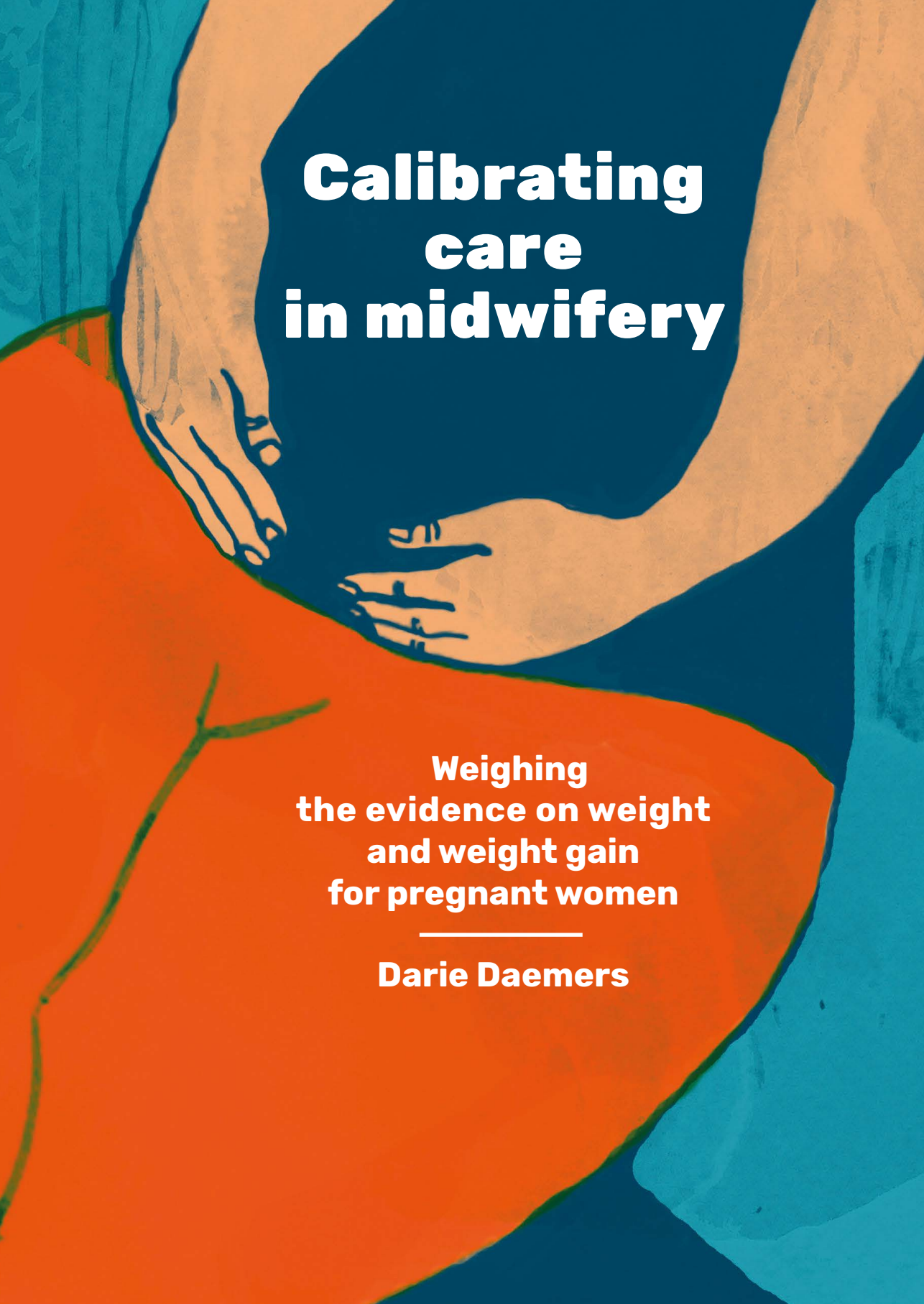

Calibrating care in midwifery

Weighing the evidence on weight and weight gain for pregnant women

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Calibrating care in midwifery:

weighing the evidence on weight and weight gain for pregnant women

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Knowledge is proud that he has learn'd so much;
Wisdom is humble that he knows no more.

Kennis is trots dat zij zo veel heeft geleerd;
Wijsheid is bescheiden dat zij zo weinig weet.

(W. Cowper (1731-1800)- The task)

List of abbreviations

ANOVA: analysis of variance
aOR: adjusted odds ratio
BMI: body mass index
CBS: statistics Netherlands
CI: confidence interval
EPRS: electronic patient record system
GDM: gestational diabetes mellitus
GWG: gestational weight gain
GWL: gestational weight loss
ICM: international confederation of midwives
IOM: institute of medicine
IOMr: Institute of medicine recommendations
IUGR: intrauterine growth retardation
KNOV: Dutch organisation of midwives
LGA: large for gestational age
NHG: Dutch society of general practitioners
NICU: neonatal intensive care unit
NR: not referred (i.e. women not referred to obstetrician-led care)
NVK: Dutch society for paediatrics
NVOG: Dutch society for obstetrics and gynaecology
OGTT: oral glucose tolerance test
OIL: obstetric indication list
PRN: perinatal registration in the Netherlands
PROM: prelabour rupture of membranes
R: referred (i.e. women referred to obstetrician-led care)
SES: socio-economic status
SGA: small for gestational age
Tc: traditional criteria (i.e. for GWG)
UK: United Kingdom
US: Unites States
VeCaS: midwifery case registration system
VIL: obstetric indication list
WHO: world health organisation

Table of Contents

List of abbreviations 6

Chapter 1 General introduction 9

Chapter 2 Patterns of gestational weight gain in healthy, low-risk pregnant women without co-morbidities 27

Chapter 3 The impact of obesity on outcomes of midwife-led pregnancy and childbirth in a primary care population: a prospective cohort study 43

Chapter 4 Pregnant and overweight: at home in midwife-led primary care? Multiparity positively affects outcomes of obese pregnant women 63

Chapter 5 The effect of gestational weight gain on likelihood of referral to obstetric care for women eligible for primary, midwife-led care after antenatal booking 73

Chapter 6 Use of midwife-led primary antenatal care by obese women in The Netherland: an explorative cohort study 95

Chapter 7 Factors influencing the clinical decision-making of midwives: a qualitative study 111

Chapter 8 General discussion 137

Summary 159

Samenvatting 169

Valorisation 181

Dankwoord 191

Curriculum vitae 195

List of publications 199

Chapter 1

General introduction

At the beginning of the twenty first century obesity entered Dutch maternity care as a 'new illness' challenging traditional approaches to care. Based on studies - most of which were done in the United States (US) and the United Kingdom (UK) - it became clear that obese women faced more reproductive problems than normal weight women, including higher risks of infertility, miscarriage, congenital anomalies, and a variety of pregnancy complications. [1, 2] This evidence created concern among Dutch obstetricians and midwives who - in the absence of national guidelines - developed local protocols or made autonomous clinical decisions regarding obesity in pregnancy and childbirth.

Increased attention for obesity among maternity care professionals led to an increased interest in gestational weight gain (GWG). In 2008 the Unites States Agency for Healthcare Research and Quality published an extended literature review that included evidence of an association between GWG and adverse outcomes for mother and child. [3] In the Netherlands, the most recent concrete GWG recommendation is found in an obstetric textbook that is more than 20 years old, [4] and there are no national guidelines on GWG.

To optimise care for pregnant women in the context of the Dutch maternity care system - characterised by 'midwife-led care if possible, obstetrician-led care if needed' [5] - knowledge of weight and weight gain in relation to perinatal outcomes is required. This task places special demands on primary care midwives who must decide if and how the international evidence on obesity as a high-risk condition is transferable to - a priori - healthy women, eligible for midwife-led primary care. In this introduction, I summarise the literature on obesity and GWG and the impact of each on perinatal outcomes for mother and child, explain the clinical decision-making process in Dutch maternity care, and briefly review the general aim, the research questions, and the outline of the thesis.

Obesity

Definition and epidemiology

According to the World Health Organisation (WHO) overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health. [6] Body mass index (BMI) (or Quetelet index) is a simple index of weight-for-height that is commonly used to classify overweight and obesity in adults (Table 1). It is defined as a person's weight in kilograms divided by the square of his height in meters (kg/m^2). [7] Although there is some discussion about the value of the BMI as anthropometric tool for predicting health parameters (in pregnancy), [8-10] it is accepted worldwide as a useful guide in prenatal care. BMI used in prenatal care is calculated based on the prepregnancy weight shortly before getting pregnant or on the weight measured at booking as early as possible in pregnancy.

Table 1. The WHO classification of adult underweight, overweight and obesity according to BMI.

Classification	BMI (kg/m^2)
Underweight	<18.50
Normal weight	18.50 - 24.99
Overweight	≥25.00
Pre-obese	25.00 - 29.99
Obese	≥30.00
Obese class I	30.00 - 34.99
Obese class II	35.00 - 39.99
Obese class III	≥40.00

Source: Adapted from WHO 1995, WHO 2000 and WHO 2004 [7]

The WHO estimates that about 13% of the world's adult population (11% of men and 15% of women; 600 million adults in total) was obese in 2014. [6] In a study of Guelinckx et al. [11] the international prevalence of obesity among pregnant women ranged between 1.8 and 25.3% depending on the cohort studied and the period of the evaluation. In the Netherlands, various databases provide figures on obesity. According to Statistics Netherlands, 15.1 % of all women aged 20 years and older were obese in 2015. These figures are based on self-reported weight and height. [12] The prevalence of obesity among women varies between regions with less than 12 % of obese women of 19 years and older (Gooi en Vechtstreek, Kennemerland and Midden-Nederland) and 16-17% in the regions Zaanstreek-Waterland en Flevoland (corrected for women's age) in 2012. [13] The Generation R study among pregnant women in Rotterdam revealed that the mean overweight and obesity rate (BMI ≥25) differed between ethnic groups from 23.1% among women of Dutch origin to 49.9% among women of Moroccan origin. [14] National figures give us an indication of the prevalence of obesity in women of reproductive age with 6.3% obese women between 20 and 30 years and 10.1% obese women between 30 and 40 years in 2015. [12] National figures on BMIs of Dutch pregnant women are not available.

Maternal obesity and perinatal outcomes

The impact of obesity on childbirth has been thoroughly researched. Systematic reviews and/or meta-analyses provide evidence of increased risks of adverse perinatal outcomes associated with obesity, including miscarriage, [15] congenital malformations, [16-20] gestational diabetes (GDM), [21, 22] pre-eclampsia, [23] stillbirth,[24-26] post-date delivery, induction of labour, use of epidural, failure to progress, fetal compromise, instrumental delivery, [27] caesarean section, [27-29] meconium stained amniotic fluid, low Apgar score at 5 minutes, high birthweight, postpartum haemorrhage, maternal infections and neonatal intensive care requirement, [27] problems with breastfeeding, [30, 31] and pre- and postnatal mental health disorders (Table 2). [32]

Table 2. Association between obesity and perinatal outcomes in systematic reviews

Outcome		Author	Definition obesity	OR (95% CI)
Miscarriage in spontaneous conceptions		Boots et al. (2011)[15]	≥28 or 30 kg/m^2	1.31 (1.18-1.46)
Congenital malformations	Neural tube effects	Stothard et al. (2009)[16]	Obese*	1.87 (1.62-2.15)
	idem	Rasmussen et al. (2008)[17]	Obese * Severely obese *	1.70 (1.34-2.15) 3.11 (1.75-5.46)
	Anencephaly	Stothard et al. (2009)[16]	Obese*	1.39 (1.03-1.87)
	Spina Bifida	Stothard et al. (2009)[16]	Obese*	2.24 (1.86-2.69)
	Cardiovascular anomalies	Stothard et al. (2009)[16]	Obese*	1.30 (1.12-1.51)
	idem	Cai et al. (2014)[18]	Moderately obese Severely obese**	1.12 (1.04-1.20) 1.38 (1.20-1.59)
	Septal anomalies	Stothard et al. (2009)[16]	Obese*	1.20 (1.09-1.31)
	Cleft palate	Stothard et al. (2009)[16]	Obese*	1.23 (1.03-1.47)
	idem	Blanco et al (2015)[20]	Obese***	1.22 (1.09-1.35)
	Cleft lip and palate	Stothard et al. (2009)[16]	Obese*	1.20 (1.03-1.40)
		Blanco et al (2015)[20]	Obese***	1.13 (1.04-1.23)
	Anorectal atresia	Stothard et al. (2009)[16]	Obese*	1.48 (1.12-1.97)
	Anorectal malformation incl. atresia	Zwink et al. (2011)[19]	≥30 kg/m^2	1.64 (1.35-2.00)
	Hydrocephaly	Stothard et al. (2009)[16]	Obese*	1.68 (1.19-2.36)
	Limb reduction anomalies	Stothard et al. (2009)[16]	Obese*	1.34 (1.03-1.73)
GDM		Chu et al. (2007)[21]	Obese* Severely obese*	3.56 (3.05-4.21), 8.56 (5.07-16.04)
		Torloni et al. (2009)[22]	Obese* Severely obese*	3.01 (2.34-3.87) 5.55 (4.27-7.21)
Pre-eclampsia		Wang et al. (2013)[23]	Obese: 30-34.9 kg/m^2 Severely obese: ≥35 kg/m^2	2.68 (2.39-3.01) 3.12 (2.24-4.36)
Stillbirth		Flenady et al. (2011)[25]	>30 kg/m^2	1.63 (1.35-1.95)
		Chu et al. (2007)[24]	Obese *	2.07 (1.59-2.74)
		Aune et al. (2014)[26]	Per 5 BMI units	RR: 1.24 (1.18-1.30)
Post-date delivery		Heslehurst et al. (2008)[27]	Obese*** Morbidly obese***	1.37 (1.33-1.41) 1.56 (1.48-1.64)
Induction of labour		Heslehurst et al. (2008)[27]	Obese***	1.88 (1.84-1.92)
Epidural		Heslehurst et al. (2008)[27]	Obese***	1.23 (1.19-1.27)
Failure to progress		Heslehurst et al. (2008)[27]	Obese***	2.31 (1.87-2.84)
Fetal compromise		Heslehurst et al. (2008)[27]	Obese*** Morbidly obese***	1.62 (1.55-1.71) 2.08 (1.92-2.25)
Instrumental delivery		Heslehurst et al. (2008)[27]	Obese***	1.17 (1.13-1.21)

Outcome		Author	Definition obesity	OR (95% CI)
Caesarean section (no elective)		Chu et al. (2007)[28]	Obese*, subgroup analysis for low-risk women	1.75 (1.41-2.23)
		Heslehurst et al. (2008)[27]	Obese***	1.63 (1.40-1.89)
		Poobalan et al. (2009)[29]	30-35 kg/m^2	2.23 (2.07-2.42)
Meconium stained amniotic fluid		Heslehurst et al. (2008)[27]	Obese***	1.57 (1.42-1.73)
Low Apgar score at 5 minutes		Heslehurst et al. (2008)[27]	Obese*** Morbidly obese***	1.57 (1.47-1.68) 2.10 (1.87-2.35)
High birthweight	High birthweight (not defined)	Heslehurst et al. (2008)[27]	Obese***	2.36 (2.29-2.42)
	High birthweight (>4000g)	Yu et al. (2013)[33]	Obese*	2.00 (1.84-2.18)
		Gaudet et al. (2014)[34]	≥30 kg/m^2	2.17 (1.92-2.45)
	Macrosomia (>4500 g)	Yu et al. (2013)[33]	Obese*	3.23 (2.39-4.37)
		Gaudet et al. (2014)[34]	≥30 kg/m^2	2.77 (2.22-3.45)
	Large for gestational age (>90th centile)	Yu et al. (2013)[33]	Obese*	2.08 (1.95-2.23)
		Gaudet et al. (2014)[34]	≥30 kg/m^2	2.42 (2.16-2.72)
Postpartum haemorrhage		Heslehurst et al. (2008)[27]	Obese*** Morbidly obese***	1.20 (1.16-1.24) 1.43 (1.33-1.54)
Maternal infections		Heslehurst et al. (2008)[27]	Obese***	3.34 (2.74-4.06)
Neonatal intensive care requirement		Heslehurst et al. (2008)[27]	Obese*** Morbidly obese***	1.38 (1.16-1.64) 1.33 (1.18-1.51)
Breastfeeding	No initiation of breastfeeding	Amir et al. (2007)[31]	Obese*	Range between 1.38 and 3.09
		Turcksin et al. (2012)[30]	Obese*	Range between 1.19 and 3.65.
	Delayed onset of lactogenesis	Amir et al. (2007)[31]	Overweight/obese*	RR: 2.46
	Early cessation of breastfeeding	Turcksin et al. (2012)[30]	Obese*	hazard ratios: 1.24 to 2.54
Mental health problems	Prenatal: - Depression - Anxiety Postnatal depression	Molyneaux et al. (2014)[32]	Obese*	 1.43 (1.27-1.61) 1.41 (1.10-1.80) 1.30 (1.20-1.42)

*as defined in the studies used in the systematic reviews

** moderately obese: 30.1-34.9 or 30.1-39.9 kg/m2; and severely obese:≥35.0 or ≥40.0 kg/m2 respectively

*** as defined in the included studies, in most cases using the WHO classification or a close approximation.

Moreover, the risks of these outcomes increased with increasing obesity class. [35] On the other hand, obesity also seems to protect against some adverse perinatal outcomes such as congenital gastroschisis (OR 0.17; 95% CI 0.10 - 0.30), [16] placenta praevia (OR 0.83; 95% CI 0.71 - 0.96) [27] and low birth weight (OR: 0.84; 95% CI 0.78 - 0.91 [27] and OR 0.81; 95% CI 0.80 - 0.83 [33]). [2] Obesity does not seem to affect outcomes such as

placenta abruption (OR 0.98; 95% CI 0.90 - 1.08), shoulder dystocia (OR 1.04; 0.97 - 1.13), neonatal jaundice (OR 1.04; 95% CI 0.93 - 1.16) and maternal perineal tears and lacerations (OR 1.02; 95% CI 0.97 - 1.08). [27]

Gestational weight gain

Description and epidemiology

Gestational weight gain (GWG) is a physiological phenomenon that supports the functions of growth and development of the foetus resulting in bodily changes of the woman. [36] Woman's individual amount of GWG is determined by the weight of foetus (3.5 kg) and placenta (0.5 kg), growth of uterus (1kg) and mammary gland (0.4 kg), water accretion, in, for example, amniotic fluid (1kg), maternal blood (1.6 kg) and extracellular fluid, and fat mass accretion. [4, 36]

A review of studies in the US on GWG in singleton, normal-term pregnancies showed considerable variation with mean GWG ranging from 10.0 to 16.7 kg in normal-weight adult women. [36] Several European studies showed a mean GWG between 14.0 and 15.5 kg with standard deviations between 4.7 and 5.9, mostly based on the self-reported or measured weight at delivery minus the self-reported prepregnancy weight. [37-41] Nulliparae gain on average more weight than multiparae. [38, 39, 42] Regarding GWG in relation to BMI classification, a decrease in the mean GWG is seen with increasing BMI class. [38, 39, 41, 43]

In the Netherlands there are no national figures on GWG available. Althuizen et al. [41] performed a small study of 144 pregnant women and reported a mean GWG of 14.4 (SD 5) kg with a mean GWG for underweight women (<19.8 kg/m^2) of 16 kg (SD 4.5) and 9.8 (SD 4.2) kg for obese women (≥29 kg/m^2).

