 96%; OU 96.4%) and were married or cohabiting with a partner (FMU 97%; OU 97.4%).

Table 2 Participant characteristics

Characteristics	FMU	OU		
	N	(%)	N	(%)
Low obstetric risk of complications	839	(100)	839	(100)
Primiparas	215	(25.6)	215	(25.6)
Multiparas	624	(74.4)	624	(74.4)
Non-smokers	684	(81.4)	684	(81.4)

Smokers	156	(18.6)	156	(18.6)
First language Nordic or Western European	805	(96.0)	809	(96.4)
Other first language	34	(4.0)	30	(3.6)
No post-secondary education	230	(27.4)	230	(27.4)
Post-secondary education	609	(72.6)	609	(72.6)
Low level of employment*	535	(63.8)	535	(63.8)
High level of employment	304	(36.2)	304	(36.2)
Living with partner	815	(97.1)	819	(97.6)
Living alone	24	(2.9)	20	(2.4)
	mean	**(SD)**	**mean**	**(SD)**
BMI	24.2	(3.9)	24.0	(3.9)
Age	29.4	(4.6)	30.2	(4.5)

Unskilled work, skilled work (vocational), work requiring maximally 2 years of post-secondary training

Education and income levels in the North Denmark Region were low compared to the Danish population in general [79], conditions which are reflected in the characteristics of the pregnant women in the predominantly rural catchment areas of the two FMUs. Thus, 27.4% of the women had no post-secondary education, 63.8% were had a low level of employment (or were unemployed). Smokers made up 18.6%. Means for BMIs were 24.2 and 24.0, for age 29.4 and 30.2 years in the FMU and OU groups, respectively.

Results

We analysed the effect of educational level on a range of outcomes, presented in Table 3.

Table 3 Outcomes by level of social disadvantage

Outcome	No post-secondary education 230 FMU/ 230 OU OR (95% CI)		Post-secondary education 609 FMU / 609 OU OR (95% CI)		Effect ratio OR (95% CI)
	N FMU / N OU	FMU / OU	N FMU / N OU	FMU / OU	No post sec./Post sec .
Optimal outcome of birth*	192/156	2.4 (1.5-3.9)	510/434	2.7 (1.9-3.7)	0.9 (0.5-1.6)
Perinatal outcomes					
Apgar score <9/5 min	5/5	1.0 (0.3-3.5)	10/15	0.7 (0.3-1.5)	1.5 (0.3-6.6)
NICU admission >24 hours	7/10	0.7 (0.3-1.8)	11/13	0.8 (0.4-1.9)	0.8 (0.2-3.0)
Infant readmission 0–28 days p.p.	8/7	1.1 (0.4-3.2)	15/28	0.5 (0.3-1.003)	2.1 (0.6-7.0)
Maternal outcomes					
Intact perineum	159/144	1.4 (0.9-2.1)	355/322	1.3 (1.002-1.6)	1.1 (0.7-1.8)
3rd-4th degree perineal tear	5/6	0.8 (0.6-2.7)	14/18	0.8 (0.4-1.6)	1.1 (0.3-4.5)
Maternal readmission 0–28 days p.p.	4/10	0.4 (0.1-1.3)	20/30	0. 7 (0.4-1.2)	0.6 (0.2-2.2)
Interventions					
Caesarean section	6/11	0.5 (0.2-1.5)	13/23	0.5 (0.3-1.1)	1.0 (0.3-3.5)
Instrumental delivery	5/11	0.4 (0.1-1.3)	20/50	0.3 (0.2-0.6)	1.2 (0.3-4.2)

Syntocinon augmentation of labour	19/40	0.4 (0.2-0.7)	50/114	0.3 (0.2-0.5)	1.0 (0.5-2.3)
Pain relief and position for birth:					
Epidural analgesia	10/27	0.3 (0.1-0.7)	25/59	0.3 (0.2-0.6)	0.8 (0.3-2.1)
Water birth	33/15	2.5 (1.3-4.9)	126/56	2.6 (1.8-3.7)	1.0 (0.4-2.0)
Upright position for birth	43/28	1.6 (0.8-3.2)	145/130	1.9 (1.4-2.7)	0.8 (0.4-1.8)

Defined as uncomplicated birth with spontaneous onset of labour between 37 + 0 and 42 +0 weeks of gestation leading to spontaneous birth of an infant with a minimum Apgar score at 9 or 10 at 5 minutes. No shoulder dystocia, 3–4 degree perineal tear, no bleeding >500 ml, retained placenta, no caesarean section, no instrumental delivery, no medical augmentation of labour, and no episiotomy. (Women having medical analgesia (including epidural analgesia), CTG monitoring and amniotomy are included if not experiencing the mentioned complications or interventions)

Optimal outcome of birth

Compared to women in the OU group, women in the FMU group were significantly more likely to have an uncomplicated, spontaneous birth with good outcomes for mother and child (OR 2.6; CI 2.0-3.4). This effect was also found for women with post-secondary education: OR 2.7; CI 1.9-3.7 and without post-secondary education: OR 2.4; CI 1.5-3.9 (effect ratio 0.9; CI 0.5-1.6).

Perinatal outcomes

No significant differences were found between FMU and OU women with respect to Apgar scores <9/5 min, NICU admission >24 hours or infant readmission to hospital 0–28 days postpartum. The same findings applied regarding perinatal outcomes when the two groups of women were compared by level of education. Nor was any significant effect difference between subgroups found.

Maternal birth outcomes

Women in the FMU group were significantly more likely to have intact perineum (OR 1.3; CI 1.1-1.6) and avoid readmission to hospital during the first four weeks after birth (OR: 0.6; 0.4-0.99).

For intact perineum, similar trends were found for both women with (OR 1.3; CI 1.002-1.6) and without (OR 1.4; CI 0.9-2.1) post-secondary education, but for the latter the result was not significant. Effect ratio was OR 1.0; CI 0.3-3.5. For maternal readmissions, there were similar but non-significant trends for both subgroups of women (effect ratio OR: 0.6; 0.2-2.2).

The occurrence of third or fourth degree tears was similar in both study groups and in both education level subg

Birth interventions

A caesarean section was significantly less likely in women in the FMU group compared to the OU group (OR 0.5; 95% CI 0.3-0.9). Similar, but non-significant trends were found both for women with (OR 0.5; CI 0.3-1.1) and without (OR 0.5; CI 0.2-1.5) post-secondary education (effect ratio 1.0; CI 0.3-3.5).

Instrumental delivery (OR 0.4; 95% CI 0.2-0.6) and augmentation of labour (OR 0.4; 95% CI 0.3-0.5) were significantly less frequent in women in the FMU group compared to the OU group. There were similar findings by the level of education. In the post-secondary education group: instrumental delivery (OR 0.3; 95% CI 0.2-0.6) and augmentation of labour (OR 0.3; 95% CI 0.2-0.5). Women without post-secondary education: instrumental delivery (OR 0.4; 95% CI 0.1-1.3) and augmentation of labour (OR 0.4; 95% CI 0.2-0.7).

Effect ratio for instrumental delivery was (OR 1.2; CI 0.3-4.2) and for augmentation of labour (OR:1.0; 0.5-2.3)

Pain relief and position for birth

Overall, epidural analgesia (OR 0.3; CI 0.2-0.5) was significantly less likely among FMU women compared to OU women whereas water birth (OR 2.6; CI 1.9-3.5) and use of an upright position for birth (OR 1.9; CI 1.4-2.5) were significantly more likely.