GWG recommendations

In the 1970s, the US used a GWG recommendation for all pregnant women of 9 - 12 kg. [3] In 1990 the Institute of Medicine (IOM) provided GWG recommendations that differed by BMI classification: 12.5 - 18 kg for women with a low BMI (<19.8 kg/m^2); 11.5 - 16 kg for normal weight women (19.8 - 26 kg/m^2), 7 - 11.5 kg for overweight women (>26 - 29 kg/m^2) and weight gain of at least 7 kg for obese women. [44] These guidelines were developed as an effort to prevent low birth weight deliveries. [3] Twenty years later, the focus on weight gain in pregnancy had shifted from low birth weight to the problems of obesity and high birth weight. As a result of this shift, the IOM published new GWG guidelines in 2009. The two most important modifications in the new guidelines were the use of the WHO BMI classification (Table 1) and a restricted GWG margin of 5 - 9 kg for obese women. [3, 36] Using these new recommendations, 52.6% of pregnant women in the

US exceed recommended GWG and 16.7% have inadequate GWG and in Canada, 49.4% of pregnant women exceed and 17.6% fall short of recommended GWG. [45, 46] In the Netherlands, Althuizen et al. found 38% exceeding GWG and 19% inadequate GWG, using the 2009 IOM cut-off points. [47]

Since the publication of the IOM guidelines in 2009, several studies confirmed their clinical value. [48-59] However, there is also criticism of the recommended lower limits of weight gain for obese women. [60-67] Moreover, lower and/or wider optimal GWG ranges have been proposed, based on studies using different populations and different outcomes. [37, 68-70] A review by Scott et al. [71] demonstrated that internationally there is a great variation in formal and informal policies regarding the management of gestational weight gain.

In the Netherlands, the most recent concrete recommendation on optimal GWG - namely, between 10 and 15 kg - was made in 1993. [4] This recommendation was based on the physiological components of GWG as described above. Variation in weight gain during pregnancy was emphasised and it was mentioned that there is little evidence to relate inadequate or exceeding GWG to obstetric pathology. However, in practice exceeding GWG was mentioned as a signal for the presence of oedema, indicating pregnancy hypertension. Over the last decades, doubt about the clinical relevance of weighing women, the unreliability of the measurement, and the fact that a lot of women disliked being weighed, led to the disappearance of routine measurement of weight at every prenatal control in most midwifery practices and hospitals. Currently, as a result of concerns about obesity, there is a renewed interest in GWG recommendations. However, there are no national guidelines on GWG in the Netherlands. The 2009 IOM guidelines have not been validated in a Dutch (primary care) population. They are known but not commonly used.

GWG and perinatal outcomes

In contrast to BMI, where there is a broad acceptance of the WHO BMI classification (Table 1), there is an ongoing debate about the ideal boundaries for GWG. A firm foundation for the 2009 IOM guidelines was laid by the extended work of Viswanathan et al., [3] published in 2008. They found strong evidence for an association between weight gain above the 1990 IOM recommendations and high birthweight, macrosomia and Large for Gestational Age (LGA); moderate to strong evidence for the association of GWG below 1990 IOM recommendations and preterm birth, low birth weight , Small for Gestational Age (SGA), and failure to initiate breastfeeding; moderate evidence for the association between weight gain above the IOM recommendations and caesarean delivery and postpartum weight retention. [3]

After 2009, most studies on the impact of GWG on perinatal outcomes used the cut-off points of the revised IOM guidelines. The results generally confirmed the earlier established impact of GWG. [3] Gaining weight above the IOM recommendations is

associated with an increased risk of LGA, [51-57, 59] macrosomia, [53, 57] gestational hypertension/preeclampsia, [56, 57, 59] caesarean section, [49, 51, 54-57, 59] postpartum weight retention [49] and seem to protect against SGA [49, 52, 54, 57, 59] and low birth weight. [57] Gaining weight below the IOM recommendations is associated with an increased risk of SGA, [49, 52-55, 57] low birth weight, [57] asphyxia [57] and seem to protect against LGA, [52, 57, 59] macrosomia, [57] caesarean section [57, 59] and postpartum weight retention. [49] In addition to the outcomes described above, in their study among 2,102,642 US nulliparae Truong et al. [59] found an association between gaining weight above IOM guidelines and an increased risk of labour induction, chorioamnionitis, blood transfusion, mother's use of antibiotics, 5 minute Apgar score <4, mechanical ventilation >6 hrs, Neonatal Intensive Care Unit (NICU) admission, birth trauma, neonate's use of antibiotics and neonatal transfer. Gaining weight below the IOM recommendations was associated with an increased risk of neonatal transfer but seem to protect for gestational hypertension and pre-eclampsia; induction of labour; chorioamnionitis; mother's use of antibiotics; maternal intensive care admission, GDM, birth trauma and neonate's use of antibiotics. [59]

Although these results demonstrate the overall value of the IOM guidelines, there are studies that challenge some of the recommendations. First, there is debate about the value of the lower GWG limit for obese women. While SGA and preterm birth are two unfavourable outcomes associated with inadequate weight gain, some studies were not able to detect the association of gaining weight below the IOM recommendations and SGA in obese women [48, 51, 56, 72] and Faucher et al. [63] could not establish an association of inadequate GWG and spontaneous preterm birth in their review. Second, many studies looked only for confirmation of the IOM cut-off points using a restricted number of outcomes such as LGA , SGA and caesarean section while the recent study of Truong et al. [59] demonstrates that many more perinatal outcomes are associated with inadequate or excessive GWG. Moreover, each GWG category has both adverse and protective influences on different outcomes, showing that the impact of GWG for mother and child is a complex phenomenon. In line with this, different authors suggested lower and/or wider optimal GWG ranges compared to the IOM recommendations based on their investigations of a specific population and varied (combination of) outcomes. [37, 68-70] Third, IOM guidelines do not take into account the variety of conditions that also influence the targeted outcomes such as age, parity, ethnicity, lifestyle and woman's individual risk profile.

The lack of convincing evidence for successful interventions capable of reducing the unfavourable outcomes of deviating from recommended GWG, underscores the complex nature of GWG. Implementing routine weighing followed by counselling according to the IOM recommendations did not reduce excessive GWG or the associated negative outcomes. [73] Intervention programmes based on diet, exercise or both may reduce excessive GWG, but showed disappointing results in decreasing unfavourable outcomes associated with excessive GWG. [74]

Midwife-led primary care in the Netherlands

Current model

Most women (86.3% in 2014) [75] in the Netherlands start their maternity care in a midwife-led primary care practice in their community. Continued risk assessment by the midwife plays a crucial role in the maternity care system. This assessment starts at the first booking appointment with an examination of a woman's medical, psychosocial, and obstetric history and parameters, and is continued throughout the prenatal period. [76] As long as a woman experiences a physiological pregnancy the independent midwife is authorised to supervise her pregnancy. When risk factors arise or complications occur, the midwife refers the pregnant woman to obstetrician-led specialised care. When the pregnancy remains healthy, the woman is eligible for a midwife-led birth and can choose for a homebirth or a midwife-led hospital birth. Again, when risk factors arise or complications occur during midwife-led childbirth, the woman is referred to obstetrician-led care. Of all referrals during childbirth, 89% are not urgent because there is no life-threatening situation for mother and child. [77] If a referral from home to hospital is urgent, ambulance transport is available. Women who are referred to obstetrician-led care in pregnancy are only eligible for a midwife-led birth, when they were referred back to primary care because the expected complication (e.g. preterm birth) did not occur.

In 2009, the report 'On safe care of pregnancy and childbirth' [78] was published in response to a perceived problem of high perinatal mortality rates in the Netherlands. [79] Recommendations aimed to reinforce local collaboration among primary and secondary maternity caregivers. As a consequence, a variety of local pilots all over the Netherlands have been set up to explore new, more integrated methods of working where the former sharp boundaries between primary and secondary care are being removed.

Clinical decision-making

According to the International Confederation of Midwives (ICM) the provision of evidence based care is an essential competency for midwives. [80] Evidence based medicine is defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external evidence from systematic, clinical relevant and patient-centred research. Individual clinical expertise means the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. [81, 82]

In Dutch maternity care clinical decision-making is guided by the Obstetric Indication List (OIL), a national multidisciplinary guideline which indicates the appropriate level of maternity care for a number of obstetrical conditions. [83] Furthermore, the Dutch Organisation of Midwives (KNOV), the Dutch Society for Obstetrics and Gynaecology (NVOG), the Dutch Society of General Practitioners (NHG), the Dutch Society for Paediatrics (NVK) but also other organisations and medical disciplines construct - mono- or multidisciplinary - guidelines, relevant for maternity care in general and for midwife-led primary care specifically. [84-88] On a local level, midwives and obstetricians collaborate to translate national guidelines into local protocols in order to guide daily practice. As a consequence of the appeal to enhance local collaboration, the focus of national - mostly monodisciplinary - guidelines is shifting towards the development of multidisciplinary local care pathways, challenging the competences of local maternity care professionals in constructing evidence based guidelines, sustained by all parties involved.

Care for obese women

A midwife's care for the individual woman is hampered by the lack of national multidisciplinary consensus regarding obesity and weight gain. Obesity has not yet been included in the OIL. [83, 89] In 2009, the NVOG published the guideline 'pregnancy and obesity' and stated that class-III obesity (BMI ≥40 kg/m2) is considered a medical condition that requires obstetrician-led care. [90] This viewpoint is endorsed by the KNOV. The level of evidence of this recommendation indicates that it is based on professional common sense, not on evidence. This demonstrates some pressure points in guideline construction. First, the impressive number of studies finding several negative outcomes for obese women in pregnancy and childbirth point to a high-risk situation and - consequently - creates questions about whether primary care is appropriate for obese pregnant women. However, caution should be exercised in extrapolating these study results to the population of - a priori - healthy women, eligible for midwife-led primary care. The reason for this caution is the fact that the generalisability of results from systematic reviews to a specific population is connected with the study settings and the selection and characteristics of the patients in the underlying studies. [91, 92] International reviews on outcomes of obesity may not be applicable to a low-risk population or a midwife-led care setting: the women in the underlying studies are mostly recruited in hospitals or data are sampled from large databases, relevant co-morbidities and interventions are not always excluded or corrected for (women in Dutch midwife-led care are healthy, without co-morbidities and do not get interventions which may lead to other complications), women's characteristics and health care systems often differ significantly. Not taking these aspects into account, especially the inclusion of women with co-morbidities, could lead to an overestimation of the risks of obesity in primary care women. Second, the literature on enhanced risks alone does not give tools to

underpin clinical decision-making and to apply appropriate care. Therefore, insight into national results of midwife-led clinical decision-making and care is needed to evaluate whether these procedures meet the challenges of obesity and whether adjustments should be made.

Because professionals feel responsible for optimal care for women in relation to their BMI and because there are no national guidelines and limited knowledge of the Dutch results of everyday care for obese women, the care of these women is decided by local protocols or individual clinical decisions. This results in variation in recommended place of birth, in the timing of referral to specialised care, in screening for e.g. GDM and foetal growth, and in the use of psychosocial and lifestyle support.

The lack of knowledge on the effect of inadequate or excessive weight gain on perinatal outcomes in Dutch midwife-led care, limits the opportunities to evaluate care and promote healthy GWG.

Another important but under-researched theme is the adherence of obese women to prenatal care services. There are contrary indications regarding the use of primary care by obese pregnant women. On the one hand, they may have more minor complications than normal weight women, need more screening during pregnancy and therefore use more primary care services. [93-95] On the other hand, obese women may feel themselves stigmatised by health workers, [96] may experience this as a barrier for obtaining care [97] and consequently use less care. So far studies show that obesity does not seem to function as a barrier to obtaining adequate prenatal care. [98 99]

General aim and specific research questions

This thesis has two goals 1) to gain insight into the prevalence and distribution of weight and weight gain in - a priori - healthy pregnant women in the Netherlands and 2) to examine the results of midwife-led primary care for women with regard to their weight and weight gain. Our works contributes to the body of knowledge on weight and weight gain as a basis for optimal care for the individual woman in primary, midwife-led care.
The following research questions guided our research:

- What is the prevalence of overweight and obesity among women in midwife-led primary care and what are their patterns of GWG? (chapter 2)
- What are the perinatal outcomes of obese women receiving midwife-led care using established risk assessment tools without a specific focus on obesity? (chapter 3)
- What is the influence of parity on the association between women's BMI and perinatal outcomes? (chapter 4)

- What are the perinatal outcomes of women in midwife-led primary care in relation to their GWG? (chapter 5)
- What is the effect of BMI on the use of prenatal midwife-led care? (chapter 6)
- What factors influence midwives' clinical decision-making in their care for the individual (obese) woman? (chapter 7)

Outline of this thesis

Chapter 2 describes the findings of a secondary analysis of a prospective cohort study into the prevalence of underweight, normal weight, overweight and obesity as well as the pattern of gestational weight in relation to BMI among women eligible for midwife-led primary care after antenatal booking.

Chapter 3 presents the results of a secondary analysis of a prospective cohort study focussing on the impact of obesity on the likelihood of remaining in midwife-led care throughout pregnancy and childbirth.

Chapter 4 explains the use of two different studies to explore the effect of parity on the association between BMI and perinatal outcomes.

Chapter 5 compares the likelihood of referral to secondary care among women eligible for primary midwife-led care after antenatal booking, using two different GWG guidelines.

Chapter 6 reports the results of an exploratory cohort study analysing whether obese pregnant women in midwife-led practices delayed or avoided prenatal care.

Chapter 7 presents the results of a qualitative study of the factors influencing midwives' clinical decision-making in their care for the individual obese woman.

Chapter 8 summarises and discusses the main study results, outlines implications and recommendations for maternity care practice and describes topics for future research.

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Chapter 2

Patterns of gestational weight gain in healthy, low-risk pregnant women without co-morbidities

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Midwifery. 2013 May;29(5):535-41

Abstract:

Background: Little is known of the impact of GWG in relation to BMI classification on perinatal outcomes in healthy pregnant women without co-morbidities. As a first step, the prevalence of obesity and the distribution of GWG in relation to the 2009 IOM guidelines for GWG was examined.

Methods: Data from a prospective cohort study of - a priori - low-risk, pregnant women from five midwife-led practices (n = 1449) were analysed. Weight was measured at 12, 24 and 36 weeks.

Findings: At 12 weeks, 1.4% of the women were underweight, 53.8% had a normal weight, 29.6% were overweight and 15.1% were obese according to the WHO classification of BMI. In our study population, 60 % of the women did not meet the IOM recommendations: 33.4 % had insufficient GWG and 26.7 % gained too much weight. Although BMI was negatively correlated to total GWG (p <0.001), overweight and obese women class I had a significant higher risk of exceeding the IOM guidelines. Normal weight women had a significantly higher risk of gaining less weight than recommended. Obese women classes II and III were at risk in both over- and undergaining.

Conclusions: Our data showed that the majority of women were unable to stay within recommended GWG ranges without additional interventions. The effects on pregnancy and health outcomes of falling out the IOM guidelines remain unclear for - a priori - low-risk women. Since interventions to control GWG would have considerable impact on women and caregivers, harms and benefits should be well-considered before implementation.

Introduction

In developed countries, there is a growing concern about the combined effect of obesity and GWG on perinatal outcomes. Worldwide, maternal obesity (BMI ≥30 kg/m^2) occurs in a range of 1.8 - 25.3% [1] and is associated with increased risk of adverse perinatal outcomes such as fetal congenital anomalies, [2, 3] gestational diabetes, [4] pre-eclampsia, [5] caesarean delivery, [6] stillbirth, [7] macrosomia [8-10] and lower breastfeeding rates. [11] Both low and - although less consistent - high GWG is correlated with a higher risk of preterm birth. Low GWG is associated with a higher risk of low birth weight and SGA infants while a high GWG is correlated with a higher risk of macrosomia, LGA infants, caesarean delivery and postpartum weight retention. [12] Postpartum weight retention is related to higher prepregnancy BMIs and more adverse perinatal outcomes in subsequent pregnancies. [13-16] The combination of a high BMI and a high GWG is associated with a higher risk of LGA, pre-eclampsia, caesarean delivery, postpartum weight retention but with a lower risk of SGA. [17-19]

During the last decades, the guidelines on GWG have changed. In 1990 the IOM [20] published guidelines for GWG according to a BMI classification. These guidelines were developed in an effort to prevent premature births and SGA infants. Studies confirmed that gaining weight below the IOM guidelines was related to preterm birth, low birth weight, SGA and failure to initiate breastfeeding. [12] Since 1990 concern has shifted to the effects of obesity and increasing weight gain in pregnancy, with a focus on the relation between weight gain above the IOM recommendations and macrosomia, LGA, caesarean delivery and postpartum weight retention. [8, 12] Previous North American studies showed that only 30 - 44 % of pregnant women gained weight within the recommended ranges of the 1990 IOM guidelines, 20 - 34 % gained less weight and 36 - 44 % had excessive weight gain. [18, 21-24] BMI is known to be negatively correlated with GWG, meaning that obese pregnant women gain less weight than their normal weight counterparts. [19, 25-27] However, 64 - 70% of the overweight women gained more weight than recommended by the IOM compared to 40 - 49% of the normal weight women. [25, 28, 29] In a small Dutch sample (n = 144) 31% of the normal weight and 62% of the overweight women showed excessive weight gain. [26] For obese women, excessive weight gain could not be calculated because the 1990 IOM guidelines had no upper limit of weight gain for this category. Given these new insights, the IOM re-evaluated their guidelines and published new recommendations in 2009. These were based on a systematic review by Viswanathan et al. [12] including studies published between 1990 and 2007. The new recommendations specified GWG ranges for obese women using the BMI classification of the WHO (Table 1). [8]

Table 1. BMI classification according to the WHO and IOM guidelines for GWG

Classification	BMI (kg/m^2)*	IOM guidelines for GWG (kg) †
Underweight	<18.50	12,5 - 18
Normal weight	18.50 - 24.99	11.5 - 16
Overweight	25.00 - 29.99	7 - 11.5
Obese	≥30.00	5 - 9
- Class I	- 30.00 - 34.99	
- Class II	- 35.00 - 39.99	
- Class III	- ≥40.00	

* Adapted from WHO, 1995, WHO, 2000 and WHO 2004 [30]

† IOM, 2009.

Recently, Simas et al. [31] showed that the new guidelines are of great impact on women's BMI categorisation and thus on their GWG recommendations: Compared to the 1990 guidelines, fewer women were classified as underweight, normal weight or obese and more as overweight. Fewer women gained insufficient and appropriate weight while considerable more women gained too much weight. [31]

The Dutch obstetric system is based on risk assessment by independent midwives in primary care. If risk factors arise or complications occur during pregnancy, delivery or puerperium, the midwife refers the woman to secondary or tertiary obstetric care. This policy is based upon the OIL, a national guideline specifying indications for referral based on best evidence and/or consensus by the professionals involved. [32] In 2008, at the start of the pregnancy, 84% of all women had a low-risk profile and began their perinatal care in a primary care, midwife-led practice. [33] If pregnancy remains healthy up to the beginning of labour, women can choose for midwife-led home or hospital birth. Although obesity is a significant problem in the Netherlands with a prevalence of 10% among women between 25 and 45, [34] obesity has not been mentioned in the OIL and no national guidelines on GWG have been implemented. A diversity of regional guidelines aims to deal with weight and weight gain but these local guidelines lack sound supporting evidence.

In order to individualise obstetric care, to avoid unnecessary medicalisation, and to guarantee free choice in perinatal care for healthy women who are overweight, the criteria for risk assessment related to obesity and GWG in midwife-led care should be based on the results of research among women without co-morbidities. At present this is not the case: Researchers look at excessive or insufficient weight as risk factor in itself, without separating out women without co-morbidities. Because of its unique organisation, the Dutch midwife-led care system offers a perfect setting to gather knowledge about the many overweight women who have no co-morbidities. By describing the prevalence of overweight and obesity in healthy women and the relation of GWG to BMI-status (including the distribution of GWG if the 2009 IOM guidelines are implemented), our study provides important information to caregivers who work with today's population of pregnant women.

Methods

Subjects

Our study uses data from the Kempen V Study, a prospective cohort study that examined aspects of maternal well-being and obstetrical outcomes in relation to gestational thyroid function. [35] Between 2002 and 2004, 1985 Caucasian, pregnant women in five midwife-led practices, living in and around the city of Eindhoven (the Netherlands) were invited to participate at their first antenatal visit at 10-12 weeks gestation. A total of 1601 (80.7%) agreed to participate. For the current study all women eligible for primary midwife-led care after the first antenatal booking were included. Excluded were 13 women with an abortion after the intake, 29 women who were referred to secondary obstetric care immediately after the intake because of an a priori high-risk pregnancy according to the OIL. [32] Because the focus of the research was on overweight and obesity and the sample included too few underweight women to be able to draw any statistical significant findings, 21 underweight women were excluded. There were missing data on weight at 12 weeks and/or height in 89 women, resulting in 1449 women in the study (Figure 1).The Kempen V study was approved by the Medical Ethical Committee of Máxima Medical Centre in Veldhoven, The Netherlands.

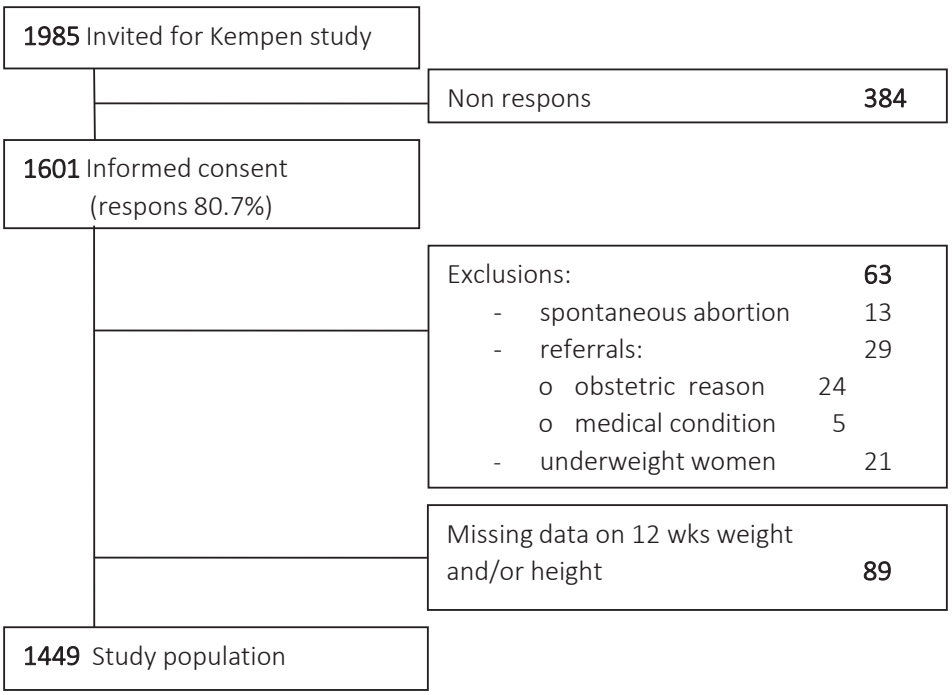

Figure 1. Flow chart study

Data collection

Data on maternal characteristics (age, education, partner, alcohol and smoking) were taken from questionnaires completed by women after the first antenatal booking. All other data were taken from the midwife's obstetrical records and/or hospital records (in cases of referral during pregnancy, childbirth, or puerperium). Weight at 12, 24 and 36 weeks of pregnancy was measured by the midwife using scales that had been calibrated. Height was self-reported. First trimester BMI was calculated as weight in kilograms at the first antenatal booking divided by squared height in meters. BMI was classified according to the WHO classification (Table 1). [30] GWG was calculated for normal weight, overweight and obese women between 12 and 24 weeks (GWG_1, n = 1412), between 24 and 36 weeks (GWG_2, n = 1337) and between 12 and 36 weeks (GWG_{Total}; n = 1343). We had missing data on weight at 24 weeks (n = 37) and at 36 weeks (n = 106).

Statistical analysis

After calculating individual BMIs in the study population, we focused our analyses on normal weight, overweight and obese women as defined by the WHO (Table 1). Maternal characteristics were compared over these BMI categories using χ^2 test for categorical variables and analysis of variance (ANOVA) for continuous variables. Furthermore, ANOVA was used to test for mean differences of GWG by BMI class. To acquire more insight in the course of GWG, a paired- t- test was used to compare mean GWG_1 and GWG_2. To examine first-trimester BMI as a predictor for GWG_1, GWG_2 and GWG_{Total} we ran three separate multiple linear regression analyses with BMI, age, parity, education, partner, smoking, alcohol and the interaction between BMI and parity as predictors. To examine the factors that predict whether women stayed below the IOM-guidelines for GWG, met these guidelines, or exceeded these guidelines (polytomous outcome) we performed a polytomous logistic regression analyses, including first trimester BMI classification, age, parity, education, partner, smoking and alcohol. This analysis enabled us to simultaneously calculate for each predictor, two adjusted odds ratio's (ORs). The first ORs for gaining weight 'below vs. within the IOM guidelines' and the other ORs for gaining weight 'above vs. within the IOM guidelines'. The Likelihood Ratio Test was used to determine the correct model. The ORs were calculated for the predictors in the final model: first trimester BMI classification, age, parity, and alcohol. We calculated the relative risks (RR) from the adjusted ORs to be able to interpret the magnitude of the association more easily, using the method proposed by Zhang et al. [36]. For each of the predictors in the final model RRs for gaining less weight than recommended and for gaining more weight than recommended were calculated. Calculating the bounds of the RR confidence intervals from the OR confidence intervals with the above mentioned formula is not appropriate. [37] Therefore,

the calculated RRs must be regarded as indicators for the real point estimates. All statistical analyses were done, using SPSS version 15.01. [38] *P*-values of <0.05 were considered statistically significant.

Findings

Our study population included 1470 women. Mean age was 30 years and 47.2% were nulliparae. Almost all women (98%) had a partner and 83% finished at least secondary school. The women lived in urban and semirural areas.

First trimester BMI

All participating women were classified according to their first trimester BMI. A total of 21 women (1.4%) were underweight; 791 (53.8%) were of normal weight; 435 (29.6%) were overweight and 223 (15.1%) were obese (Figure 2). Characteristics of normal weight, overweight and obese mothers are shown in Table 2 (n = 1449). The distribution of maternal characteristics in these BMI classes showed no differences except that women in the obese categories had a lower education than normal weight and overweight women (*p* <0.05)

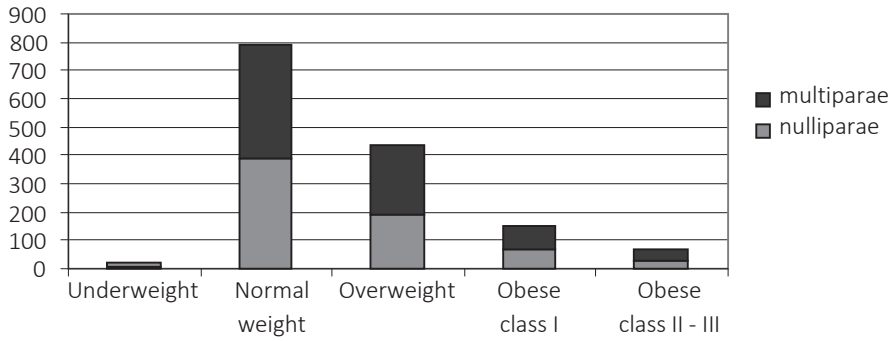

Figure 2. Distribution of first trimester BMI according to WHO classification in low-risk nulli - and multiparae.

Table 2. Demographic and obstetric characteristics of normal weight, overweight and obese (class I-III) women.

Characteristics	Normal weight (n = 791) Mean(SD)/n(%)	Overweight (n = 435) Mean(SD)/n(%)	Obese class I (n = 152) Mean(SD)/n(%)	Obese class II and III (n = 71) Mean(SD)/n(%)	Total (n = 1449) Mean(SD)/n(%)	*p*-Value
Demographic:						
Age	30.13 (3.9)	30.35 (3.4)	30.40 (3.6)	29.90 (3.9)	30.21 (3.7)	0.686 ‡
Height	1.70 (0.1)	1.69 (0.1)	1.69 (0.1)	1.69 (0.1)	1.70 (0.1)	0.143 ‡
Partner						
No	13 (2.1)	4 (1.1)	5 (3.9)	0	22 (1.9)	0.159 †
Yes	616 (97.9)	352 (98.9)	124 (96.1)	60 (100.0)	1152 (98.1)	
Education						
Low	101 (16.1)	53 (14.9)	29 (22.5)	15 (25.4)	198 (16.9)	0.03 † *
Mid	287 (45.8)	162 (45.5)	65 (50.4)	30 (50.8)	544 (46.5)	
High	238 (38.0)	141 (39.6)	35 (27.1)	14 (23.7)	428 (36.6)	
Lifestyle habits						
Smoking:						
No	552 (87.8)	318 (89.6)	110 (85.3)	52 (85.2)	1032 (87.9)	0.533 †
Yes	77 (12.2)	37 (10.4)	19 (14.7)	9 (14.8)	142 (12.1)	
Alcohol:						
No	540 (85.9)	305 (85.7)	117 (90.7)	5 (90.2)	1017 (86.6)	0.378 †
Yes	89 (14.1)	51 (14.3)	12 (9.3)	6 (9.8)	158 (13.4)	
Obstetric:						
Parity						
Nulliparae	390 (49.3)	194 (44.6)	70 (46.1)	30 (42.3)	684 (47.2)	0.339 †
Multiparae	401 (50.7)	241 (55.4)	82 (53.9)	41 (57.7)	765 (52.8)	
First trimester weight	64.76 (6.4)	77.45 (7.0)	91.60 (7.2)	108.80 (9.8)	73.55 (13.7)	0.000 ‡*

**p*-Value <0.05 † X^2 test ‡ Analysis of variance (ANOVA)

Gestational weight gain

The mean gestational weight gain (GWG_{Total}) was 11.3 kg (SD 4.2). The mean GWG_2 (5.9 kg; SD 2.7) was significantly higher than the mean GWG_1 (5.4 kg; SD 2.7) (p <0.000). Moreover, in normal weight, overweight and obese class I women, the difference between GWG_2 and GWG_1 increased with decreasing GWG_{Total} (Table 3). In both periods nulliparae gained approximately 1 kg more than multiparae (p <0.000). Table 3 shows also that the mean GWG was influenced by women's first trimester BMI classification (p <0.001). With increasing BMI class, mean GWG_1 significantly decreased. With respect to GWG_2, the post hoc test showed that women in the obese classes II and III gained significantly less weight compared to women in the other BMI classes.

Table 3. Mean gestational weight gain in kg between 12 and 24 (GWG_1), 24 and 36 (GWG_2) and 12 and 36 (GWG_{Total}) weeks of pregnancy, according to first trimester BMI-classification

Mean GWG	Normal weight Mean (SD)	Overweight Mean (SD)	Obese class I Mean (SD)	Obese class II & III Mean (SD)	Total Mean (SD)	*p*-Value
GWG_1 (N= 1412)	5.92 (2.34)	5.16 (2.61)	4.37 (3.37)	2.74 (3.23)	5.37 (2.71)	0.000*
GWG_2 (N=1337)	6.09 (2.52)	5.83 (2.72)	5.62 (2.69)	3.73 (2.95)	5.85 (2.67)	0.000*
GWG_{Total} (N=1343)	12.03 (3.64)	10.99 (4.30)	9.99 (4.70)	6.53 (4.53)	11.25 (4.20)	0.000*

* p <0.001

Multiple linear regression showed that 13.1 % of the variance in GWG_{Total} was explained by first trimester BMI, age, parity and the interaction between BMI and parity. There is a negative effect of BMI on GWG_{Total}: the higher the BMI, the lower GWG_{Total}. Moreover, because of the significant interaction between BMI and parity the effect of BMI on GWG_{Total} differed for multiparae and nulliparae: with every 1 kg/m2 increase of the BMI, multiparae gained 569 g less weight and nulliparae 168 g less. GWG_1 influenced weight gain later in pregnancy: with every 1 kg of weight gain between 12 and 24 weeks, a woman gained 176 g extra weight between 24 and 36 weeks (Table 4).

Table 4. Multiple linear regression analysis with GWG_{Total}, GWG_1 and GWG_2 as dependant variables, final model.

	Model GWG_{Total} *ß (p*-Value*)*	Model GWG_1 *ß (p*-Value*)*	Model GWG_2 *ß (p*-Value*)*
BMI	-0.168 (0.000)	-0.271 (0.000)	-0.061 (0.040)
Age	-0.091 (0.003)		-0.174 (0.000)
Parity	0.176 (0.281)	-0.148 (0.000)	-0.112 (0.000)
GWG1			0.176 (0.000)
BMI*Parity	-0.401 (0.016)		
R^2(%)	13.2*	9.9*	10.7*

*p <0.001

GWG and the IOM guidelines

Table 5 shows the results had the 2009 IOM guidelines been implemented at the time of the study. Using these guidelines, 39.9% (n = 536) of all women fell in the recommended range for GWG, 33.4% women (n = 448) gained less weight than recommended, and 26.7% (n = 359) exceeded the recommendations. Polytomous logistic regression showed that overweight and obese (classes I and II-III) women had a significant higher risk of exceeding the recommended GWG than women of normal weight. Normal weight women had a significant higher risk of gaining weight below the IOM guidelines than overweight and obese class I women. The odds for insufficient weight gain for obese class II and III women did not differ significantly from the normal weight women. Nulliparae had a significant higher risk of gaining weight above the IOM guidelines, while multiparae had more risk to gain weight below the guidelines (Table 6).