A significant reduction in use of epidural analgesia was also found both for women with post-secondary education (OR 0.3; CI 0.2-0.6) and for women without post-secondary education (OR 0.3; CI 0.1-0.7), (effect ratio OR 0.8; CI 0.3-2.1)

In the case of water birth a significant increase was seen both for women with post-secondary education (OR 2.6; 1.8-3.7), and women without post-secondary education (OR

For the use of an upright position for birth, a significant increase was found in women with post-secondary education (OR 1.9; 1.4-2.7). Similar but insignificant trends were found for women without post-secondary education (OR 1.6; CI 0.8-3.2).

Other analyses

One hundred and twenty-four women in the FMU group (14.8%) were transferred during the intrapartum period and less than two hours after birth (see figure 1). The rate of transfer was unaffected by the women's educational status (14.3%; 14.9%).

Discussion

Freestanding midwifery units form part of the maternal health services in several countries, where they provide women at low risk of obstetric complications with a choice among birthing facilities and more accessible care. In this study, we investigated whether the effect of birthplace on perinatal and maternal morbidity, birth interventions and use of pain relief among low risk women intending birth in two freestanding midwifery units versus two obstetric units in Denmark differed by level of social disadvantage measured b

Key results

Overall, women in the FMU group had a higher likelihood of spontaneous, uncomplicated birth with good outcomes for both mother and child compared to women in the matched control group who received the standard OU care. Furthermore, FMU women had a higher likelihood of intact perineum, water birth, and use of an upright position for birth and a lower likelihood of caesarean section, instrumental delivery, augmentation of labour, epidural analgesia for pain relief and maternal hospital readmission. No difference in perinatal outcomes or 3rd-4th degree tears was found between groups.

While the level of education is generally found to be high among women opting for out-of-hospital settings for birth [44,58,65-68], we found that as many as 27.4% of the women had no post-secondary education and 63.8% had unskilled work, vocational work or other low level of employment.

For the two subgroups of women with or without post-secondary education, both perinatal and maternal birth outcomes were equal to and more positive for women intending to give birth in an FMU compared to women intending to give birth in an OU.

When we compared women without post-secondary education according to their intended birthplace, the FMU women were found to have a significantly higher likelihood of spontaneous, uncomplicated birth and water birth and a significantly lower likelihood of augmentation of labour and epidural analgesia than the OU women. No differences in perinatal outcomes were detected.

Overall the effect of birthplace on birth outcomes did not differ with women's level of education.

Study limitations and strengths

This study presents a secondary analysis of the study data. In consideration of the study's limited power to investigate rare adverse outcomes, we opted for the composite outcome "uncomplicated, spontaneous birth with good outcome for mother and infant". This outcome defined the optimum outcome of birth and took into account all serious perinatal and maternal morbidity and was inspired by the World Health Organisation's definition of normal birth [80]. Confidence intervals are provided for ease of interpretation of the study results; they are relatively wide for Apgar scores <9 at 5 min, infant readmission and water birth.

The non-randomised design of the study represents an overall limitation. Although the two study groups were very closely matched and supplementary control for matching factors was performed, the risk of residual confounding and confounding by unknown factors related to women's choice of birthplace cannot be fully eliminated. The delay of data collection for the FMU participants from 2004 may also entail a risk of bias. The risk was however considered to be minimal as the data collection was individual and project-specific and the study inclusion criteria were very closely observed. The participating unit's routine statistics were monitored for changes in clinical practices or use of technology and none detected. A subgroup analysis of the 2004-data was performed as part of the overall study to revival potential differences between these data and the main body of data, and reassurance was provided by the finding of concordance of the results.

This issue is further discussed in the open-access publication of the overall study results [59].

Our use of education as a proxy for social disadvantage may also be seen as a limitation as no single measurement is likely to be able to capture the full complexity and meaning of a person's social position and level of social disadvantage. The association between education and birth outcomes is however well documented and believed to be mediated through employment, economical circumstances and psycho-social resources and constraints. In this population, levels of education and income overlapped but we considered education as a key indicator for the following reasons: Danish women have an employment participation rate of 77% which is the highest in EU and among the highest in the world. In a population of pregnant women, education is likely to be a stronger indicator of social position than employment or income because pregnant women are more liable to be (temporarily) outside the active labour force than women overall. Furthermore, education has a stronger influence on women's ability to obtain, understand and react to knowledge (e.g. when to seek help or ask for advice) and to influence health/pregnancy related behaviours and choices. Income was not considered as useful an outcome as education because most women were employed in the skilled trades or the public sector (extremely few were professionals) and the difference in income would be very small. Women in unskilled jobs would typically have a lower income but some would be able to achieve a higher income than women employed in the public sector. Unemployed women and women receiving social benefit or social pension would have a smaller income but because of the Danish welfare system there financial situation would be better than in many other countries.

The use of project-specific and high-quality data collected at the time of birth is a major strength of the study. The accuracy of key information on women's educational level and obstetric risk status and on medical outcomes is thus extremely high. Furthermore, no data are missing.

Overall, our dataset has unique completeness in comparison to several of the few available controlled studies of FMU care [44,58,81,82] as all eligible women planning to give birth in the FMUs were included and full background data and follow-up on all participants were obtained.

In contrast to some earlier studies of FMU care [81,83], our study setting was advantageous by including four regional units following the same multi-disciplinary practice guidelines with midwives as lead caregivers in all overall setting of a national/public health service. Confounding by difference in caregiver, clinical practice and patient's ability to pay was thus reduced.

Interpretation

Our overall findings that perinatal outcomes were comparable for OU and FMU women and that FMU women had fewer interventions corroborate the results of other controlled studies of FMU care[44,81,83-88], only one of which was undertaken in a population of low-income women [81]. Moreover, the results were in line with the results of a large German register study of FMU care [89].

In our restricted sample of healthy low-risk women with spontaneous onset of labour at term after an uncomplicated pregnancy, the positive results of FMU care as compared to OU care

were found to hold for both women with post-secondary education and the potentially vulnerable group of FMU women without post-secondary education.

In all cases, FMU women without post-secondary education had comparable and in some respects favourable outcomes when compared to the individually matched group of OU women with the same level of education.

Most importantly, a significantly higher likelihood of "uncomplicated, spontaneous birth with a good outcome for mother and infant" was seen for FMU women with no post-secondary education compared to OU women with no post-secondary education. We found the FMU women were significantly more likely to avoid interventions and epidural analgesia, and to have a water birth and this effect of birthplace did not differ with level of education. Richmond's contention that water birth is "mainly pursued by educated, middle class women" thus seems unfounded in this context[90]. Neither did effect ratio differences indicate that option of having a water birth, epidural analgesia or using upright positions for birth as suggested by other studies were less open to disadvantaged women [19-21,90].

In contrast to studies of out-of-OU birth in general, university- or college-educated women constituted only a minority in this study, while women with no post-secondary education or vocational training comprised the majority. Overall, the level of education among women who chose FMU care was considerably lower than in most studies, a difference that may be ascribed to two factors: the location of the FMUs in peripheral and partly rural areas where the level of education is among the lowest in Denmark and, secondly, to the FMUs' offer of care close to home. For our sample of low risk women, the results provide no support for the claim that women pursue different birth models and that their aims and wants for pregnancy and birth vary according to their socio-demographic backgrounds [33,34]. Neither was such a claim supported by the responses to our questionnaire survey exploring the birth experiences and care perceptions of the participating women [63]. As the Danish Birth Register does not include data on women's education [91], we were unable to establish whether the choice of local FMU care varied with the women's level of education. An investigation of potential inequalities in relation to women's choice of birthplace, including their knowledge of options available to them, would be relevant.

Considering that Denmark has seen a rising trend for markers of social inequality in birth outcomes such as low birth weight and infant mortality [76,92], we consider it an important finding that birth outcomes of FMU care for low risk women at term did not differ by women's level of education.

The results indicate that the strict low-risk criteria used for this study (reflecting the NICE guidelines for intrapartum care [74]) are helpful in selecting a group of women with low risk of obstetric complications for whom FMU care is very suitable.