The majority of women (56%) who gained more weight than recommended (n = 202) and 64% of the women who gained less weight than recommended (n = 286) did so with 1.1 - 5 kg. Of all women gaining more weight than recommended, 21.4 % (n = 77) gained ≤1 kg too much and 22% (n = 80) gained ≥5.1 kg too much. Of all women gaining insufficient weight, 25.9% (n = 116) gained ≤1 kg too little and 10% (n = 46) gained ≥5.1 kg too little (Table 7).

Table 5. Prevalence of not meeting the IOM guidelines in relation to BMI-classification and parity

	Normal weight (n = 736) n (%)	Overweight (n = 406) n (%)	Obese class I (n = 137) n (%)	Obese class II and III (n = 64) n (%)	Total (n = 1343) n (%)
Below IOM guidelines*					
Nulliparae	134	18	5	9	166
Multiparae	201	49	15	17	282
Total	335 (45.52)	67 (16.50)	20 (14.60)	26 (40.63)	448 (33.36)
Within IOM guidelines*					
Nulliparae	162	54	19	9	244
Multiparae	144	114	21	13	292
Total	306 (41.58)	168 (41.38)	40 (29.20)	22 (34.37)	536 (39.91)
Above IOM guidelines*					
Nulliparae	59	106	38	11	214
Multiparae	36	65	39	5	145
Total	95 (12.90)	171 (42.12)	77 (56.20)	16 (25)	359 (26.73)

* IOM recommendations in kg: normal weight: 11.5 - 16; overweight: 7 - 11.5; obese: 5 - 9.

Table 6. Polytomous logistic regression: predictor variables on the contrasts 'below vs. within the IOM guidelines' and 'above vs. within the IOM guidelines'.

	below vs. within the IOM guidelines			above vs. within the IOM guidelines		
Predictor variables	OR	95% CI	RR	OR	95% CI	RR
BMI overweight (vs. BMI normal weight)	0.341**	0.236-0.493	0.487	4.049**	2.284-5.780	2.90
BMI obese class I (vs. BMI normal weight)	0.480*	0.257-0.894	0.631	8.850**	5.291-14.705	4.38
BMI obese class II & III (vs. BMI normal weight)	0.950	0.496-1.821	0.969	2.660*	1.280-5.525	2.18
Age	1.043*	1.001-1.087	1.022	0.978	0.934-1.024	0.98
Alcohol (vs. no alcohol)	1.692*	1.109-2.577	1.281	1.376	0.843-2.247	1.31
Nullipara (vs. multipara)	0.713*	0.521-0.975	0.775	2.351**	1.676-3.298	1.99

*p <0.05 ** p <0.001

Table 7. Extent of not meeting IOM-recommendations by BMI-classification

		≤1 kg n (%)	1.1-5 kg n (%)	5.1-10 kg n (%)	>10 kg n (%)
Gaining more weight than recommended					
Normal weight	(n = 95)	34 (35.5)	49 (52.3)	9 (9.2)	3 (3.0)
Overweight	(n = 171)	27 (15.8)	108 (63.2)	30 (17.5)	6 (3.5)
Obese class I	(n = 77)	15 (19.5)	35 (45.5)	23 (29.8)	4 (5.2)
Obese classes II and III	(n = 16)	1 (6.3)	10 (62.5)	5 (31.2)	0 (0.0)
Gaining less weight than recommended					
Normal weight	(n = 335)	89 (26.5)	210 (62.8)	35 (10.4)	1 (0.3)
Overweight	(n = 67)	16 (23.8)	48 (71.7)	3 (4.5)	0 (0.0)
Obese class I	(n = 20)	6 (30.0)	11 (55.0)	3 (15.0)	0 (0.0)
Obese classes II and III	(n = 26)	5 (19.2)	17 (65.4)	4 (15.4)	0 (0.0)

Discussion

Our prospective study gives us insight into variations in GWG by BMI for pregnant women with no co-morbidities. In our study population 15 % of the women were obese (BMI ≥30 kg/m2) according to their first trimester BMI. Had the 2009 IOM guidelines been implemented at the time of the study, more than half of our study population would have fallen outside of the IOM. Although the amount of weight gain declined with increasing BMI, overweight and obese women (classes I and II-III) were at higher risk for exceeding GWG recommendations. One third of all women in the study had insufficient weight gain, most of them normal weight and obese class II and III women.

Findings in relation to other studies

The mean GWG of 11.3 kg (SD 4.2) in our sample of Dutch women was lower than the mean weight gain of 14.0 - 15.1 kg (SD 4.7 - 5.9) reported among several European

populations. [17, 26, 27, 39] This could be the result of the calculation of GWG in our study. In contrast to other studies were GWG measurement is often based on the (self-reported) last weight before delivery minus the prepregnancy weight, we used weight at 12 and 36 weeks of pregnancy.

We found a lower rate of weight gain between 12 and 24 weeks compared to 24 - 36 weeks in contrast with other studies that reported a higher weight gain in the 2nd trimester than in the 3rd trimester. [8, 29, 40] This difference could be the result of the timing of the GWG measurements in our study, which was not consistent with pregnancy trimesters.

In agreement with other studies, we found that with increasing BMI, GWG decreased and that multiparae gain less weight in pregnancy than nulliparae. [8, 19, 25-27]

Not in line with the study of Simas et al. [31], which was also based on the 2009 guidelines, are the findings on falling out the IOM guidelines. We found twice as many women with insufficient weight gain (33.4% vs. 16.7%) and half of the number of women with excessive weight gain (26.7% vs. 52.6%). [31] These results could be related to a different extent of the obesity problem in the general population, a difference in risk profile of the included women, and/or differences in maternal characteristics including differences in lifestyle and in public health approach between the US and the Netherlands.

The added value of our study is that we offer in-depth knowledge on the different subcategories of the obese class in relation to the IOM recommendations and on the quantity of the inappropriate weight gain. Dividing the obese women in two groups - class I versus classes II and III - allowed us to see that women in obese class I were at higher risk for excessive weight gain than women in class II and III: RR 4.38 and 2.18 respectively (Table 6). More women of class II and III had appropriate (40% versus 34%) and insufficient (41% versus 15%) weight gain than obese women class I (Table 5). The diversity of the distribution of GWG in relation to BMI is confirmed by the variety of the amount of inadequate weight gain in Table 7.

Strengths and limitations

Our study sample included only low-risk Caucasian women, limiting generalisability. The timing of the data collection (2002 - 2005) could be seen as a limitation of this study given increasing obesity rates and interventions between then and now. In our opinion, our data can be considered current because the prevalence of obesity among women between 25 and 45 years in the Netherlands is unaltered between 2004 and 2009, according to the latest national figures: 10.2% vs. 10.3%. In the period between 2002 and 2009 (last available year), the range of prevalence of obesity was situated between 8.4% (2002) and 11.3% (2006).[34]

The prevalence of obesity in our study (15%) was higher than the national prevalence of 10.2 % among women between 25 and 45 years in 2004. [34] It is likely that

this difference is the result of the disparity between self-reported (and therefore underestimated) weight in the national database and the measured weights in our study [41-43]. It is also true that BMI at 12 weeks will be higher than the prepregnancy BMI. On average women gain 2 kg in the first trimester. [29, 40] This makes a comparison with other studies difficult: our *first trimester* BMIs could be higher compared to the *prepregnancy* BMI used by the IOM, resulting in more women being classified as overweight or obese. This means that more women in our population had to fulfil restrictive weight gain recommendations, resulting in a likely overestimation of women exceeding IOM guidelines. In our study most women delivered after 36 weeks. Their total GWG was thus higher than reported, resulting in an underestimation of exceeding IOM guidelines.

Our study has several strengths. This is the first study of GWG in a low-risk population, using the 2009 IOM thresholds. In contrast to other research, we eliminated bias by using measured weight at fixed moments during pregnancy instead of self-reported weight. In studies using self-reported height and weight, 15 % of the BMIs are underestimated, resulting in an underestimation of women exceeding IOM guidelines. Although the literature is inconsistent, the overestimation of self-reported vs. measured height seems to be less than the underestimation of self-reported vs. measured weight. [42, 43] Because weight and weight gain in pregnancy was not yet an issue in the Netherlands in the period between 2002 and 2005, it is unlikely that our results were influenced by guidelines, medical advice, or caregiver's personal opinions.

Meaning of the study and future research

Risk assessment in pregnancy related to obesity is now based on international research among women with a diversity of health profiles. This knowledge tells us little about how to handle obesity and GWG in a population with no co-morbidities. In order to avoid unneeded medicalisation and overtreatment of pregnant women it is essential that we develop evidence on overweight and obesity among healthy pregnant women.

Should primary care midwives implement the IOM thresholds for GWG? On the one hand, we are aware, as we indicated in our introduction, of international evidence for adverse perinatal outcomes related to excessive or insufficient weight gain. [12] Furthermore, a high GWG is correlated with postpartum weight retention and higher prepregnancy BMIs and more adverse perinatal outcomes in subsequent pregnancies. [13-16] Women who receive advice on GWG are more likely to gain weight within recommendations than women who are not. [44, 45] On the other hand, the differences in prevalence of falling out the 2009 IOM recommendations between the US and the Netherlands, especially the doubled amount of insufficient weight gain, suggest differences in perinatal outcomes between the two countries. Besides, our study suggests that efforts to get all women to meet the IOM guidelines will have a substantial impact on women's lives and will demand extra work on the part of

midwives and other caregivers. Weight gain in pregnancy is influenced by a number of reproductive, demographic, socioeconomic, behavioural and psychosocial factors, making managing weight gain a very complex phenomenon. [8, 26] The fairly low explained variances (of 9.9% - 13.2%) in our multiple linear regressions support this observation, suggesting that our model with BMI explains only a modest part of the variance in GWG in the different periods in pregnancy (Table 4). Furthermore, as the authors of the IOM guidelines stated, current research is inadequate to assess objectively the range of harms and benefits of providing all women the same recommendations for weight gain, irrespective individual characteristics such as age or ethnicity. [12] If we agree that guidelines on managing weight gain in pregnancy contribute to healthy mothers and children, the challenge then becomes finding a way to respond to the complex sources of problematic weight gain in pregnancy by tailoring guidelines to different populations.

To provide cost-effective guidelines for midwife-led care on weight and weight gain in pregnancy more research among pregnant women without co-morbidities is required. We need to know more about the association between BMI classes, GWG and perinatal outcomes, in current and consecutive pregnancies. In-depth research on obesity subgroups will provide useful insights enabling us to optimise care for this group of women. Future work on the best methods for implementing programs to manage weight gain should incorporate women's perspectives to address the complex factors involved in managing weight gain.

In conclusion, more than half of the normal weight, overweight and obese women in our study population did not meet the IOM recommendations. Obviously it is hard for women to gain an adequate amount of weight in pregnancy: 60% of all women would have needed extra support to reach this goal. This implies that if the 2009 IOM guidelines are to be implemented in primary care settings, a substantial personal, organisational and financial investment will be needed. The question arises if this is the right thing to do without research on the impact of falling out IOM guidelines on perinatal and health outcomes in low-risk populations. Harms and benefits of the IOM guidelines for healthy pregnant women without co-morbidities should be well-considered before implementation.

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Chapter 3

The impact of obesity on outcomes of midwife-led pregnancy and childbirth in a primary care population: a prospective cohort study

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Abstract

Objective: To assess the impact of obesity on the likelihood of remaining in midwife-led care throughout pregnancy and childbirth.
Design: Secondary analysis of a prospective cohort study.
Setting: Dutch midwife-led practices.
Population: A cohort of 1369 women eligible for midwife-led care after their first antenatal visit.
Methods: First-trimester BMI was calculated as weight measured at booking divided by height squared. Obstetric data were retrieved from medical records. Multiple logistic regressions were performed to examine the effects of BMI classification on midwife-led pregnancies and childbirths.
Main outcome measures: Percentages of women remaining in midwife-led care throughout pregnancy and throughout childbirth.
Results: Of women in obesity classes II and III, 55% remained in midwife-led care throughout pregnancy and 30% remained in midwife-led care throughout pregnancy and birth. Compared with women of normal weight, women in obesity classes II and III women had fewer midwife-led pregnancies (OR 0.38, 95% CI 0.21 - 0.69), and women who were overweight or in obesity class I had fewer midwife-led childbirths (OR 0.63, 95% CI 0.44 - 0.90; OR 0.49, 95% CI 0.29 - 0.84, respectively). Compared with women of normal weight, women who were obese had higher referral rates for hypertensive disorders (4 versus 14%), prolonged labour (4.6 versus 10.4%) and intrapartum pain relief (4 versus 10.4%). The women who were eligible for midwife-led birth and who were overweight or obese, had no more urgent referrals than women of normal weight. Women who were obese and who completed a midwife-led birth had no more adverse outcomes than women of normal weight, with the exception of higher rates of LGA babies (>97.7 centile; 12.1%, versus 1.9% in normal weight and versus 3.3% in overweight women).
Conclusion: Although fewer women who were obese remain in midwife-led care during pregnancy and childbirth, there was no increased risk of unfavourable birth outcomes for women who were obese and eligible for a midwife-led birth when compared with women of normal weight. This indicates that when primary care midwives use a risk assessment tool throughout pregnancy and childbirth they are able to safely assign women who are obese to either midwife-led or obstetrician-led care.

Introduction

Managing obesity in pregnancy and childbirth is a challenge for professionals who provide maternity care. Reported rates of obesity (BMI ≥30 kg/m^2) in pregnancy range from 1.8 to 25.3%. [1] Systematic reviews and meta-analyses indicate an association between maternal obesity and higher risks of adverse perinatal outcomes. [2-9]

In the Netherlands, maternal care is primarily provided by midwives. If risk factors arise or complications occur, the midwife refers the woman to obstetrician-led care. This continuing risk assessment is based on the OIL, a national guideline that specifies indications for referral based on evidence and/or the consensus of professionals. [10] Obesity has not yet been included in the OIL, but class-III obesity (BMI ≥40 kg/m^2) is mostly considered a medical condition that requires obstetrician-led care. [11] Given the evidence, the question arises as to whether obesity (≥30.00 kg/m^2) should always be treated as a high-risk situation that requires obstetrician-led care.

Restraint should be exercised in extrapolating research results from hospital-based populations to primary care populations, however. The generalisability of study results depends on the resemblance of study settings and participants between the underlying studies and the target population. [12] Published reviews on obesity may therefore not be applicable to midwife-led care populations: the women in the included studies are, for the most part, recruited from those admitted to hospitals or the data are sampled from large hospital-based databases, relevant co-morbidities are not always excluded or corrected for, and the characteristics of the women and the care they received may differ. Not taking the above aspects into account could lead to an overestimation of the risks of obesity for women in primary care. Furthermore, as a solitary risk factor, (a high) BMI has not proven to be a useful single predictor for complications such as pre-eclampsia or abnormal fetal growth. [13, 14] Considering this, obesity could be viewed as a risk modifier of obstetric pathology (e.g. hypertensive disorders, gestational diabetes), that can be detected in a timely way in midwife-led care using an agreed-upon risk assessment tool.

The aim of this study is to examine how many women continue to receive midwife-led care throughout pregnancy and childbirth, and to gain insight into the likelihood of, and reasons for, referral to obstetrician-led care in relation to first-trimester BMI in a primary care population. In addition, we evaluate the effect of the current risk assessment tools on the number of urgent referrals and birth outcomes after midwife-led birth for women who are obese, compared with women of normal weight.

Methods

Study and participants

This study analysed data of the Kempen V study, a prospective cohort study of aspects of maternal well-being and obstetrical outcomes in relation to gestational thyroid function.[15] Women were included between July 2002 and November 2004. White, pregnant women in five midwife-led practices, living in and around the city of Eindhoven (the Netherlands), who were eligible for midwife-led care after their first antenatal visit at 10 - 12 weeks of gestation, were invited to participate. This study excluded women who subsequently had a miscarriage after the first antenatal booking, women who were immediately referred to obstetrician-led care because of the pregnancy was considered to be of high risk at the outset (according to the OIL), and women referred to obstetrician-led care around 36 weeks of gestation because of a presumed increased delivery risk based on their obstetric history (e.g. for a previous caesarean section). [10] These criteria for referral to obstetrician-led care were agreed on at the outset of the pregnancy, and were not influenced by the maternal BMI. We also excluded women who were underweight because our focus was on obesity and because of the differences in pathophysiology between overweight and underweight in obstetrics.

Setting of the study

In the Netherlands, midwives are authorised to supervise physiological pregnancy, childbirth and puerperium (primary care). Continued risk assessment by the midwife plays a crucial role in the maternity care system. This assessment starts at the first antenatal booking appointment, with an examination of a woman's medical, psychosocial and obstetric history and is continued throughout the perinatal period. [16] If an obstetric risk factor, as defined by the OIL, is identified during pregnancy, the woman is then referred to obstetrician-led care. If not, she is eligible for primary care in a midwife-led practice. A woman can only choose for a midwife-led home or hospital birth if her pregnancy remains healthy up to the beginning of labour. During a midwife-led birth, the maternal and fetal condition and progress of the birth process are observed. Again, if risk factors arise or complications occur, women are referred to secondary care. The great majority of referrals during childbirth are not urgent because they are not life-threatening for the mother or child, and often the family's own transport is used to reach an obstetric hospital. [17] In the event of an urgent referral, professional transport is available.

During the study period, obesity was not an indication for referral to obstetrician-led care in the OIL or in any other national or regional guideline. Therefore, the obstetric outcomes from this study reflect the impact of obesity itself. In the participating region,

a selective screening protocol was used for GDM: this protocol includes indications for macrosomia and GDM in the obstetric history, maternal weight ≥90 kg at the initial antenatal check-up, the suspicion of a LGA fetus, high GWG, and glycosuria. If indications were present, an O'Sullivan test was performed at 24-28 weeks of gestation (or later in pregnancy), followed by an oral glucose tolerance test (OGTT) in case of a value ≥7.8 mmol/l.