The questionnaire survey of the participating women's birth experience and care perceptions documented significantly improved outcomes in the FMU group compared to the OU group and found a mitigating effect of FMU care on the effects of social disadvantage on birth experience [63]. This ability of the FMUs to serve disadvantaged women particularly well was not seen in this study of clinical birth outcomes, where, as compared to OUs, the advantaged and disadvantaged women were found to benefit equally well from FMU care.

In their qualitative study of inequality in maternity care services Hart & Lockley found an absence of clear and specific strategies to combat inequality in maternity care and a pervading assumption that the concept of woman-centred care would provide an appropriate and focused response to the problem of social inequality[40]. At the time of data collection for this study, social inequality in birth outcomes received limited attention in both national [93] and regional [94] recommendations for maternity care. The initiatives outlines were directed towards women with severe problems such as drug addiction while the concept of individualised and patient-centred care was much stronger emphasised. It thus seems unlikely that the absence of signs of overall social inequality in perinatal and maternal outcomes found in this study should be credited to a special focus among Danish midwives on inequality of care or special strategies or initiatives directed towards social inequality in the maternity care sector. However, as documented by Cliff, Danish midwives' have a longstanding tradition of caring for women from all social groups and focusing on the impact of social disadvantage for women and infants[95,96]. Although our earlier study [63] found social disadvantage to be a factor in women's birth experience and perception of care in OUs compared to FMUs, maternity units in the North Denmark Region that were not struggling with understaffing or shortage of midwives may very well be capable of providing clinical care that were sensitive to the impact of social disadvantage on health of women's and infants. Studies of social inequalities in care provision are few, but little socioeconomic variation has also been found for neonatal care [97].

Overall, we found that FMUs were capable of offering clear benefits for disadvantaged, low-risk women with no obvious drawbacks while the group of more advantaged women was also well catered for. In a public health perspective, FMU care holds great potential for improvement of birth outcomes for the population of low-risk women. It is the responsibility of policy makers and health professionals to consider how FMU care can be made accessible to more low-risk women, and how women of all social positions can be supported in making an informed choice of birthplace.

Generalisability

It has been convincingly argued that a country's level of social inequality is reflected in the health of its population [98]. Any generalisation of the study results should take into account that the Danish levels of social equality are among the highest in the world while rates of perinatal and maternal mortality and morbidity are among the lowest [1,99]. The socially disadvantaged women in this study may therefore have been less burdened than women of comparable social status in countries with greater social inequality and/or less comprehensive welfare systems. Furthermore, the free access to maternity care services may have mitigated the effect of social inequality in birth outcomes. Although a straightforward association between the Nordic welfare model and a low degree of social inequality in health has not been demonstrated, these factors should be taken into consideration when generalising the results of the study.

With regard to the ability of FMUs to serve disadvantaged women, it should be noted that the FMU care concept was based on strict, multi-disciplinary criteria for referral and transfer of women, indicating growth retardation, substance or drug abuse, and social factors such as a history of child neglect as risk factors. Neither smoking nor social factors such as poor housing, dependence on social benefit or social pension, dyslexia, or young age were however considered as risk factors on their own.

Conclusions

The present study of FMU versus OU care with midwives as lead caregivers in a public health care system identified several benefits of FMU care for the mother with no additional risk to the infant.

Women intending to give birth in an FMU were found to have significantly increased likelihood of uncomplicated, spontaneous birth with good outcomes for mother and infant. The positive effect of FMU care on perinatal and maternal morbidity, birth interventions and use of pain relief was not found to differ by women's level of social disadvantage.

The strict risk assessment criteria used in the study proved useful in defining a group of women with low risk of obstetric complications. As results for both perinatal and maternal outcomes for women with no post-secondary education intending to give birth in an FMU were similar to or favourable in comparison to the results for women with no post-secondary education intending to give birth in an OU, FMU care must be considered as appropriate for this group of women as for other women with low risk of obstetric complications.

The potential of FMU care to improve maternal health without increasing perinatal risk lead us to suggest that the option of FMU care is made available to low-risk women in all social groups and that all women are provided adequate information about different care models and their benefits and harms in order that they are enabled to make an informed decision about where they want to give birth.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CO is responsible for the study's conceptual design, designed the data collection tools, monitored all data collection, and cleaned the data. She also participated in the data analysis and the interpretation of data, drafted and revised the article after comments and wrote the final version. MFG participated in the data analysis and revised the article for important intellectual content. JS participated in the interpretation of data and revised the manuscript for important intellectual content. All of the authors read and approved the final version that was submitted for publication.
Findings of a matched cohort study of two different models of intrapartum care for low risk women.

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FMU

839 primary participants

230 with no post-secondary education
609 with post-secondary education

OU

839 matched controls

230 with no post-secondary education
609 with post-secondary education

124 FMU women (14.8%) transferred to OU
during labour or <2 h after birth

Full follow-up on all women

Of the 124 women transferred
33 (14.3%) had no post-secondary education
91 (14.9%) had post-secondary education

Analysis by intention to treat

839 women analysed
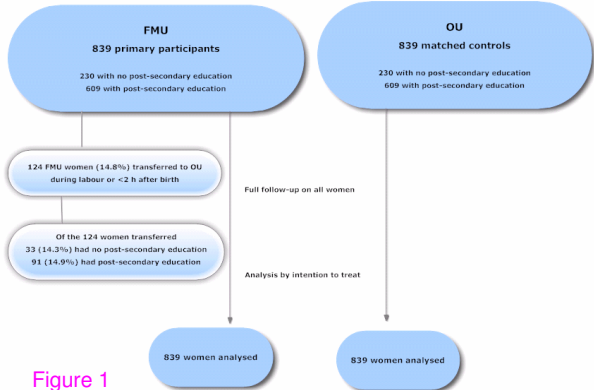
839 women analysed

Figure 1

The impact of birthplace on women's birth experiences and perceptions of care

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A B S T R A C T

Overall birth experience is an important outcome of birth, and studies of psycho-social birth outcomes and women's perspectives on care are increasingly used to evaluate and develop maternity care services. We examined the influence of birthplace on women's birth experiences and perceptions of care in two freestanding midwifery units (FMU) and two obstetric units (OU) in north Denmark, all pursuing an ideal of high-quality, humanistic and patient-centred care. As part of a matched cohort study, a postal questionnaire survey was undertaken. Two hundred and eighteen low-risk women in FMU care, admitted between January–October 2006, and an obstetrically/socio-demographically matched control group of 218 low-risk women admitted to an OU were invited to participate. Three hundred and seventy-five women (86%) responded. Birth experience and satisfaction with care were rated significantly more positively by FMU than by OU women. Significantly better results for FMU care were also found for specific patient-centred care elements (support, participation in decision-making, attentiveness to psychological needs and to wishes for birth, information, and for women's feeling of being listened to). Adjustment for medical birth factors slightly increased the positive effect of FMU care. Subgroup analysis showed that a significant, negative effect of low education and employment level on birth experience was found only for the OU group. Our results provide strong support of FMU care and underline the big challenges in providing individual and supportive care for all women, especially in OUs. Policy-makers and professionals need to consider how the advantages provided by FMU care can support the effort to improve women's birth experience and possibly also the combat of the negative effect of social disadvantage on health.

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Introduction

System responsiveness and patient-centredness has become an important quality indicator of national health services (Committee on Quality of Health Care in America, 2001; World Health Organisation, 2000).The assessment and development of services are increasingly influenced by concepts of patient-centred care that underline the importance of information, communication, emotional support, and respect for patients' values, preferences, and their expressed needs (Gerteis, Edgman-Levitan, & Daley, 1993).

In the field of maternity care, the patient-centred perspective exerts a strong and justified influence on reform and development initiatives as it is well-documented that women's experience of birth and the care provided during this important life event have immediate as well as long term effects on their well-being and health (Gibbins & Thomson, 2001; Parfitt & Ayers, 2009).

While positive birth experiences contribute to women's feeling of accomplishment and self-esteem and lead to psychological growth, empowerment, and easier adaptation to motherhood (Simkin, 1991), negative experiences are associated with a number of complications such as postpartum anxiety, depression, post-traumatic stress syndrome (White, Matthey, Boyd, & Barnett, 2006), fear of childbirth (Waldenström, Hildingsson, & Ryding, 2006), reduced future reproduction (Gottwall & Waldenström, 2002), and request for caesarean section (Tschudin et al., 2009).

Four key dimensions of patient-centred care (Gerteis et al., 1993) have been identified as prominent aspects of the childbirth experience: the woman's perceptions of intrapartum support, participation in decision-making, information, and control (Green & Baston, 2003; Lavender, Walkinshaw, & Walton, 1999; Séguin, Therrien, Champagne, & Larouche, 1989; Waldenström et al., 2006).

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Several studies have established a relationship between a high level of intervention and a negative birth experience (Salmon & Drew, 1992; Waldenstrom, Hildingsson, Rubertssson, & Radestad, 2004; Wilde-Larsson, Sandin-Bojô, Starrin, & Larsson, 2011), thus supporting the claim that natural childbirth improves women's experience (Oakley, 1980). Others, however, have argued that findings of better childbirth satisfaction among women reporting low pain levels (Salmon & Drew, 1992; Waldenström, 1999) provide support for effective medical pain relief as essential to a positive birth experience (Kangas-Saarela & Kangas-Kärki, 1994). However, a positive effect on birth experience has not been documented, even for epidural analgesia, the most effective type of pain relief (Anim-Somuah, Smyth, & Howell, 2005).

Environment and birthplace

In terms of environment and context, birthplace and care provider have been identified as influencing the above, with the medical paradigm of childbirth said to be dominant in most high and middle income countries (Davis-Floyd, 1992). Its hegemony is reflected in an almost full hospitalisation of births and a global trend over the last decades towards rising rates of interventions and medical pain relief and centralisation/specialisation of maternity units (Stephenson et al., 1993; Tracy, Sullivan, Wang, Black, & Tracy, 2007) but has attracted criticism for being inhumane, disempowering, unaccommodating of women's and infants' psychosocial needs, and for exposing women to unnecessary risks (Johanson, Newburn, & Macfarlane, 2002; Roundtable discussion, 2006).

In contrast, the social/holistic paradigm emphasises a spirit of "body-mind oneness" (Davis-Floyd, 2001, p. S16) and totally individualised care. It encompasses a diverse range of beliefs and propounds "natural" childbirth as a social event and a normal bodily process where women may obtain control by letting go (Gaskin, 2003). Midwife-led care and out-of-hospital settings have been identified as more likely to support such philosophies (Walsh, 2006). However, this paradigm is under strong criticism for ignoring medical risk and jeopardising mothers' and infants' welfare. Its opponents sees it as representing a romantic utopian dream, while feminist critics attack its "essentialist" approach to birth and gender as a perpetuation of the repression of women (Beckett, 2005; Moscucci, 2002).

Although commonly purported as dichotomous views by their respective proponents, these understandings fail to grasp the complexity of childbirth and have been challenged. Thus, it has been reported, that women may in fact experience empowerment through the rigorous management and control of the birth process and perceive elimination of pain or choice of a caesarean section as the ultimate form of control (Beckett, 2005; Sargent & Stark, 1989), and that some women are capable of influencing their care within the medical system (Zadoroznyj, 2001). Furthermore, women's perceptions of birth have been found to be influenced by e.g. their expectations (Green, Coupland, & Kitzinger, 1998) or medical factors such as a long labour or the condition of the newborn (Rijnders et al., 2008). Negative influences stemming from sociodemographic factors such as young age, primiparity, and especially low education/low social class have been suggested (Wilde-Larsson et al., 2011; Zadoroznyj, 1999), but findings are inconsistent (Brown & Lumley, 1994; Ranta et al., 1995; Waldenström, 1999; Waldenstrom et al., 2004).

In her later work Davis-Floyd identifies a third, "humanistic" paradigm emerging from inside the medical health care system in an attempt to reform care from within, making it "relational, partnership-oriented, individually responsive and compassionate" (2001, p.S10). We see the broad support for this perspective,

nourished by general societal trends towards patient-centredness, reflected in maternity care policies in countries with public health care systems and the global opening of midwifery units (Morano et al., 2007; Rana, Rajopadhyaya, Bajracharya, Karmacharya, & Osrin, 2003; Riesco et al., 2009).

Midwifery units

Midwifery units providing care for women with low risk of obstetric complications are managed and staffed exclusively by midwives. The units may be located in the vicinity of a hospital obstetric unit, hence termed an "alongside" midwifery unit (AMU), or form a physically separate, freestanding midwifery unit (FMU) (National Perinatal Epidemiology Unit, 2007) from which transferral to an obstetric unit (OU) is made in case of complications. Midwifery units have developed from the "alternative" birth centres of the 1970s and 1980s into today's often publicly financed units forming part of established birth services (Department of Health, 2007; Helsedirektoratet, 2010). The safety of such units continues to be contested despite the findings of a Cochrane review comparing AMU and OU care regimes. This review reported significant reductions in medical interventions in AMUs and comparable perinatal mortality and morbidity and maternal morbidity (Hodnett, Downe, Walsh, & Weston, 2010). Moreover, consistent reports of better psycho-social outcomes of care in midwifery units when compared to OUs (Fraser et al., 2000; Hodnett et al., 2010; Hunter, 2009; Saunders, Boulton, Chapple, Ratcliff, & Levitan, 2000; Walker, Hall, & Thomas, 1995) corroborate the claims that midwifery units provide "individualised and family-centred maternity care with a strong emphasis on skilled, sensitive and respectful midwifery" (Shallow, 2003, 13).

Though there is some evidence to support this claim for AMUs, some studies were weakened by factors such as low response rates (Begley, Devane, & Clarke, 2009; Burne, Crowther, & Moss, 2000), small sample sizes (Burne et al. 2000; Hunter, 2009) or differences in the antenatal care offered (Waldenström & Nilsson, 1994). Furthermore, in some studies the two groups had different sociodemographic characteristics and/or different lead care providers (Begley et al., 2009; Fraser et al., 2000). An unequivocal conclusion is thus precluded.

Research on FMUs is scarce and no ready generalisation based on findings from AMUs studies is possible, especially because of the difference in transfer times and OU attachment. A study of a British FMU has suggested that FMUs have distinct, nonbureaucratic characteristics that facilitate flexibility and relational care and allow for alternative responses to clinical problems (Walsh, 2006). The findings contradicted the results of an older American study where FMU users' best interests were not always considered by midwives hoping to achieve natural childbirth (Annandale, 1987). This may be explained by differences in the health care system (private/public) and the role of midwifery profession (marginal/extensive) in the two study settings.

In this article we seek a deeper insight into women's birth experiences and the role of patient-centred care on the basis of women's rating of their experiences of birth, care element such as the feeling of being listened to, opportunity to participate in decision-making, information provided, and care satisfaction. We present data from a quantitative study of the influence of birthplace in the context of a Scandinavian welfare society where midwives are part of the mainstream maternity care system and the lead carer for all healthy women with low-risk pregnancies and where midwives and most obstetricians subscribe to the humanistic paradigm (DSOG & DADJ, 2001).

Aims and objectives

The aim of this study was 1) to compare women's birth experience, care satisfaction and perception of specific patient-centred care elements in two FMUs versus two OUs and 2) to explore the influence of specific medical and socio-demographic factors on women's birth experience.