Data collection

Data on maternal characteristics (age, education, partner, alcohol, and smoking) were taken from questionnaires completed by women after their first antenatal booking. Maternal weight at 10-12 weeks of gestation was measured by the midwife using calibrated scales. Maternal height was self-reported**.** The first trimester BMI was then calculated as weight at the first antenatal booking divided by height squared (kg/m^2). BMI was classified according to the WHO classification: underweight (<18.5 kg/m^2), normal weight (18.5 - 24.99 kg/m^2), overweight (25 - 29.99 kg/m^2), obese class I (30 - 34.99 kg/m^2), obese class II (35 - 39.99 kg/m^2), obese class III (≥40.00 kg/m^2). [18]

All other data were retrieved from the midwife's obstetrical records and/or hospital records (in cases of referral to obstetrician-led care during pregnancy, childbirth or the puerperium).

Outcomes

Primary outcomes were completion of a 'midwife-led pregnancy' and a 'midwife-led childbirth'. A midwife-led pregnancy is defined as a pregnancy supervised by a midwife without any referral to secondary care before the onset of term labour (defined as contractions and/or rupture of the membranes between 37 and 41^{+6} weeks of gestation). A midwife-led birth is a birth supervised by a midwife, either at home or in the hospital, without any referral to secondary care from the onset of labour until 2 hours after the birth of the placenta.

The secondary outcomes of this study are outlined in Figure 1. These include *indications for referral during pregnancy and childbirth* and *birth outcomes* in midwife-led and obstetric-led care. In this study, the referrals registered in the midwives' records were based on the procedures of the Perinatal Registration in the Netherlands (PRN), which records only the main reason for referral. An indication for referral does not always reflect the actual outcome. For example, a referral for a SGA fetus during pregnancy does not always result in a neonate actually being born SGA. Concerning referrals during childbirth, we distinguished between referrals with and without urgency based on the list presented by Amelink et al. [17]. The following referrals were coded as urgent: suspected fetal distress, placental problems (blood loss during birth, placenta praevia, placental abruption, vasa praevia, retained placenta), abnormal fetal

presentation together with ruptured membranes (cord prolapse included), postpartum haemorrhage >1000 ml, intrapartum fetal death, Apgar score <7 at 5 minutes, respiratory problems (including meconium aspiration) and congenital malformations requiring immediate care. The authors have also added preterm labour in the active phase as an indication for an urgent referral. Urgent referrals were registered in both midwife-led home births and midwife-led hospital births.

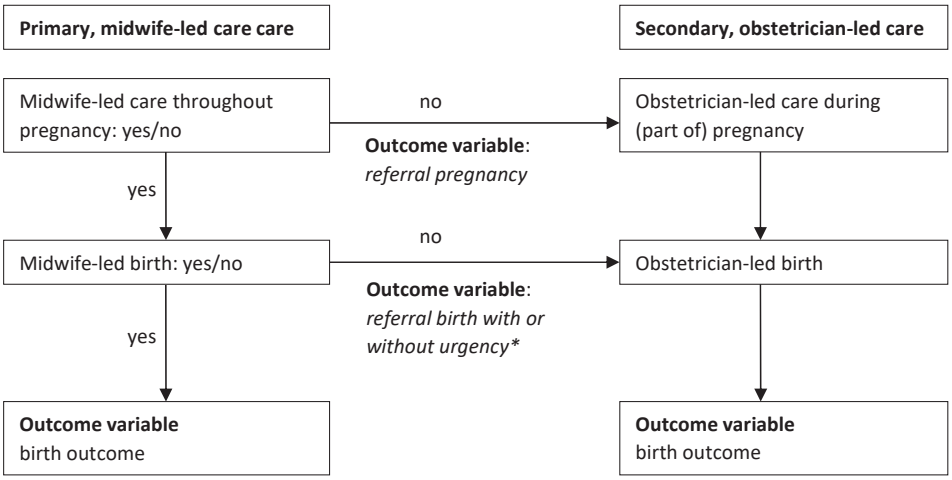

Figure 1. Outline of secondary outcomes in the study
* urgent referrals birth: suspected fetal distress, placental problems (blood loss during birth, placenta praevia, placental abruption, vasa praevia, retained placenta), abnormal fetal presentation together with ruptured membranes (cord prolapse incl.), postpartum haemorrhage >1000 cc, intrapartum fetal death, preterm labour in active phase, Apgar score <7 at 5 min., respiratory problems incl. meconium aspiration, congenital malformations with need of immediate care.

Birth outcome measures were stillbirth, induction of labour, use of pain relief, instrumental delivery (ventouse or forceps), caesarean section, shoulder dystocia, Apgar score <7 at 5 minutes, birth trauma, SGA <2.3 centile (SGA <2.3), LGA >97.7 centile (LGA >97.7), congenital malformations, and other neonatal problems within 24 hours postpartum. Stillbirth was defined as intrauterine death or death immediately postpartum. Use of pain relief comprised any analgesic or sedative medicine (oral, intramuscular, intravenous, spinal or epidural) administered during labour. The definition of shoulder dystocia was a birth requiring more than one manoeuvre to deliver the infant's shoulders. Birth trauma covered Erb's Palsy, cephalic haematoma, clavicle fracture and 'other birth trauma'. SGA <2.3 and LGA >97.7 were determined according to the 'Kloosterman centiles', adjusted for gestational age at delivery, parity and sex of the infant. [19] Other neonatal problems within 24 hours postpartum included problems or events concerning the neonate during the first day postpartum, as registered by the midwives (e.g. routine paediatric examination after instrumental

delivery or symptoms of infection), except for Apgar score <7 at 5 min, birth trauma and congenital malformations.

Analysis

To assess the influence of BMI category on midwife-led pregnancies and childbirths, two separate multiple logistic regressions were run using a backward selection method with the likelihood ratio criterion for exclusion. Maternal education, age, parity, smoking, alcohol use, having a partner, and the interactions between each BMI category and parity were included as covariates in the model on midwife-led pregnancy. In the model on midwife-led childbirth the same covariates were included, except for the interactions between BMI category and parity, because of the small numbers in the obese categories. Dummy variables were made for all the (categorical) independent variables except for age, which was recorded as a continuous variable. A multiple linear regression was performed in order to study the association between BMI as a continuous variable and moment of referral in pregnancy, including the covariates as described above. To test the effect of BMI classification on the indications for referral and the various birth outcomes, we performed chi-square or Fisher's exact tests, where appropriate. Chi-square and Fisher's exact tests were also used to determine differences in the distribution of particular birth outcomes over the BMI categories, between those who were referred to obstetrician-led care during pregnancy and childbirth and those who were not. *P* of <0.05 was considered statistically significant. Odds ratios (ORs) with 95% confidence intervals (95% CIs) were used to quantify the risk. The analyses were conducted using SPSS 15.01.

Results

A total of 1601 (80.7%) women who met the inclusion criteria agreed to participate. After the exclusion of 97 women with missing data and an additional 135 women for a variety of other reasons, 1369 women were included in the analysis (Figure 2).

Of all the women in our study, 55.2% (n = 756) were of normal weight, 30.1% (n = 412) were overweight, 10.0% (n = 137) were obese class I, and 4.7% (n = 64) were in obese classes II and III, according to their first-trimester BMIs. Maternal characteristics were equally distributed over these BMI categories, with the exception of maternal education. Women in the obese categories tended to have a lower level of education than those in the normal weight and overweight categories (p = 0.01) (Table 1).

Table 1. Maternal characteristics of women with a normal and increased body mass index (BMI)

Characteristics	Normal weight (n = 756) Mean (SD)/n (%)	Overweight (n = 412) Mean (SD)/n (%)	Obese class I (n = 137) Mean (SD)/n (%)	Obese classes II- III (n = 64) Mean (SD)/n (%)	Total (n = 1369) Mean (SD)/n (%)	*p*-Value
Demographic						
Age	30.10 (3.86)	30.26 (3.38)	30.40 (3.45)	29.87 (4.06)	30.17 (3.68)	0.76 ***
Height	1.70 (0.06)	1.70 (0.06)	1.69 (0.06)	1.69 (0.06)	1.70 (0.06)	0.27 ***
No partner	11 (1.8)	4 (1.2)	3 (2.5)	0 (0.0)	18 (1.6)	****
Education:						
low	98 (16.2)	52 (15.4)	27 (22.7)	15 (28.3)	192 (17.2)	0.01 *,**
middle	276 (45.7)	157 (46.4)	61 (51.3)	28 (52.8)	522 (46.9)	
high	23 (38.1)	129 (38.2)	31 (26.1)	10 (18.9)	410 (35.9)	
Lifestyle habit						
smoking	74 (12.2)	36 (10.7)	17 (14.3)	9 (16.7)	136 (12.2)	0.53 **
alcohol	87 (14.3)	48 (14.2)	9 (7.6)	5 (9.3)	149 (13.3)	0.18 **
Obstetric						
Parity						
nulliparous	384 (50.8)	194 (47.1)	68 (49.6)	30 (46.9)	676 (49.4)	0.65 **
multiparous	372 (49.2)	218 (52.9)	69 (50.4)	34 (53.1)	693 (50.6)	
First-trimester weight	64.80 (6.34)	77.66 (6.94)	91.46 (7.21)	108.90 (9.78)	73.40 (13.57)	0.00 *,***
First-trimester BMI	22.40 (1.55)	27.01 (1.40)	31.99 (1.34)	37.92 (2.65)	25.48 (4.45)	0.00 *,***
GWG	12.05 (3.66)	11.14 (4.31)	10.05 (4.67)	6.54 (4.62)	11.32 (4.20)	0.00 *,***

Education: low - primary education or secondary education, not completed; middle - secondary education completed; high - degree at university level.

GWG: gestational weight gain, defined as weight at 36 weeks of gestation minus weight at 12 weeks of gestation.

Total: missing values for age, n = 259; weight gain, n = 81; education, n = 255; partner and smoking in pregnancy, n = 252; and alcohol, n = 251.

*p <0.05.

**Chi-square test.

***Analysis of variance (ANOVA).

****Conditions chi-square not fulfilled.

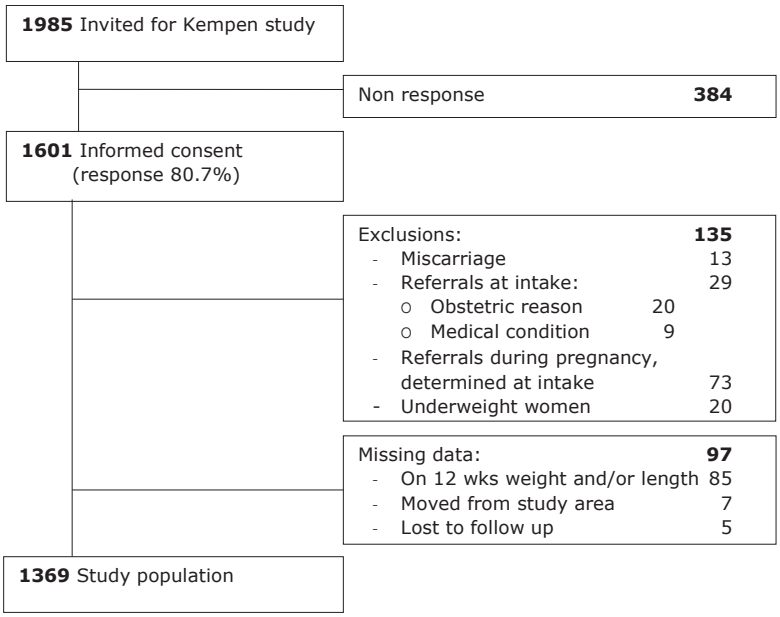

Figure 2. Flow chart of study population

Of the 1369 women who were eligible for primary midwife-led care, 44.3% (n = 607) had a pregnancy, childbirth and puerperium without the need for specialised obstetric care (Figure 3). During pregnancy, 27.8% (n = 380) of women were referred to secondary care, leaving 72.2% (n = 989) of women with an uncomplicated pregnancy. During labour, 38% of women (n = 376) were referred to secondary care, resulting in almost half of the initial sample having a midwife-led childbirth either at home or in the hospital (44.8%; n = 613). Another 6 (1%) referrals occurred in the puerperium because of neonatal indications.

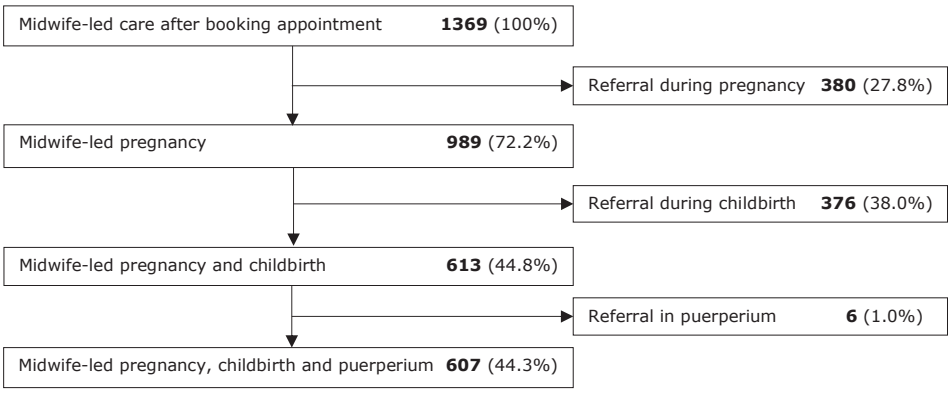

Figure 3. Number of midwife-led pregnancies, childbirths and puerperia

Midwife-led pregnancy and childbirth

The association between BMI category and the likelihood of remaining in midwife-led care for pregnancy and childbirth is presented in Table 2. Of the women of normal weight who started their pregnancy in primary care, 75% had a midwife-led pregnancy. This percentage decreased with increasing BMI, to 55% of women in obese classes II and III. Multiple logistic regression analyses showed that only women in obese classes II and III had fewer midwife-led pregnancies compared with women of normal weight (adjusted odds ratio, aOR, 0.38, 95% CI:0.21 - 0.69). The proportion of variance explained by the model was 6.7% (Nagelkerke). BMI category alone explained 1.5% of the variance. The interaction between parity and BMI was tested but did not reach statistical significance. This means that the effect of multiparity on having a midwife-led pregnancy was the same for all BMI categories.

In the group of women who started their labour in primary care, the likelihood of remaining in midwife-led care during childbirth decreased with increasing BMI categories. Compared with women of normal weight, women who were overweight or in obese class I had a lower likelihood of having a midwife-led childbirth: aOR 0.63 (95% CI:0.44 - 0.90) and aOR 0.49 (95% CI:0.29 - 0.84), respectively. Of women in obese classes II and III, 30% had a midwife-led childbirth. The proportion of variance explained by this model was 22.7% (Nagelkerke). BMI category alone explained 1.7 % of the variation in the occurrence of a midwife-led birth.

Table 2. Multiple logistic regression: predictor variables on midwife-led pregnancy and childbirth

		Midwife-led pregnancy (n = 989)		Midwife-led childbirth (n = 613)	
Predictor variables		n (%)	aOR (95% CI)	n (%)	aOR (95% CI)
Multiparous (vs. nulliparous)			**2.35 (1.76-3.15)**		**6.18 (4.39-8.70)**
Age			0.98 (0.94-1.02)		0.99 (0.95-1.04)
Partner					2.23 (0.65-7.67)
Education					
Low			1*		-
Middle			**1.45 (1.01-2.10)**		-
High			**1.72 (1.15-2.55)**		-
BMI					
Normal weight	(n = 756)	570 (75.4)	1*	365 (48.3)	*
Overweight	(n = 412)	294 (71.4)	0.81 (0.60-1.10)	182 (44.2)	**0.63 (0.44-0.90)**
Obese class I	(n = 137)	90 (65.7)	0.66 (0.43-1.01)	47 (34.3)	**0.49 (0.29-0.84)**
Obese classes II-III	(n = 64)	35 (54.7)	**0.38 (0.21-0.69)**	19 (29.7)	0.48 (0.21-1.12)

Covariates included in the model were parity, age, alcohol, smoking, maternal education, having a partner, BMI classes and the interactions between each BMI class and parity (interactions only in model midwife-led pregnancy).

aOR (adjusted odds ratio) >1 means a favourable effect on midwife-led pregnancy/childbirth.

*Used as reference in log. regression.

Reasons for referral

If women were referred to obstetrician-led care during *pregnancy*, linear regression showed that BMI as a continuous variable had no effect on when the referral occurred (regression coefficient $b = 0.07$, $p = 0.17$). The four most frequent reasons for referral in pregnancy were hypertensive disorders (n = 89, 23.4%), post-term gestation (n = 66, 17.4%), abnormal fetal positions at term pregnancy (n = 58, 15.3%) and preterm labour (n = 45, 11.8%), accounting for 68% of all referrals during pregnancy (n = 380). During *childbirth*, 71% of all referrals were due to meconium-stained amniotic fluid (n = 105, 27.9%), prolonged labour (n = 56, 14.9%), prelabour rupture of membranes (PROM) (n = 54, 14.4%) and requests for pain relief (n = 50, 13.3%). BMI was found to have a significant effect on three of the reasons for referral to obstetrician-led care during pregnancy and childbirth. Referrals for hypertensive disorders increased with increasing BMI category: 4% for women of normal weight, 7.5% for women who were overweight, and 14% for women in obesity classes I-III ($\chi^2(2) = 26.94$, $p < 0.001$). Referrals for prolonged labour ($\chi^2(2) = 6.55$, $p = 0.04$) and requests for pain relief ($\chi^2(2) = 8.73$, $p = 0.01$) doubled in women who were obese, compared with women who were normal weight or overweight. None of the referrals in the puerperium (respiratory problems (n = 3), birth at 36 weeks of gestation (n = 1), and anal atresia (n = 2)) were for women who were obese.