Pre-specified hypotheses

Our study of the literature led us to hypothesise that FMU care, with its emphasis on psycho-social birth aspects and parent-infant bonding, would have a positive influence on a number of outcomes, including women's overall birth experience and care satisfaction, and on their perception of patient-centred care elements such as information, support, and participation in decision-making. Furthermore, it was hypothesised that the association between birthplace and birth experience would be influenced by a differential use of interventions between groups and that the woman's level of education and employment would correlate positively with her birth experience and perception of care elements.

Design and methods

Postal questionnaire survey, performed as part of a prospective cohort study with a matched control group.

Study population

The study population consisted of 436 women: 218 low-risk women receiving FMU care and a matched control group of 218 low-risk women receiving standard OU care.

Women were categorised as low-risk if they were healthy and had straight-forward pregnancies as outlined by the NICE intrapartum guidelines (National Institute for health and clinical excellence, 2007).

Procedure

All women admitted to one of the two studied FMUs between 1 January 2006 and 30 October 2006 and their matched controls were invited to participate in the study.

Data on women's birth experience, perceptions of patient-centred care elements and experience of postnatal care was collected by use of a postal questionnaire distributed 28 days after birth. Socio-demographic and medical data were collected from medical records.

Women were introduced to the study by project staff via telephone on the day the questionnaire was mailed. A stamped envelope was enclosed as well as a study information sheet, informing women that participation was entirely voluntary and anonymous. Women consented to participation when returning the questionnaire.

To ensure optimal response rate, non-responders were reminded by telephone after 3 weeks.

Setting

The study was undertaken in two FMUs and two OUs in the North Denmark Region. Denmark has full public coverage of maternity care services and a strong tradition for midwifery-led care for low-risk women regardless of birth setting. Recent years have seen a strong centralisation of maternity care services with >98% of all births now taking place in OUs and rising intervention rates, although intrapartum care is less medicalised than in most comparable countries. FMUs are rare in Denmark and mainly located in community hospitals in sparsely populated areas. The North Denmark Region was the first to transform two of the its four maternity units into FMUs and to organise its maternity services on the basis of close co-operations between FMUs and OUs and shared, interdisciplinary guidelines on referral and transfer.

The FMUs were converted from small maternity units and in a style less home-like than typical for FMUs, although some "softening" of colours and decor had been done. However, efforts were made to make women and their birth companions feel at home and use all the units' facilities such as the kitchen and common room. Ambulation and the use of water and music for pain relief/relaxation were encouraged. The FMUs were staffed by community midwives working in flexible shifts in a team model and generally providing one-to-one care during labour. In case of complications, women/infants were transferred to the nearest OU located 25–35 min away (transfer rate ~7%). Annually ~300 infants were born in the two FMUs.

The supporting OUs were the region's specialist maternity units (3500 and 1400 births annually), both offering 24-h service for epidural analgesia, acupuncture, and use of water tub for pain relief/water birth. The birthing rooms were traditionally equipped with a labour bed as a central feature and some had "soft" colours. Electronic foetal monitoring was only used in case of complications. One-to-one care and continuous support were generally not provided until late in the first stage of labour.

The matching process

For each FMU participant, a control participant was identified among the low-risk women intending to give birth in the nearest OU. The women were prospectively included at the start of care in labour. Matching was done on nine criteria with an established influence on medical birth outcomes and a potential influence on psycho-social outcomes: low-risk status, parity, smoking, body mass index (BMI), age, ethnicity, educational level, occupation, and co-habitation status.

Variables and data measurement

The primary study outcome was overall birth experience. Other outcomes were: care satisfaction, support, midwife presence, information, feeling of being listened to, attentiveness towards psychological needs and birth wishes, participation in decision-making, usefulness of suggestions for pain relief, support for partner, support from partner, and loss of internal and external control. Intended birthplace at the start of care in labour was considered the exposure.

Socio-demographic variables used were age, parity, education, employment, first language, and co-habitation. A number of medical variables such as Apgar score, admittance of infant to neonatal ward, caesarean section, instrumental delivery, augmentation of labour, amniotomy, long labour, epidural analgesia, and water birth were included as control factors. Both socio-demographic and medical data were obtained from medical records.

Power calculation and sample size

The inclusion of 218 women in each group was based on power calculations. This sample provided power (5% significance level, 80% power) to detect an increase in the number of women rating their birth experience as positive from the expected 90.0%

in the OU care group to 97.1% in the FMU group. The estimates used were based on a regional maternity report (Center for Kompetenceudvikling, 2005).

Materials

No nationwide maternity surveys or controlled studies of birthplace and Danish women's perceptions of care have been published. To optimise the capture of the special characteristics of intrapartum care in the Danish setting and take into account the understandings of women in the partly rural North Denmark Region, a questionnaire was developed on the basis of a literature study supported by semi-structured pilot interviews with new mothers and health professionals. The respondents were encouraged to give a chronological account of their perceptions and to ponder various aspects of their birth experience before assessing their overall experience and satisfaction with care. Questions relating to control in childbirth required special attention as the concept, in the words of Fox and Worts, clearly "meant different things to different women" (1999, p.340). Contrary to this, our pilot study participants easily identified and recalled the feeling of loss of control over both their body/reactions and staff actions, respectively defined as internal and external control (Green & Baston, 2003). The questionnaire therefore focused on e.g. "opportunity to participate in decision-making" and "the feeling of being listened to" as expressions of control and of perceived loss of control.

The questionnaire was validity tested and revised during pilot studies that included interviews with respondents from different social backgrounds exploring their understanding of questions and choice of answers. Furthermore, 24 women participated in a questionnaire test-retest and answered the questionnaire twice with two weeks interval. The test-retest reliability coefficient (Spearman) was 0.95 for birth experience and between 1 and 0.8 for all other questions. Pilot testing lead to corrections of the terms used to describe medical issues and additional text clarifying the line of some questions.

The final version of the questionnaire was a Likert-item derivative, containing 15 intrapartum questions. It had a horizontal presentation and thirteen questions used a 6-point scale. For the primary question: "*Overall, how would you describe your experience of giving birth?*" the answers ranged from 1) "very negative" to 6) "outstanding". For rating of satisfaction the answers ranged from 1) extremely dissatisfied to 6) extremely satisfied, and for patient-centred care elements from 1) "unacceptable" to 6) "optimal". The two questions related to loss of control used a 5-point scale ranging from 0) "no loss" to 4) "control lost all through birth". All questions contained a "Don't know"/"not relevant"-option. No open-ended questions were used but women were invited to elaborate on their answers in an open space (data reported elsewhere).

Cronbach's alpha for internal consistency reliability in the total study sample was 0.936. No missing responses was found for birth experience and care satisfaction and for all other questions missing responses were <1%.

Statistical analysis

Data were analysed by use of STATA 11 statistical software. Analysis was by intention-to-treat.

To fully exploit the robustness of the matched study design with respect to influence from the matched parameters as well as their interactions, groups were compared using Wilcoxon's sign-rank test for paired continuous data. For incomplete pairs, the missing part was multiple imputed using a logistic or, where relevant, ordered logistic regression model on the outcome of the observed party (van Buuren, 2007). The findings were compared with the findings of a supplementary complete-case analysis, performed on only the fully observed pairs, to check for concordance.

As both groups generally gave very positive responses, all primary ordinal outcomes (including the multiply imputed observations) were dichotomised into optimal (score 6) and all other (scores 5–1) and the two groups were compared by use of McNemar's test for paired binary data, which allowed for the calculation of odds ratios and confidence bands, and the findings compared with the findings of the primary analysis.

The influence of selected socio-demographic factors (parity, age, education, and employment) on women's birth experience and psycho-social care elements was tested by logistic regression.
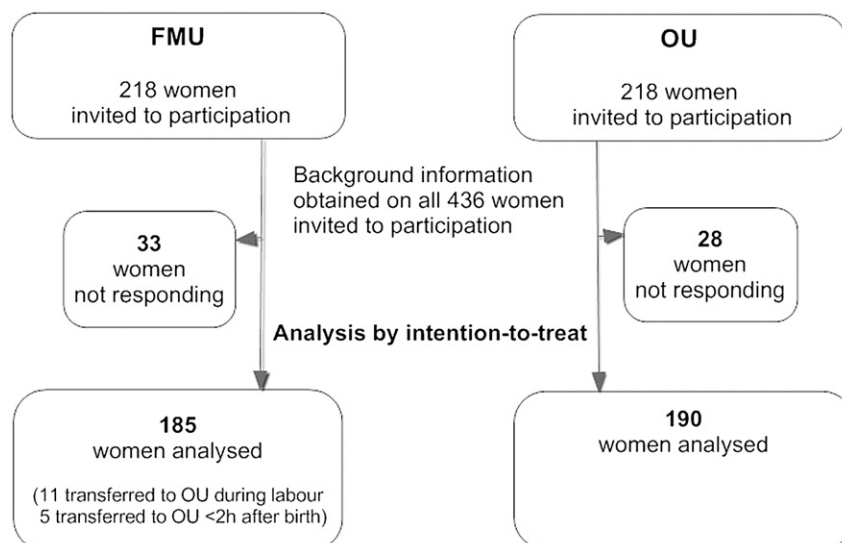

Fig. 1. Flow chart.

Subgroup analyses were performed on the OU and FMU groups, respectively.

To control for a possible effect of medical factors the dichotomised data on birth experience, birthplace, medical factors, and socio-demographic factors was entered into a logistic regression model. Multiple imputation was not relevant as the analysis was unmatched and the data complete or containing very few missing.

The overall level of statistical significance was 5%. The Bonferroni method was used to correct for multiple comparisons.

Data security and ethics

Data were treated in strict confidentiality. Ethical approval was provided by Danish Data Protection Agency (reference number: 2005-41–5352), as stipulated by Danish legislation on the use of patient data in research (Justitsministeriet, 2000).

Sample description

Of the total of 436 women invited to participation, 185 in the FMU group and 190 in the OU group returned the questionnaire, giving a total response rate of 86% (FMU: 85%; OU: 87%). See Fig. 1.

Table 1
Characteristics of all the 436 women invited versus the 375 respondents.

	Invited		Responders		Non-responders		P-value[a]
	N	(%)	N	(%)	N	(%)	
Parity							0.370
Primipara	98	22.5	87	23.2	11	18.0	
Multipara	338	77.5	288	76.8	50	82.0	
Smoking status							0.006
Non-smokers	355	81.4	313	83.5	42	68.9	
Smokers	81	18.6	62	16.5	19	31.1	
Body Mass Index (BMI)							0.313
BMI $\leq$ 25	296	67.9	258	68.8	38	62.3	
BMI > 25	140	32.1	117	31.2	23	37.7	
Age							0.583
$\leq$30 years	257	58.9	223	59.5	34	55.7	
>30 years	179	41.1	152	40.5	27	44.3	
First language							0.000
Danish	412	94.5	366	97.6	46	75.4	
Other first language than Danish	24	5.5	9	2.4	15	24.5	
Cohabitation status							0.000
Living with partner	422	96.8	368	98.1	54	88.5	
Living alone	14	3.2	7	1.9	7	11.5	
Education							
No post-secondary education	104	23.9	72	19.2	32	52.5	0.000
Education within the skilled trades	132	30.3	119	31.7	13	21.3	0.100
1–2 years post–secondary education	50	11.5	43	11.5	7	11.5	0.998
3–4 years post–secondary education	129	29.6	123	32.8	6	9.8	0.000
5–6 years post–secondary education	21	4.8	18	4.8	3	4.9	0.968
Employment							0.000
Low level of employment	285	65.5	233	62.1	52	85.2	
High level of employment	151	34.6	142	37.9	9	14.8	
Total	436	100	375	86	61	14	

[a] Chi-square test, respondents versus non-respondents.

Responders versus non-responders

Full background information on the socio-demographic characteristics of all the invited women were obtained, thus enabling us to compare the characteristics of responders and non-responders.

As seen in Table 1, most responders had Danish as their first language (97.6%) and lived with a partner (98.1%). No differences in parity, age, and BMI were found between responders and non-responders. Smokers (p-value (p) < 0.006), women without post-secondary education (p < 0.000), or low employment level (p < 0.000) and women living alone (p < 0.000) were significantly less willing to respond. A significantly higher response level was found among women with 3–4 years of post-secondary education (p < 0.000). Of the 21 FMU women who were transferred to an OU, 16 returned the questionnaire. Seventeen percent of women in the study were smokers and 31% had a BMI >25. With 19% of the women having no post-secondary education and less than 5% in academic/managerial positions, our data reflected accurately conditions in the predominantly rural catchment area of the FMUs where the educational level is among the lowest and the level of unemployment among the highest in Denmark (Danmarks Statistik, 2011).

Respondents by study group

Although participants were matched in the overall study, different response rates may have altered the distribution of socio-demographic characteristics (confounders) between women in the two groups. As shown in Table 2, an equal distribution of characteristics was maintained for the two groups of respondents.

Table 2
Characteristics of the 375 responders by study group.

	FMU		OUN		P-value[a]
	N	%	N	%	
Parity					0.822
Primipara	42	22.7	45	23.7	
Multipara	143	77.3	145	76.3	
Smoking status					0.909
Non-smokers	154	83.2	159	83.7	
Smokers	31	16.8	31	16.3	
BMI					0.162
BMI $\leq$ 25	121	65.4	137	72.1	
BMI > 25	64	34.6	53	27.9	
Age					0.998
$\leq$30 years	110	59.5	113	59.5	
>30 years	75	40.5	77	40.5	
First language					0.331
Danish	182	98.4	184	96.8	
Other first language than Danish	3	1.6	6	3.2	
Cohabitation status					0.729
Living with partner	182	98.4	186	97.9	
Living alone	3	1.6	4	2.1	
Education					
No post-secondary education	37	20.0	35	18.4	0.698
Education within the skilled trades	56	30.3	63	32.2	0.548
1–2 years post–secondary education	22	11.9	21	11.1	0.799
3–4 years post–secondary education	62	33.5	61	32.1	0.772
5–6 years post–secondary education	8	4.3	10	5.3	0.671
Employment					0.840
Low level of employment	114	61.6	119	62.6	
High level of employment	71	38.4	71	37.4	
Total	185	100	190	100	

[a] Chi-square test. No significant differences between the FMU and the OU group are found.

Findings

Place of birth and women's birth experience

The 375 respondents gave generally positive evaluations of their birth experience and the care provided in both settings. Fifty-seven percent in the FMU group and 35% in the OU group rated their experience of giving birth as "outstanding" (score 6); no FMU women and only 1% of OU women reported a "very negative" birth experience (score 1). FMU women also rated their overall birth experience significantly more positively than did the OU women (mean:5.5(FMU)/5.0(OU); $p < 0.0000$) (see Table 3).

Care satisfaction and patient-centred care elements

Moreover, satisfaction with care was significantly better among FMU women (5.7/5.3; $p < 0.0000$). Compared to OU women, their rating of several patient-centred care elements was consistently higher: midwife support (5.7/5.4; $p < 0.0000$), midwife presence when wanted (5.7/5.4; $p < 0.0000$, staff attentiveness to psychological needs (5.4/4.9; $p < 0.0000$) and to wishes for birth (5.6/4.9; $p < 0.0000$), feeling of being listened to (5.4/5.0; $p < 0.0000$), information (5.4/5.0; $p < 0.0000$), participation in decision-making (5.4/4.9; $p < 0.0000$), and staff support for partner (5.3/5.0; $p < 0.0013$).