Birth outcomes

Table 3 summarises the *birth outcomes* of the total study population eligible for midwife-led care after their first check-up, and irrespective of any referral during pregnancy and childbirth. Of all birth outcomes, there was a significant association between BMI classification and induction of labour ($\chi^2(3) = 19.07$, $p < 0.001$), pain relief administered ($\chi^2(3) = 24.99$, $p < 0.001$), caesarean section ($\chi^2(3) = 9.10$, $p < 0.05$) and LGA >97.7 ($\chi^2(3) = 25.11$, $p < 0.001$).

In order to acquire more in-depth information about the effect of BMI category on childbirth, we examined *birth outcomes* of women who were referred and who were not referred to secondary care *in pregnancy* by BMI category. In the group who experienced a referral during pregnancy and had obstetrician-led care during birth, induction of labour increased with increasing BMI categories ($\chi^2(2) = 7.32$, $p < 0.05$). Significantly more requests for intrapartum pain relief and more LGA >97.7 babies occurred in women from obesity classes I-III, compared with other BMI categories, in both the referred and non-referred women. Among the women not referred during pregnancy, a significant association was found between BMI category and caesarean section ($\chi^2(2) = 6.75$, $p < 0.05$). All six cases of stillbirth happened during pregnancy, none of them to women who were obese.

Table 3. Birth outcomes in study population in relation to BMI classification

Perinatal outcomes	Normal weight n = 756 n (%)	Overweight n = 412 n (%)	Obese class I n = 137 n (%)	Obese class II-III n = 64 n (%)	Total n = 1369 n (%)	χ^2	*p*-Value
Stillbirth	3 (0.4)	3 (0.7)	0	0	6 (0.4)	***	0.39
Induction of labour	78 (10.3)	58 (14.1)	30 (21.9)	14 (21.9)	180 (13.1)	19.07	0.000*
Intrapartum pain relief	85 (11.2)	55 (13.3)	35 (25.5)	15 (23.4)	190 (13.9)	24.99	0.000*
Instrumental delivery	68 (9.0)	34 (8.3)	15 (10.9)	8 (12.5)	125 (9.1)	1.82	0.61
Caesarean section	69 (9.1)	42 (10.2)	23 (16.8)	10 (15.6)	144 (10.5)	9.10	0.03†
Shoulder dystocia	12 (1.6)	11 (2.7)	3 (2.2)	2 (3.1)	28 (2.0)	***	0.39
Apgar score <7 at 5 min	10 (1.3)	3 (0.7)	0	1 (1.6)	14 (1.0)	***	0.37
Birth trauma	1 (0.1)	0	0	0	1 (0.1)	***	0.85
SGA <2.3 centile	6 (0.8)	3 (0.7)	2 (1.5)	0	11 (0.8)	***	0.50
LGA >97.7 centile	19 (2.5)	17 (4.1)	14 (10.2)	7 (10.9)	57 (4.2)	25.11	0.000*
Congenital malformations	15 (2.0)	9 (2.2)	5 (3.6)	0	29 (2.1)	***	0.43
Neonatal problems <24 hrs	57 (7.5)	32 (7.8)	8 (5.8)	8 (12.5)	105 (7.7)	2.78	0.43

* p <0.001
** p <0.05
***Fisher's exact obese vs. non-obese

Unfavourable outcomes in midwife-led birth

Looking at the effect of risk assessment in relation to obesity, we specifically studied two unfavourable outcomes: urgent referrals during midwife-led birth and adverse birth outcomes after midwife-led birth. No significant effect was found for BMI category on the urgency of referrals during or immediately after childbirth ($\chi^2(2) = 1.4$; $p = 0.50$).

Of all the birth outcomes of women with a midwife-led birth (i.e. women who were not referred, NR; Table 4), only LGA >97.7 was affected by BMI category ($\chi^2(2) = 17.6$, p <0.001). We thoroughly investigated the 41 caesarean sections among women referred during childbirth and found that none were performed for urgent fetal or maternal indication diagnosed in primary care. We found no significant difference in the distribution of the relevant birth outcomes over the BMI categories between the referred and non-referred groups (X^2**** in Table 4).

Table 4. Birth outcomes of women referred and not referred during birth, in relation to normal weight, overweight and obesity

Birth outcomes		Normal weight R (n = 205) NR (n = 365) n (%)	Overweight R (n = 112) NR (n = 182) n (%)	Obese class I-III R (n = 59) NR (n = 66) n (%)	Total R (n = 376) NR (n = 613) n (%)	χ^2*** R NR	*p*-Value	χ^2****	*p*-Value
Stillbirth	R	0	0	0	0	-	-	-	-
	NR	0	0	0	0	-	-		
Intrapartum pain relief	R	53 (25.9)	36 (32.1)	24 (40.7)	113 (30.1)	5.12	0.08	-	-
	NR	-	-	-	-	-	-		
Instrumental delivery	R	50 (24.4)	28 (25.0)	15 (25.4)	93 (24.7)	0.03	0.98	-	-
	NR	-	-	-	-	-	-		
Caesarean section	R	16 (7.8)	16 (14.3)	9 (15.3)	41 (10.9)	4.49	0.11	-	-
	NR	-	-	-	-	-	-		
Shoulder dystocia	R	5 (2.4)	5 (4.5)	1 (2.3)	11 (2.9)	**	0.46	**	0.38
	NR	4 (1.1)	2 (1.1)	2 (3.0)	8 (1.3)	**	0.21		
Apgar score <7 at 5 minutes	R	8 (3.9)	1 (0.9)	1 (1.7)	10 (2.7)	**	0.52	-	-
	NR	0	0	0	0	-	-		
Birth trauma	R	1 (0.5)	0	0	1 (0.3)	**	0.84	-	-
	NR	0	0	0	0	-	-		
SGA <2.3 centile	R	1 (0.5)	0	0	1 (0.3)	**	0.84	**	0.83
	NR	3 (0.8)	1 (0.5)	1 (1.5)	5 (0.8)	**	0.44		
LGA >97.7 centile	R	6 (2.9)	6 (5.4)	3 (5.1)	15 (4.0)	**	0.43	1.39	0.50
	NR	7 (1.9)	6 (3.3)	8 (12.1)	21 (3.4)	17.6	0.00*		
Congenital malformation	R	1 (0.5)	1 (0.9)	0	2 (0.5)	**	0.71	**	0.60
	NR	6 (1.6)	6 (3.3)	4 (6.1)	16 (2.6)	**	0.08		
Neonatal problems <24 hours	R	16 (7.8)	9 (8.0)	7 (11.9)	32 (8.5)	1.02	0.60	**	0.18
	NR	6 (1.6)	2 (1.1)	0	8 (1.3)	**	0.40		

* p <0.001.

** Fisher's exact test for obese versus non-obese.

*** χ^2 on association between BMI classification and particular birth outcome within R (women referred during childbirth to secondary obstetric care) and NR (women not referred during childbirth, i.e. midwife-led care) groups, respectively.

**** χ^2 on the distribution of a particular birth outcome over BMI classes between R and NR groups, respectively.

Discussion

Main findings

In this study of 1369 women in midwife-led care, 55% of women in obesity classes II and III had no need for referral to secondary care during pregnancy, and 30% remained in midwife-led care throughout pregnancy and childbirth. Fewer women who were obese remained in midwife-led care throughout pregnancy and childbirth; however, no increased risk of unfavourable birth outcomes was noted for women who were obese and eligible for a midwife-led birth compared with women of normal weight when risk assessment occurred at regular intervals throughout pregnancy and childbirth, except for an increase in LGA babies with higher maternal BMI. Risk assessment was based on an agreed risk assessment tool without any particular guideline on maternal weight or BMI.

Strengths and limitations

We believe that this study offers new evidence on obesity in midwife-led care, a topic that has received only limited study to date. Our study measured weight (i.e. not self-reported), which enhances the accuracy of women's calculated first-trimester BMI. The timing of the data collection (2002 - 2005) could be seen as a strength given increasing obesity interventions between then and now. By using data from a period before the implementation of guidelines on obesity that now influence risk assessment and outcomes, we were able to examine the impact of obesity itself on the course of pregnancy and childbirth. Regarding the prevalence of obesity, these data can still be considered current: the prevalence of obesity among women of 20 years and older in the Netherlands has not changed between 2002 and 2011, according to the latest national figures (10.8%). Within this period, this figure has varied between 10.8 to 12.7%.[20, 21]

The generalisability of our study is limited because only white women were included. Because some adverse outcomes occurred infrequently in this low-risk population, we were unable to study the association between these outcomes and BMI category. In our study we combined obesity classes II and III (with prevalence of 10 and 4.7%, respectively) because of the small number of participants. Because normality decreases with increasing BMI class, caution should be taken when extrapolating our results to the obese classes II and III (≥35 kg/m^2) in populations with other proportions of obese women in class II versus class III. There is not a linear relation between GWG and our primary outcomes: midwife-led pregnancy and childbirth. The outcome variables are composites that may have been negatively affected by both inadequate and excessive GWG (i.e. a U-shaped relationship). Therefore, we were unable to correct for GWG as a potential confounding factor in our logistic regression models.

Interpretation in light of other evidence

Although the decrease of midwife-led pregnancies and childbirths with increasing BMI categories could be expected based on the published literature, [2-9] we have established that a considerable number of women that were obese (BMI ≥30 kg/m^2) had an uncomplicated pregnancy and/or childbirth, and could remain in primary care. The finding that the association between obesity classes II-III and a lower likelihood of having a midwife-led birth did not reach statistical significance can be explained by the small number of participants in this obesity category.

Women who are overweight and obese have been reported to have higher risks of hypertensive disorders, prolonged labour, intrapartum pain relief, induction of labour, caesarean section, and LGA >97.7 centile, which is consistent with the findings from our study. [5, 7-9] In line with previous studies, our data show no association between BMI class and referral for (spontaneous) preterm birth. [7, 22, 23] Unlike the review by Heslehurst et al.,[7] we found no association between BMI classes and meconium-stained amniotic fluid, post-term gestation, instrumental delivery, low Apgar score and other neonatal problems. The difference between the conclusions of our study and those found by Heslehurst et al. [7] are not the result of insufficient power in the studies. The groups of participants with meconium-stained amniotic fluid, post-term gestation, instrumental delivery and 'other neonatal problems' were large enough to allow us to discover a statistically significant association with BMI category, but we found no such association. Very few neonates in our study had an Apgar score <7 at 5 minutes, but a Fisher's exact test showed no significant difference in the likelihood of low Apgar scores for neonates born to women who were obese and for those born to women who were not obese (in both the total population and in the referred group after midwife-led birth). The small number of low Apgar scores in our population is likely to result from the fact that women in our study were at low-risk, and those that were referred had low rates of interventions (e.g. 10.5% caesarean sections and 9.1% instrumental delivery). Only seven women were referred to secondary care because of GDM, with the need for treatment with insulin (women with GDM treated only by diet were not referred). The frequency of a referral for GDM with insulin in this population was too small to be able to draw any conclusion about an association between BMI category and GDM as established in previous research. [4] The finding that there was no association between BMI and the timing of the referral limits the possibility of using BMI category as a possible proxy indicator for subsequent pregnancy complications.

The only unfavourable outcome after midwife-led birth was a higher risk of a neonate with LGA >97.7 centile among women who were obese. LGA and macrosomia (15% of the newborns in our study had birthweights >4000 g) are related to both short-term complications (e.g. mechanical birth problems, obstetric interventions, maternal/neonatal problems as a result of birth problems/interventions and neonatal hypoglycaemia) [24-31] and long-term complications (e.g. metabolic syndrome in

childhood, [32] childhood leukaemia, [33] and adult cancers [34]). Thus, prevention of LGA might be advisable from an obstetric and public health point of view. Two possible options should be considered for changing our risk assessment guidelines. First, a stricter gestational diabetes (GDM) screening protocol, especially among women who were overweight or obese, should be considered. Motherhood GDM increases the risk of macrosomia/LGA in the offspring, [35] and exacerbates some of the short- and long-term problems related to LGA and macrosomia. [24, 27, 31, 32, 36] A stricter GDM screening protocol may diagnose more women with GDM, and the subsequent control of maternal glucose may result in fewer LGA infants. [37] In the Netherlands there is a continuing debate about using an unselective (all women) versus a selective (women who fulfil relevant criteria) screening protocol for GDM. [38] In this study, a selective GDM screening protocol was used. Second, further research should be undertaken to test whether managing a healthy GWG could prevent LGA. Earlier research on this same study population has shown a higher risk of excessive GWG in women who are overweight or obese, [39] and we know that LGA is also related to excessive GWG. [40]

Conclusion

Although a higher maternal BMI category is associated with a reduced likelihood of remaining under midwife-led care in pregnancy and childbirth, our study indicates that a system of risk assessment throughout pregnancy and childbirth enables primary care midwives to select women with higher BMIs in a way that allows for appropriate care. Obesity is defined in the medical literature as a high-risk situation requiring the need for high-risk care. In our study, a considerable number of women who were obese remained in primary care throughout pregnancy and childbirth without unfavourable outcomes for mother and child. From a client's perspective, these are important results given the knowledge that labelling women as being at 'high risk' might result in more unnecessary interventions, negative psychological sequelae, [41] and reduced choices throughout pregnancy and around birth. [42]

As there is increasing interest in the creation of maternal care pathways for women who are obese, [7, 43] our findings are also of interest for professionals outside the Netherlands. Although our study contributes to the body of knowledge necessary to underpin care for women who are obese, further research is needed. A larger study would enable a more detailed evaluation of infrequent birth outcomes and midwife-led risk assessment in higher BMI classes, and would allow adjustments for client characteristics such as parity, GWG (inadequate, adequate and excessive), ethnicity, lifestyle and socio-economic status. In order to prevent LGA, Dutch risk assessment guidelines should aim at a stricter screening protocol on GDM, and at optimising GWG in women who are overweight and obese.

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Chapter 4

Pregnant and overweight: at home in midwife-led primary care? Multiparity positively affects outcomes of obese pregnant women

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Introduction

International reviews and meta-analyses show obesity to be associated with increased risk of several negative obstetric outcomes for mother and child.[1-8] These findings raise the question of whether Dutch obese women should receive midwife-led care or be referred to obstetrician-led care. This question is not easily answered. First, international research results cannot always be generalised and applied to the low-risk population under the care of Dutch midwives. If research results are to be transferred to practice, the population studied and the type of care provided to those women must be similar to the target population.[9, 10] If we look at the literature on obesity, we see that most studies focus on heterogeneous populations of women with and without co-morbidity. Adverse outcomes related to obesity (such as a higher percentage of births by caesarean section) could be related to obesity (e.g. on the basis of a greater possibility of hypertension or gestational diabetes), but also to co-morbidity (pre-existing hypertension, diabetes). In other words: generalising outcomes in populations of women *with* co-morbidity to populations of women *without* co-morbidity will result in an overestimation of the risk. Another important aspect is that Dutch midwives do not perform medical interventions (e.g. labour induction), reducing the likelihood of adverse outcomes associated with these interventions (e.g. postpartum haemorrhage). International studies are rarely corrected for the connection between interventions and particular consequences, making it difficult to generalise results and to apply them to the Dutch primary care population. Second, research showed that even though increased BMI is associated with an increased risk of pre-eclampsia and abnormal fetal growth, actions taken solely on the basis of BMI do not constitute effective care. [11, 12] Clearly we need further research among a Dutch population, before using BMI, in itself, as an indication for referral to secondary care.

Recommendations found in guidelines are based upon risk-oriented studies and the effects of their implementation have been rarely studied. As a result, well-founded knowledge on what constitutes effective care and the most appropriate health care provider for obese women is scarce. This becomes evident from the lack of cogent evidence underpinning the recommendations - relevant to the care of obese women in primary care - in the guidelines of the NVOG, adopted by the KNOV.[13] There is no clause about obesity in the current OIL (national cooperation arrangement in the field of obstetrics)[14] and the local guidelines on obesity use a variety of recommendations and BMI cut-off points.

Recently, two research papers were published which give a better insight into perinatal outcomes of low-risk women in relation to BMI and parity. In this article and on the basis of these two publications, we aim to provide advice on appropriate care for obese women, especially multiparous women. We hypothesise that multiparous obese women have less adverse outcomes than normal weight nulliparous women.

The impact of obesity on the outcomes in women receiving primary care

The first study is a Dutch prospective cohort study by Daemers et al. [15] into the effect of obesity on pregnancy and childbirth in women eligible for midwife-led primary care after antenatal booking. The purpose of the study was to gain insight into the effect of these women's BMI on the physiological course of pregnancy and childbirth. In order to assess the quality of risk assessment by midwives with regard to BMI, perinatal outcomes of women - referred and not referred during pregnancy and childbirth- were studied.

Method

This study analysed data from the Kempen V study, a prospective cohort study into maternal well-being and perinatal outcomes in relation to thyroid function, which was carried out from 2002 to 2004.[16] The study group consisted of 1369 Caucasian women eligible for primary care after their first antenatal visit. BMI during the first trimester of pregnancy was determined using the measured weight at 10 - 12 weeks and self-reported height. Primary outcome measures were: uncomplicated, physiological pregnancy and childbirth led by midwives in primary care. The secondary outcomes were indications for referral as registered in Perined (Dutch perinatal registry) - urgent and not urgent - and birth outcomes. Urgent indications for referral were: premature contractions (active phase), fetal distress, placental problems (including loss of blood during parturition), anomalous fetal position or presentation with ruptured membranes (cord prolapse included), postpartum haemorrhage >1000 ml, intrapartum fetal death, Apgar score <7 after 5 minutes and congenital anomalies requiring urgent specialist care.[17] No Dutch guidelines with specific recommendations on maternal weight or BMI did exist during the study period.