There were no significant differences between the two groups with regard to their experience of loss of external control over staff actions or internal control over labour and own reactions, support provided by their partners, usefulness of the midwife's suggestions for pain relief, and opportunities for undisturbed contact with the newborn.

As is often the case in maternity surveys (Brown & Lumley, 1997), responses in both groups were skewed towards the very positive scores, and a supplementary analysis was therefore performed. In this analysis we focused on differences between groups in the women's use of the top rating (score 6) and dichotomised the outcome variables into an optimal versus an all other category. The groups were then compared by use of McNemar's test and multiple imputation of missing values. The results were consistent with the results of the imputed primary analysis, thus confirming the robustness of the findings.

Women who had experienced transfer

Eleven FMU women were transferred during labour to an OU, with slow progress of labour as the most common indication. Another five women were transferred <2 h after birth because of maternal bleeding or large perineal lacerations. Ten of the transferred women (62.5%) gave their birth experience a score of 6 or 5 (outstanding/very positive), three (19%) indicated a score of 4, and scores of 3 or 2 were given by three women (19%). No subgroup analysis was performed due to the small number of cases.

Adjustment for the influence of medical birth factors

Medical data on birth outcomes were collected from medical records as part of the overall cohort study. Comparison of medical outcomes is reported in (Overgaard, Møller, Fenger-Grøn, Knudsen, & Sandall, 2011). With birth experience treated as a dichotomous outcome, control for medical birth factors (Apgar score, transfer to neonatal ward, birth interventions, and epidural analgesia) was performed using a multiple logistic regression model. Adjustment for medical factors slightly increased the positive influence of FMU care on women's birth experience from OR: 3.9; 95% CI: 2.1,7.3 to OR: 4.0; 95% CI: 2.0,8.2.

The influence of socio-demographic factors on birth experience

In a subgroup analysis the influence of dichotomised variables on parity, age, education, and employment was tested by logistic regression. Women with no post-secondary education represented the most socio-economically disadvantaged group with some women receiving social benefit, incapacity benefit, or benefit for refugees. These women were included in the wider group of women characterised by a low level of employment, defined as jobs requiring no college/university education.

Table 4 shows an overall significant, negative effect of "no post-secondary education" (OR: 0.4, 95% CI: 0.2,0.8) and "low level of employment" (OR: 0.5, 95% CI: 0.3,0.97) on birth experience. However, individual analyses of the two groups showed a significant effect only for the OU group (no post-secondary education: OR: 0.35, 95% CI: 0.16,0.8; low level of employment: OR: 0.3, 95% CI: 0.1,0.6). No effect of age or parity was found, whether overall or for individual groups.

Table 3
Birth experience and women's perceptions of patient-centred care elements.

	FMU/OU Mean[b]	FMU/OU N/N	Wilcoxon sign-rank test		
			N complete pairs before/after imputation		P-value[a]
Overall birth experience	5.5/5.0	185/190	165	210	0.0000
Care satisfaction	5.7/5.3	185/190	165	210	0.0000
Support from midwife	5.7/5.4	182/190	162	210	0.0000
Midwife present when wanted	5.7/5.4	182/189	161	210	0.0000
Attention to psychological needs	5.4/4.9	177/180	149	208	0.0000
Feeling of being listened to	5.4/5.0	180/188	159	209	0.0000
Level of information	5.4/4.9	183/187	162	208	0.0000
Participation in decision-making	5.4/5.0	176/180	148	208	0.0000
Consideration for birth wishes	5.6/4.9	107/120[d]	58	169	0.0000
Suggestions for pain-relief	5.3/4.7	106/120[d]	57	169	0.0038
Staff support for partner	5.3/5.0	174/179	144	209	0.0013
Undisturbed contact with newborn	5.8/5.6	184/188	162	210	0.0026
Support provided by partner	5.1/5.2	182/188	160	210	0.3408
Loss of control over labour/reactions	0.1/1.2[c]	179/190	159	210	0.0310
Loss of control over staff actions	0.2/0.5[c]	181/188	159	210	0.0061

[a] The test results are based on imputed data. Level of significance adjusted to $P < 0.0025$ after Bonferroni correction.
[b] 6-point scale: 1 (unacceptable) and 6 (optimal).
[c] 5-point scale: 0 (no loss) and 4 (control lost all through birth).
[d] High number of women in both groups marked the "did-not-have-any/did-not-need-it"-category.

Table 4
Influence of socio-demographic factors on birth experience.

	N	OR (CI)	OR (CI)	OR (CI)
		FMU	OU	All
Primiparity	87	0.8(0.2–2.6)	0.5 (0.3–1.1)	0.6(0.3–1.1)
>30 years old	152	0.9 (0.3–2.6)	1.9(0.96–3.6)	1.5(0.9–2.5)
No post-secondary education	72	0.5(0.1–1.4)	0.35(0.16–0.8)[a]	0.4(0.2–0.8)
Low level of employment	233	1.9(0.7–5.6)[b]	0.3(0.1–0.6)[a]	0.5(0.3–0.97)

[a] The influence of no post-secondary education and low employment level is significant only in the OU setting.
[b] A positive trend for the influence of low employment level is seen in the FMU group.

Care experiences of socio-economically disadvantaged women

Exploring the effect of no post-secondary education on women's perceptions of psycho-social care elements, we found significant, overall negative effects with regard to midwifery support (OR:0.3, 95% CI:0.2–0.7), information (OR:0.3, 95% CI:0.2,0.5), feeling of being listened to (OR:0.3, 95% CI:0.1,0.7), consideration for birth wishes (OR:0.3, 95% CI:0.1,0.6), presence of midwife when wanted (OR:0.3, 95% CI:0.2,0.7), and care satisfaction (OR:0.3, 95% CI:0.2,0.7).

No overall effects were found for participation in decision-making, attentiveness towards psychological needs, suggestions for pain relief, or loss of internal or external control.

In regard to the FMU group a significant, negative effect was found only for two outcomes: information (OR:0.3, 95% CI:0.1,0.5) and the feeling of being listened to (OR:0.3, 95% CI:0.09,0.9). In the OU group the significant, negative effect persisted for all six care elements mentioned above: midwifery support (OR:0.3, 95% CI:0.09,0.8), information (OR:0.2, 95% CI:0.1,0.5), feeling of being listened to (OR:0.3, 95% CI:0.1,0.7), consideration for birth wishes (OR:0.3; 95% CI:0.1–0.6), presence of midwife when wanted (OR:0.3, 95% CI:0.1,0.8), and overall care satisfaction (OR:0.2, 95% CI:0.08,0.5).

In exploring the effect of low employment level we found no significant, negative effect for any psycho-social care element or for care satisfaction in the total group of women or among FMU women. As for birth experience, the primary outcome, a non-significant trend towards positive effects was observed among FMU women for: midwifery support, feeling of being listened to, consideration for wishes, participation in decision-making, and care satisfaction. In the OU group, a significant, negative effect of low employment level was found for midwifery support (OR: 0.3; 95% CI:0.09,0.8), feeling of being listened to (OR:0.3; 95% CI:0.1,0.8), and consideration for birth wishes (OR:0.4; 95% CI:0.2,0.9).

Discussion

The perspective and experience of service users and patients are taking centre stage across a variety of national health care services, including maternity care. However, in spite of wide scale initiatives to humanise and individualise care, negative birth experience remains a problem for many women (Waldenstrom et al., 2006; White et al., 2006).

We examined the influence of birthplace on women's birth experiences and perceptions of care in two different birth settings: two freestanding midwifery units and two obstetric units in north Denmark, both pursuing an ideal of high-quality, humanistic and patient-centred care.

Among the key strengths of our study is the high response rate (86%), equal representation of FMU and OU participants, and complete data on socio-demographic background and medical history. To date the study is one of the largest published to compare birthing women's experiences of care in FMUs versus OUs. The women were all prospectively categorised as low-risk and were cared for in a public health care system where patient ability-to-pay is not a concern. Moreover, both settings were well-established parts of the public maternity care system and followed identical practice guidelines, with midwives as the primary care provider.

One limitation of our study is its observational (non-randomised) design, which does not allow for the elimination of all potential confounding factors. Although the two groups were closely matched on a large number of potential confounding factors, unknown factors relating to women's self-selection to birth setting may play a role. Neither were we able to take into account the effect of women's birth expectations on their actual experiences.

Another limitation is the use of a not previously validated questionnaire that may potentially provide less reliable information than a questionnaire that has been validated in other studies and settings. Furthermore, it reduces the comparability of our results to the results of other studies. We did not find a validated tool that fitted the study aims well. On the positive side, the development of a questionnaire enabled us to tailor the questionnaire to the setting in which it was to be implemented and to take into account user experiences, opinions, priorities and suggestions. Careful pilot testing of the questionnaire strengthened the content validity and reliability, and high internal content consistency was indicated by Cronbach's alpha.

A further issue to be noted is the generally recognised effect of respondents' reluctance to express negative or critical views in patient surveys (Lumley, 1985). To meet these challenges, data collection took place four weeks after birth to allow women time for reflection on their experiences and to increase the likelihood of full reporting of views (Simkin, 1991). By eliciting women's assessment of key patient-centred care elements before their overall assessment, recall of memories was supported and a more nuanced assessment of the overall birth experiences and satisfaction with care facilitated (Olsen, 2001). Finally, to reduce the risk of underestimation of negative experiences due to the underrepresentation of certain patient subgroups (Brown & Lumley, 1997), we used multiple imputation of missing data.

The present study of two groups of women who had made their own choice of birthplace and had midwives as their primary care givers, has confirmed the positive outcomes of FMU care reported by several earlier, mainly qualitative, studies. We found FMU care to be associated with significantly more positive experiences of birth and better satisfaction with care. Women in the FMU group felt better informed and more listened to and reported better opportunities for participating in decisions about care compared to women in the OU group. Furthermore, FMU midwives were perceived to be more supportive of both the woman and her partner, more attentive towards the woman's psychological needs and her wishes for birth, and they were more likely to be present when wanted. As respondents generally give positive evaluations of care models which they themselves have chosen and with which they feel familiar (Teijlingen, Hundley, Rennie, Graham, & Fitzmaurice, 2003; Walker et al., 1995), and midwives were the lead carer in both settings of this study, we expected to find fewer or only minor differences in comparison to earlier studies, but were surprised by the high number of significant differences. Although the two types of unit shared the goal of providing patient-centred, family-friendly care, the FMUs are therefore judged to provide higher quality care as measured by women's experiences.

We investigated a range of psycho-social aspects of care and found significant differences between groups in several cases, most notably for: carer's attentiveness to psychological needs and wishes

for birth, feeling of being listened to, and information. The findings suggest that FMU midwives focused attention towards psychological dimensions of childbirth, good communication and involvement of the women and her partner and thus improved their ability to provide patient-centred, individualised, and supportive care.

The significance of a home-like physical environment, and its influence on psychological well-being, behaviour and expectations of users and staff, has previously been emphasised (Fannin, 2003). The FMUs in the present study offered more spacious and tranquil facilities compared to the OUs, but the differences in decor and equipment between units were so negligible that no differences in care quality should be ascribed to them. For example, both FMUs and OUs had water tubs and small birthing rooms with obstetric beds, but a home-like use of the unit's facilities and ambulation during labour were encouraged only in the FMUs. The key difference between FMUs and OUs may therefore lay not so much from the physical facilities but in the FMU culture that encouraged their use by the women, their companions and staff.

FMU care is a complex intervention and present study did not allow a further exploration of the FMU culture, the characteristics of the midwives working in the compared settings, or the underlying mechanisms leading to improved birth experience in the FMU group. Still, we would indicate as influencing factors increased continuity, including greater availability of one-to-one care and continuous support during labour that has been shown to be related to improved birth experience (Hodnett, Gates, Hofmeyr, Sakala, & Weston, 2011). Increased job satisfaction as a positive consequence of midwives working in a team model (Hundley et al., 1995; Turnbull, Reid, McGinley, & Shields, 1995) may also be important along with general organisational characteristic of FMUs, facilitating midwives' development of meaningful and caring relationships with women and their families, as suggested by Walsh (2006).

FMU care was significantly associated with very positive birth experiences for women with low levels of education and in particular for the wider group of women with a low level of employment. This finding is supported by a recent Swedish survey, which also reports a negative correlation between no post-secondary education and negative birth perceptions (Wilde-Larsson et al., 2011). "Working-class" women have been found to entertain a fatalistic approach to childbirth (Zadoroznyj, 1999), show little interest in psycho-social aspects of birth such as the experience of fulfilment, and to be more inclined to hand over control to the professionals and accept pain-relieving drugs. However, Green and Baston (2003), Green et al. (1998) have challenged this as a stereotyped view of both "working-class" and "middle-class" women's wishes and needs during childbirth. They found that education had little influence on women's perceptions of birth and intrapartum care, including their attitudes to the use of drugs during labour and control issues. As pointed out by Lazarus (1994), underprivileged women may feel constrained by the social conditions under which they become mothers, indicating that the important differences associated with education/social class may be differences in access to and understanding of information and the ability to transform knowledge into personal control and/or power over own care. Our view is that FMU care provides an opportunity to mitigate social disadvantage which results in significantly improved birth experience for this group of women.

Although Denmark, with its comprehensive welfare system, is among the countries with the highest degree of equality, socio-economic disadvantage persists and lifelong inequality in health, with its close links to social differences in education, employment and income is defined as a major, national challenge (Diderichsen, Andersen, & Manuel, 2011). We find it likely that the least privileged/least educated of the women in our study benefit the most

from a patient-centred care approach that emphasises communication and emotional support. Our finding, that women with no post-secondary education had significantly more negative perceptions of information provided and the feeling of being listened to, indicates the potential for further improvement, even in the FMUs. In a service development perspective, the potential of FMU care to mitigate the effect of social disadvantage on women's birth experience is promising, and we strongly recommend further investigation of this issue.

Overall, this study provides strong support for FMU care, even in settings where all frontline care is provided by midwives and where the humanistic paradigm of childbirth and patient-centred care is prevalent, as was the case in the North Denmark Region. The results show that FMU care offered important psycho-social benefits for birthing women and was associated with significantly better birth experiences and higher satisfaction with care, compared to OU care. Specific care elements, including information, the feeling of being listened to, and the opportunity to participate in decisions about care, were rated significantly higher by FMU women than by OU women; moreover, FMU women perceived their midwives as more supportive and more attentive towards their psychological needs and wishes for birth.

The findings contradict the view that "working-class" and "middle-class" women are attracted by different childbirth models and entertain different expectations, wants, and needs during childbirth. The potential of FMU care to alleviate the effect of social disadvantage on women's birth experience is promising and should be further investigated. Moreover, our study underlines the importance of truly individualised and supportive care that accommodates the needs of all birthing women, including their need for information and for being listened to, and the challenges in providing such care, especially in conventional settings. Policy makers and professionals face the task of considering how the concept of FMU care can be applied in the effort to improve women's birth experiences and develop maternity care services, and possibly also the effort to combat the effect of social inequality on health.

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