Findings

In this study, 55.2% (n = 756) of the women had a normal weight (BMI 18.5 - 24.9); 30.1% (n = 412) were overweight (BMI 25 - 29.9); 10.0% (n = 137) had class I obesity (BMI 30 - 34.9) and 4.7% (n = 64) had class II-III obesity (BMI ≥35). Women with underweight were excluded.

Physiological pregnancy and childbirth
Of all women with class II-III obesity (n = 64; 30 nulliparous and 34 multiparous women), 55% had a physiological pregnancy (n = 35; 16 nulliparous and 19 multiparous women) and 30% had a physiological pregnancy and childbirth (n = 19; 3 nulliparous and 16 multiparous women). Compared to women with normal BMIs, women with class II-III

obesity had significant fewer physiological pregnancies (adjusted OR 0.38; 95% CI 0.21 - 0.69). With regard to childbirth, overweight women (adjusted OR 0.63; 95% CI 0.44 - 0.90) as well as women with class I obesity (adjusted OR 0.49; 95% CI 0.29 - 0.84) had a reduced chance of a physiological childbirth. The group with class II-III obesity did not differ significantly from the normal weight women. This is likely the result of the small size of the research group (n = 19; adjusted OR 0.48; 95% CI 0.21-1.12). It is notable that parity was an important factor in positively affecting the physiological course of pregnancy (adjusted OR 2.35; 95% CI 1.76 - 3.15) and - to a greater degree - the physiological course of childbirth (adjusted OR 6.18; 95% CI 4.39 - 8.70).

Degree of and grounds for (urgent) referral
Compared to women with normal BMIs, obese women had higher referral percentages for hypertensive disorders (14% versus 4%), prolonged labour (10.4% versus 4.6%) and requests for pain relief (10.4% versus 4%) (p <0.05). Overweight (n = 14; 4.8%) and obese women (BMI ≥30; n = 7; 5.6%) who started childbirth in primary care, did not have a higher number of urgent referrals than women with normal BMIs (n = 34; 6.0%) (p >0.05).

Outcomes of primary care childbirth
Women with higher BMIs who gave birth in primary care did not have increased adverse outcomes (e.g. shoulder dystocia or Apgar score <7) compared to women with normal BMIs, apart from significantly higher percentages of children who were 'large for gestational age' (LGA >97.7 centile): 12.1% in obese women versus 1.9% in women with normal BMIs and 3.3% in overweight women (p <0.05).

Conclusion

Despite the fact that fewer obese women experienced physiological pregnancy and childbirth, they did not have an increased risk of urgent referrals and adverse birth outcomes compared to women with normal weight. This shows that primary care midwives are able to effectively select pregnant women for primary or secondary care on the basis of the agreed guidelines. In order to prevent LGA, stricter screening for gestational diabetes in obese women is required. Multiparity was a strong indication of a physiological course of childbirth in this group of women.

The impact of obesity on childbirth outcomes in low-risk women

The second study is a secondary analysis from the well-known English Birthplace study.[18] It is a prospective cohort study into the effect of maternal BMI on intrapartum interventions and on adverse maternal and perinatal outcomes in low-risk pregnant

women. The study also explored whether parity influenced the effect of BMI on the outcomes. Since our article is on the effect of overweight, the results of the effect of underweight are not described.

Method

The study was carried out between April 2008 and April 2010 (see also the December 2011 issue of the Journal for Midwives). The application of inclusion and exclusion criteria resulted in a group of 17,230 women who were low-risk at the start of their birth in accordance with the criteria in the 'Intrapartum care' NICE guideline. Class II-III obese women were an exception to this. Class II-III obesity is included as a risk factor in the NICE guideline, however, for the purpose of this research, these women were included in the study.[18] The research population consisted of women giving birth in a hospital, due the fact that - in accordance with the NICE guideline - class II-III obese women do not qualify for birth at home or in a midwifery unit. On the basis of the information in the article, the low-risk group studied seems more or less comparable to the group of women that qualify for primary care in the Netherlands.

As outcome measures (events) the authors considered for the woman some interventions and adverse outcomes requiring obstetric care, both separately and as a combined composite outcome measure including augmentation, instrumental delivery, intrapartum caesarean section, general anaesthesia, blood transfusion, 3rd/4th degree perineal tear and maternal admission for higher level of care. A similar combination of outcome measures was used for the child and consisted of referral to neonatal care within 48 hours after birth or death during, or shortly after, birth.

Findings

When compared to women with normal BMIs, the composite outcome measure relating to *maternal* interventions showed a moderate increase in nulliparous as well as in multiparous women with class I obesity (adjusted RR 1.12; CI 1.05 - 1.18 and adjusted RR 1.22; CI 1.05 - 1.42, respectively). Neither group showed significant results in women with class II-III obesity (adjusted RR 1.08; CI 0.99 - 1.18 and adjusted RR 1.24; CI 0.97 - 1.59, respectively). In the total group of class II-III obese women, a significant increased risk of the composite outcome measure was found (adjusted RR 1.12; CI 1.02 - 1.23). In absolute numbers, however, class I obese multiparous women (n = 212; 14.3%) and class II-III obese multiparous women (n = 117; 7.8%) had fewer events (included in the composite outcome measure) than nulliparous women with normal BMIs (n = 2524; 53.6%). The outcomes from the composite *neonatal* outcome measure revealed the same pattern: the risk doubled in both nulliparous and multiparous women with class II-III obesity (adjusted RR 2.00; CI 1.31 - 3.05 and adjusted RR 1.83; CI 1.22 - 2.75, respectively). In absolute terms, however, adverse perinatal events occurred less in

class I obese (n = 19; 12.4%) and class II-III obese multiparae (n = 15; 9.8%) than in nulliparae with normal BMIs (n = 180; 54.2%).

Conclusion

Low-risk obese pregnant women had an increased risk of interventions during birth. However, in absolute terms, these interventions occurred less in class II-III obese multiparous than in nulliparous women with normal weight. The risk of interventions in class II-III obese multiparous women appears lower than previously assumed.

Discussion

A higher BMI in a low-risk population negatively affects the physiological course of pregnancy [15] and childbirth.[15, 18] Multiparity has a positive effect on pregnancy [15], but more so on childbirth.[15 18] Together these effects may lower the risk of adverse outcomes in (severe) obese multiparous women more than previously assumed.

The Kempen study included Caucasian women only which limits generalisability (first study). The study's timing may seem dated in the context of the global increase of obesity. However, the opposite is true. In accordance with the national figures published by Statistics Netherlands (CBS), the prevalence of obesity in women aged ≥20 in the Netherlands between 2002 and 2013 was more or less stable (10.8% and 11.1%, respectively)[19, 20]. During the period over which the study was carried out, obesity was not the subject of specific policy in Dutch maternity care, so this study covers the outcomes of the effect of BMI itself, without taking into account the effect of guidelines on referral percentages. Both studies lack statistical power to adequately research less frequently occurring complications, a problem that was solved by using relevant composite outcome measures.

Comparing the two studies is difficult, as the obstetric systems differ and, consequently, so do the design of the studies, outcome measures, and the statistical analyses. Nevertheless, a couple of similarities can be established. In both research populations low-risk women were studied who, based on information from the articles, were more or less comparable. About 48% of English women with class II-III obesity developed at least one risk factor at the end of their pregnancy, resulting in their exclusion from the study. In the Netherlands, these women would not have been eligible for primary care childbirth either. In the Dutch study, 45.7% of women in this BMI category were referred during pregnancy, a comparable result. The studies did use different outcome measures: the English study used measures that included a number of maternal interventions and adverse neonatal conditions. The Dutch study defined physiological childbirth as an uncomplicated birth during which women are not referred. In the Netherlands, women are referred when the risk of an adverse outcome

or an intervention increases. Thus referral percentages will always be higher than the intervention percentages in the English study. Furthermore, the Dutch outcome measure includes referrals on the basis of maternal and perinatal indications, while the Birthplace study applies two distinct outcome measures. In short, it is difficult to compare the numbers, but the trend is clear: rising BMIs have an adverse effect on birth outcomes, even in low-risk populations.

Each of the studies charts the effect of parity in a different way. In the English study, separate relative risks were calculated for the effect of BMI on outcome measures for nulliparous and multiparous women. In the Dutch study, logistic regression is used on the entire study group and included parity as a covariate. To get better insight in what this means for class II-III obese multiparous versus nulliparous women with normal BMIs (equal characteristics apart from this), we calculated an OR of 2.19 based on the logistic model. This means that in the study of Dutch women, class II-III obese multiparous women had a greater possibility of a physiological childbirth than nulliparous women with normal BMIs. In absolute numbers, 84% (n = 16; 3 women were referred during childbirth) of class II-III obese multiparous women who started their births in primary care also completed these in primary care, compared to 42.6% (n = 110; 148 women were referred during childbirth) of nulliparous women with normal weight.

During pregnancy, the interplay of the factors 'parity' and 'class II-III obesity' worked out differently. Based on the logistic model, we calculated an OR of a physiological pregnancy of 0.90, which indicates that class II-III obese multiparous women had a smaller possibility of a physiological pregnancy as nulliparous women with normal weight. In absolute numbers, 56% (n = 19; 15 women were referred during pregnancy) of class II-III obese multiparous women had a physiological pregnancy, compared to 67% (n = 258; 126 women were referred) of nulliparous women with normal weight.

Conclusion

Class II-III obese multiparous women were referred more often during pregnancy than nulliparous women with normal weight. However, after a normal pregnancy, these women had a significantly greater possibility of a physiological childbirth than nulliparous women with normal weight. Based on these two studies, we may conclude that it is justifiable to take into consideration parity in obese women during risk assessment. A referral indication for childbirth in multiparous women solely based on class II-III obesity appears to be unnecessary and therefore constitutes inappropriate care for this group. A review of this policy in clinical pathways and in the information supplied to these women is recommended.

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Chapter 5

The effect of gestational weight gain on likelihood of referral to obstetric care for women eligible for primary, midwife-led care after antenatal booking

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Abstract

Objective: To examine the effect of GWG on likelihood of referral from midwife-led to obstetrician-led care during pregnancy and childbirth for women in primary care at the outset of their pregnancy.

Design: Secondary analysis of data from a prospective cohort study

Setting: Dutch midwife-led practices

Participants: A cohort of 1288 women of Northern European descent, with uncomplicated, singleton pregnancy at antenatal booking who consequently were eligible for primary, midwife-led care.

Measurements: Because of the absence of an established GWG guideline in the Netherlands, we compared the effect of inadequate and excessive GWG according to two GWG guidelines: the criterion traditionally used, which is based on knowledge of the physiological components of GWG, advising 10 - 15 kg as a normal GWG irrespective of a woman's BMI category, and the 2009 Institute of Medicine recommendations (IOMr) on GWG, which provide BMI related advice. Outcome measures were: number of women referred from midwife-led to obstetrician-led care during pregnancy and during childbirth; indications of referral and birth outcomes.

Findings: GWG above traditional criteria (Tc; >15 kg between 12 and 36 weeks) was associated with increased odds for referral during childbirth (aOR 1.88; 95% CI 1.22 - 2.90), but had no effect on referral during pregnancy (aOR 0.86; 95% CI 0.57 - 1.30). No associations were established between GWG below Tc (<10 kg) and referral during pregnancy (aOR 1.08; 95% CI 0.78 - 1.50) or childbirth (aOR 1.08; 95% CI 0.74 - 1.56). No associations were found between GWG below and above the IOMr and referral during pregnancy (below IOMr: aOR 1.01; 95% CI 0.71 - 1.45; above IOMr: aOR 0.89; 95% CI 0.61 - 1.28) or childbirth (below IOMr: aOR 0.85; 95% CI 0.57 - 1.25; above IOMr: aOR 1.09; 95% CI 0.73 - 1.63). With regard to the effect of GWG according to both recommendations on indications for referral and birth outcomes, GWG above Tc was associated with higher rates of referral for hypertensive disorders (aOR 1.91; 95% CI 1.04 - 3.50) and for meconium stained amniotic fluid (aOR 2.22; CI 1.33 - 3.71) after adjusting for BMI and parity

Conclusions: GWG above Tc - irrespective of BMI category - was associated with doubled odds of referral to specialist care during childbirth. GWG below or above IOMR and GWG below TC were not associated with adverse obstetric outcomes in women who were eligible for primary care at the outset of their pregnancy.

Implications for practice: Weight gain <15 kg between 12 and 36 weeks is advised for women in all BMI categories in this population. It is important to validate GWG guidelines in a target population before implementing them.

Introduction

Several studies indicate an association between inadequate and excessive GWG and a variety of adverse perinatal outcomes. [1] In 2009 the IOM published guidelines on GWG, taking into account the BMI classification of the WHO. [2] These guidelines were developed to prevent inadequate GWG which is associated with preterm birth and SGA and excessive GWG, associated with macrosomia, LGA, caesarean delivery and postpartum weight retention. [1] Studies assessing the applicability of the 2009 IOM cut-off points in specific populations found evidence that the guidelines were useful for predicting adverse outcomes, especially SGA, LGA, and caesarean delivery. [3-13] However, several authors reported *no* association between GWG below the IOM (0 - 4.9 kg) and SGA for obese women. [7, 11, 13, 14] The findings for gestational weight loss (GWL) vary, but increasing obesity severity appears to attenuate the association between GWL and adverse outcomes. [7, 10, 11, 14, 15]

Moreover, other studies report alternative optimal GWG ranges depending on the population and the different (combinations of) outcomes studied [16-19]. Cedergren [16] recommends lower optimal GWG ranges than those in the IOM guidelines for Swedish women of all BMI classes, based on her examination of a variety of maternal and fetal outcomes. The study of Oken et al.[18] looked at five adverse outcomes and concluded that the IOM guidelines worked well for Massachusetts mothers of normal weight, but should be lowered for overweight and obese mothers. For obese women in their study, the lowest-risk weight change appeared to be weight loss. [18] A German study that focused on birthweight advised wider optimal GWG ranges for all BMI categories, including GWL for overweight and obese women. [17] Using birth weight and preterm birth as outcomes, Bodnar et al. [19] calculated optimal GWG ranges higher than those of the IOM for obese class I women and lower optimal ranges for obese class III women. Potti et al. [20] compared two established GWG recommendations and found that changing optimal GWG ranges showed improvements in some outcomes but poorer result in others. These results indicate that the debate about the definition of inadequate and excessive GWG in relation to different populations and to different (combination of) outcomes is ongoing and no widely agreed upon consensus is available for clinicians to advise pregnant women at this moment. [21]

In the Netherlands, midwives are authorised to supervise physiological pregnancy, childbirth and puerperium in primary care. In 2004, 80 % of the pregnant women started their maternity care in out-of-hospital, midwife-led care practices in the community. [22] If risk factors arise (such as suspected intra uterine growth retardation (IUGR) or meconium stained amniotic fluid) or complications occur (such as fetal distress or blood loss because of a retained placenta) during pregnancy or childbirth, local midwife-led care is broken off and the woman is referred to obstetrician-led care in a regional hospital. This ongoing risk assessment, based on the OIL - the national, interprofessional guideline defining indications for referral - plays a crucial role in the

maternity care system. [23] Women can choose for a midwife-led home or hospital birth only if pregnancy remains healthy up to the beginning of labour. At present, there are no national guidelines for GWG. Customarily, Dutch midwives recommend a weight gain between 10 and 15 kg, irrespective of BMI classification. These Tc are based on knowledge of the physiological components of GWG. [24] The 2009 IOMr are known in the Netherlands, but are not commonly used. We do know that 60% of the women in a Dutch, midwife-led care population did not meet the IOMr: 33.4% had GWG below IOMr and 26.7% GWG above IOMr. [25] Neither the IOMr nor the Tc has been validated in a Dutch population in primary, midwife-led care. In an earlier study we reported that obesity impacts pregnancy and childbirth in this primary care population. [26] In this study we examine the effect of GWG on rates of referral and perinatal outcomes irrespective of, *and* in relation to, women's BMI classification.

Materials and Methods

Study population

Our study uses data from the Kempen V study, a prospective cohort study of aspects of maternal well-being and obstetric outcomes in relation to gestational thyroid function. [27] Between July 2002 and November 2004, pregnant women of Northern European descent, of five midwife-led practices in the Netherlands were invited to participate. We included women eligible for midwife-led care after their initial antenatal visit at 10 - 12 weeks gestation. We excluded women if weight or height at 12 weeks was not registered and women who had a miscarriage after their antenatal booking. Women referred to obstetrician-led care immediately after intake were excluded because they were considered high-risk according to the OIL. This latter includes medical conditions for immediate referral such as maternal diabetes, essential hypertension, kidney disease and autoimmune disease and obstetric reasons such as a twin pregnancy, previous stillbirth and preterm birth <24 weeks in history. Similarly, we excluded women referred around 36 weeks for a presumed increased delivery risk based on women's obstetric history (e.g. caesarean delivery in history). [23] These indications for referral were agreed upon at the beginning of the pregnancy and were not influenced by women's current maternal BMI and GWG, during this pregnancy. We also excluded underweight women because there were too few to draw valid conclusions from statistical analysis. The Kempen V study was approved by the Medical Ethical Committee of Maxima Medical Centre in Veldhoven, The Netherlands (no. 116).

Data collection

Weight at 10 - 12 and 36 weeks of pregnancy was measured by the midwife using calibrated scales. A fixed measurement at 36 weeks aimed to enable us to study total weight gain not biased by duration of pregnancy. Height was self-reported**.** First trimester BMI was calculated as weight (kg) at 10 - 12 weeks divided by squared height (m^2) and classified according to the WHO classification. [28] GWG was calculated by subtracting weight at 10 - 12 weeks of pregnancy from the weight at 36 weeks. Data on maternal characteristics (Table 1) came from questionnaires filled out by the women after the first antenatal booking. All other data were extracted from the midwife's obstetrical records and/or hospital records.

Outcomes

The primary outcomes of this study were rate of referral during pregnancy and rate of referral during childbirth. In Dutch midwife-led care, rate of referral is a proxy measure for adverse outcomes: when a medical complication occurs or the risk of a complication increases - as defined by the OIL - women are referred to obstetrician-led care. [23] For pregnant women the impact of a referral is substantial as their status changes from 'healthy' to 'requiring medical care'. A referral means a switch from midwife-led care in the community focusing on healthy pregnancy and childbirth - with a free choice for birth at home or in a hospital - to obstetrician-led care in regional hospitals with a focus on the pathological aspects of their pregnancies. 'Referral during pregnancy' is defined as referral for a variety of medical reasons taking place before the onset of term labour (for examples: see Table 4). The onset of labour is defined as contractions and/or rupture of the membranes between 37 and 41^{+6} weeks. 'Referral during childbirth' is referral for medical care of women who were eligible for a birth supervised by a midwife either at home or in the hospital at the onset of labour until two hours after the birth of the placenta (for examples: see Table 4). We chose 'referral' as our primary outcome because it is a generic outcome that captures the complex of conditions associated with higher risk on adverse perinatal outcomes. Optimal GWG ranges should consider both adverse and favourable effects of GWG on maternal and neonatal outcomes. [29] By using referral we were able to balance these effects in a way that they were only considered relevant if they led to an increased risk according to the OIL and thus required referral. Secondary outcomes were indications for referral during pregnancy and childbirth, according to the OIL, and birth outcomes. We distinguish indications for referral and birth outcomes because an indication for referral (e.g. suspected IUGR) does not always reflect the actual outcome (e.g. SGA). Registration of the indications of referral was based on the procedures of the Perinatal Registration in The Netherlands (PRN), which recorded the main indication for referral. Birth outcomes included stillbirth, induction of labour, administered pain relief, instrumental delivery

(ventouse or forceps), caesarean delivery, shoulder dystocia, SGA <2.3 centile (SGA <2.3), LGA >97.7 centile (LGA <97.7), congenital malformations and neonatal problems revealed between birth and 24 hours postpartum (neonatal problems <24 hours).

Statistical analysis

Differences in maternal characteristics by GWG category were assessed by a χ^2 test and analysis of variance. We performed separate multiple logistic regression analyses to estimate the risks of referral in pregnancy and childbirth. Because our outcome variables may be negatively affected by both *inadequate* and *excessive* GWG (i.e. a U-shaped relationship), there is not a linear relationship between these outcomes and GWG. Therefore we could not include GWG as a continuous variable in our logistic regression models. Instead we categorised this variable. Since neither the IOMr nor the Tc have been validated in our target population we decided to run the regression analyses including GWG below, within, and above Tc and IOMr respectively. Inadequate GWG according to the Tc was classified as: GWG < Tc (GWG <10 kg), excessive GWG as GWG >Tc (GWG >15 kg) irrespective of maternal BMI category. Inadequate GWG according to the IOMr was defined as: GWG < IOMr (normal weight: <11.5 kg; overweight: <7 kg; obese: <5 kg), excessive GWG as GWG > IOMr (normal weight: >16 kg; overweight: >11.5 kg; obese: >9 kg). [2] Other covariates included in the models were, parity, age, alcohol, smoking, maternal education, having a partner, BMI class and interaction terms between BMI class and GWG class. Models were specified using a manual backward selection strategy. The likelihood ratio criterion for exclusion was used to determine the correct model. We used χ^2 tests to look at the differences in indications for referral and birth outcomes across the GWG categories. Separate multiple logistic regression analyses were run for those indications for referral and birth outcomes that showed a significant association with GWG categories based upon the χ^2 tests. We chose a manual forward selection method because of the small numbers of the dependent variables. This method allowed us to enter the covariates one by one in order to reach the best fitting model. We started with GWG (below, within, above Tc and IOMr respectively) as predictor and included - one by one - parity, BMI (continuous variable) and interaction terms between GWG categories and BMI. Realising that missing data on GWG could be traced back to referrals before 36 weeks, we performed sensitivity analyses to examine whether the effect of GWG on referral changed if we included women who were referred before 36 weeks for preterm labour and hypertensive disorders, cases that represented about half of the missing data on GWG. Studies are consistent on the association between preterm labour and inadequate GWG [1, 30] but inconsistent on the association with excessive GWG. Furthermore, and relevant for our study, no association between *spontaneous* preterm birth and excessive GWG has been found. [31] Hypertensive disorders are associated with excessive GWG. [4, 32, 33]

We labelled women's GWG presuming the pessimistic scenario: in the sensitivity analyses all women referred for preterm labour were labelled as having inadequate GWG and all women referred for hypertensive disorders as having excessive GWG according to Tc and IOMr. Effect estimates were expressed as adjusted odds ratios (aOR) with 95% confidence interval (CI). Statistical significance was set at p <0.05. SPSS version 15.01 was used for the analyses.[34]

Findings

Of the 1985 pregnant women eligible for inclusion, 1601 (80.8%) agreed to participate. We excluded 220 women and there were missing data for another 93, resulting in a study population of 1288 women (Figure 1). Of these women, 55.5% (n = 715) were of normal weight, 30% (n = 386) were overweight, 9.8% (n = 126) obese class I and 4.7% (n = 61) obese class II-III.

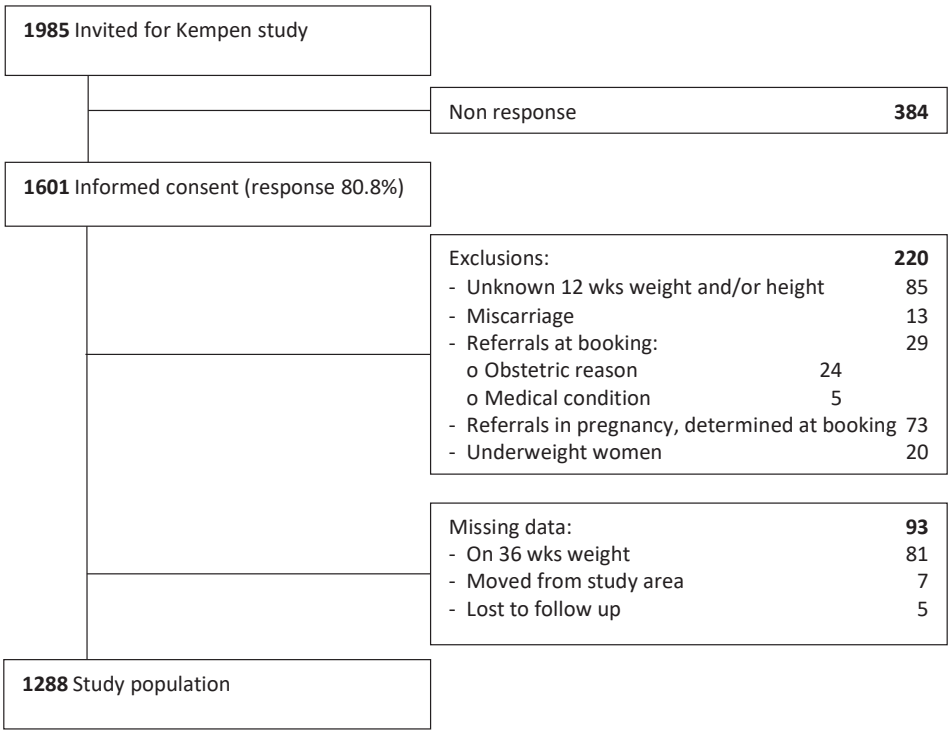

Figure 1. Flow chart study population

Gestational weight gain

Mean GWG between 12 and 36 weeks of pregnancy was 11.3 kg (SD 4.2). Women gained less weight as BMI class increased: mean GWG was 12.1 kg (SD 3.7) in normal weight women, 11.1 kg (SD 4.3) in overweight women, 10.1 kg (SD 4.7) in obese class I and 6.5 kg (SD 4.6) in obese class II-III women. Table 1 illustrates that age, use of alcohol (only for IOMr), parity and first trimester BMI showed a significantly different distribution across the different GWG categories. For the whole group, applying Tc versus IOMr resulted in more women with inadequate and adequate GWG but fewer women with excessive GWG. We registered maternal baseline-characteristics of 55 women with missing data on GWG and when we compared these women with the study population we found a higher percentage of nulliparous women in the missing data group.

Referral in pregnancy and childbirth

Of all women, 307 (23.8%) were referred to obstetrician-led care during pregnancy and 370 (28.7%) during childbirth. This resulted in 611 (47.4%) women with an uncomplicated pregnancy and childbirth in primary care (Table 2).

We found no significant differences in the rates of referral during pregnancy between the different GWG categories of both recommendations (Tc: $\chi^2(2) = 1.18$, $p = 0.55$ and IOMr: $\chi^2(2) = 1.39$, $p = 0.50$). By contrast, GWG categories of both recommendations seemed to associate with the referral rate during birth: with a higher GWG category women experienced more referrals in childbirth (Tc $\chi^2(2) = 17.97$, $p = 0.000$ and IOMr: $\chi^2(2) = 14.62$, $p = 0.001$). After performing multiple logistic regression analyses, the association between GWG categories of IOMr and referral rate during childbirth could no longer be established. However, gaining weight above the Tc was associated with almost doubled odds on being referred during childbirth (aOR 1.88, 95%CI 1.22 - 2.90); we found no effect of GWG below the Tc on the rate of referral during childbirth. Furthermore, we found no interaction between GWG categories and BMI categories indicating that the above-described association did not differ across the different BMI categories (Table 3).

Of the 81 women with missing data on GWG, we lacked weight at 36 weeks for 78 women who were referred beforehand. Of these women, 18 were referred because of hypertensive disorders, 25 because of preterm labour and 35 for a variety of reasons. We performed three series of sensitivity analyses (including only women referred for preterm labour, only women referred for hypertensive disorders, and women referred for preterm labour and hypertensive disorders) and all of them supported our findings: only GWG above Tc was associated with higher odds of referral during childbirth (aOR 1.88 CI 1.22 - 2.90; GWG below Tc: aOR 1.09 CI 0.75 - 1.58; GWG above IOMr: aOR 1.09 CI 0.73 - 1.63; GWG below IOMr: aOR 0.86 CI 0.58 - 1.26; results of the model including women with preterm labour and hypertensive disorders).

Table 1. Distribution of maternal characteristics by GWG below, within and above Tc and IOMr

Characteristics	Tc				IOMr			
	GWG<Tc (n = 470) Mean(SD)/n(%)	GWG within Tc (n = 597) Mean(SD)/n(%)	GWG>Tc (n = 221) Mean(SD)/n(%)	*p*-Value	GWG<IOMr (n = 430) Mean(SD)/n(%)	GWG within IOMr (n = 507) Mean(SD)/n(%)	GWG>IOMr (n = 351) Mean SD)/n(%)	*p*-Value
Demographic								
Age	30.78 (3.7)	30.12 (3.5)	29.01 (4.0)	0.000*	30.86 (3.8)	30.01 (3.4)	29.58 (3.8)	0.000*
No partner	5 (1.3)	5 (1.0)	5 (2.7)	0.24	8 (2.4)	3 (0.7)	4 (1.3)	‡
Education:								
Low	67 (18.0)	73 (14.5)	38 (20.7)	0.05	56 (16.5)	68 (16.4)	54 (17.7)	0.31
Mid	180 (48.2)	226 (45.0)	91 (49.5)		158 (46.6)	184 (44.3)	155 (50.8)	
High	126 (33.8)	203 (40.5)	55 (29.8)		125 (36.9)	163 (39.3)	96 (31.5)	
Lifestyle habits:								
Smoking[$]	45 (12.0)	55 (10.9)	29 (15.7)	0.24	40 (11.8)	47 (11.2)	42 (13.8)	0.57
Alcohol[$]	56 (14.9)	66 (13.1)	20 (10.8)	0.39	61 (17.9)	46 (11.0)	35 (11.5)	0.01†
Obstetric								
Parity:								
Nulliparae	184 (39.1)	293 (49.1)	145 (65.6)	0.000*	165 (38.4)	243 (47.9)	214 (61.0)	0.000*
Multiparae	286 (60.9)	304 (50.9)	76 (34.4)		265 (61.6)	264 (52.1)	137 (39.0)	
First trimester BMI:								
Normal	206 (43.8)	374 (62.7)	135 (61.0)	0.000*	326 (75.8)	294 (58.0)	95 (27.1)	0.000*
Overweight	151 (32.1)	171 (28.6)	64 (29.0)		61 (14.2)	157 (31.0)	168 (47.8)	
Obese class I	67 (14.3)	40 (6.7)	19 (8.6)		18 (4.2)	36 (7.1)	72 (20.5)	
Obese class II-III	46 (9.8)	12 (2.0)	3 (1.4)		25 (5.8)	20 (3.9)	16 (4.6)	

IOMr: IOM recommendations 2009; TC: traditional criteria.

*p <0.001

† p <0.05

‡ Conditions χ^2 not fulfilled

$ Use of any amount in current pregnancy

Table 2. Referral in pregnancy and childbirth by Tc and IOMr

	Tc			IOMr			
Referral in	GWG<Tc (n = 470) n (%)	GWG within Tc (n = 597) n (%)	GWG>Tc (n = 221) n (%)	GWG<IOMr (n = 430) n (%)	GWG within IOMr (n = 507) n (%)	GWG>IOMr (n = 351) n (%)	Total (n = 1288) n (%)
Pregnancy	120 (25.5)	136 (22.8)	51 (23.1)	96 (22.3)	120 (23.7)	91 (25.9)	307 (23.8)
	GWG<Tc (n = 350) n (%)	GWG within Tc (n = 461) n (%)	GWG>Tc (n = 170) n (%)	GWG<IOMr (n = 334) n (%)	GWG within IOMr (n = 387) n (%)	GWG>IOMr (n = 260) n (%)	Total (n = 981) n (%)
Childbirth	116 (33.1)	166 (36.0)	88 (51.8)	103 (30.8)	147 (38.0)	120 (46.2)	370 (37.7)

IOMr: IOM recommendations 2009; Tc: traditional criteria

Table 3. Predictor variables of referral in pregnancy and childbirth using Tc and IOMr

	Referral in pregnancy		Referral in childbirth	
Predictor variables	Tc aOR (95%CI)	IOMr aOR (95%CI)	Tc aOR (95%CI)	IOMr aOR (95%CI)
GWG				
Under	1.08 (0.78 - 1.50)	1.01 (0.71 - 1.45)	1.08 (0.74 - 1.56)	0.85 (0.57 - 1.25)
Within	1*	1*	1*	1*
Above	0.86 (0.57 - 1.30)	0.89 (0.61 - 1.28)	**1.88 (1.22 - 2.90)**	1.09 (0.73 - 1.63)
Multiparae (vs nulliparae)	**0.44 (0.32 - 0.60)**	**0.44 (0.32 - 0.60)**	**0.17 (0.12 - 0.24)**	**0.17 (0.12 - 0.23)**
Age	1.02 (0.98 - 1.06)	1.02 (0.98 - 1.07)	1.01 (0.96 - 1.06)	1.01 (0.96 - 1.05)
Education:				
Low	1*	1*	-	-
Mid	0.72 (0.49 - 1.07)	0.73 (0.49 - 1.08)	-	-
High	**0.60 (0.39 - 0.92)**	**0.61 (0.40 - 0.93)**	-	-
BMI				
Normal	1*	1*	1*	1*
Overweight	1.19 (0.85 - 1.65)	1.25 (0.88 - 1.79)	**1.54 (1.07 - 2.22)**	1.43 (0.97 - 2.01)
Obese class I	1.54 (0.97 - 2.45)	**1.67 (1.02 - 2.73)**	**2.11 (1.22 - 3.66)**	**1.89 (1.06 - 3.35)**
Obese class II-III	**2.62 (1.41 - 4.87)**	**2.82 (1.53 - 5.18)**	**2.48 (1.06 - 5.79)**	2.29 (0.99 - 5.30)
Nagelkerke R^2 †			23.0/1.2/1.8%	

aOR: adjusted odds ratio; IOMr: IOM recommendations 2009; Tc: traditional criteria.

Education: low - primary education or secondary education, not completed; middle - secondary education completed; high - degree at university level.

Covariates included in the initial models were GWG (below, within, above Tc and below, within and above IOMr, respectively), parity, age, alcohol, smoking, maternal education (low, mid, high),having a partner, BMI classes, interaction between BMI classes and GWG classes (6).

*Ref in log regression.

† Explained variance of the total model/GWG categories/BMI categories.

Indications for referral and birth outcomes

Table 4 illustrates the distribution of the indications for referral during pregnancy and childbirth over the GWG categories according to Tc and to IOMr. With Tc, there was an association between the GWG categories and three indications for referral: hypertensive disorders ($\chi^2$2) = 7.91, p = 0.02) during pregnancy, and during birth for meconium stained amniotic fluid (χ^2(2) = 12.05, p = 0.002) and prolonged 2nd stage (χ2(2) = 7.43, p = 0.02). Regarding IOMr, the GWG categories showed an association with hypertensive disorders (χ^2(2) = 18.5, p = 0.000) during pregnancy and prolonged 1st stage (χ^2(2) = 7.94, p = 0.02) in childbirth. After running multiple logistic regressions to assess the independent effects of the GWG recommendations on the indications for referral, again only GWG above Tc proved to be associated with increased referrals for hypertensive disorders (aOR1.91; 95% CI 1.04 - 3.50) and meconium stained fluid (aOR 2.22; 95% CI 1.33 - 3.71). Gaining weight below the IOMr appeared to decrease the risk for referral for hypertensive disorders (aOR 0.38, 95% CI 0.18 - 0.81). No interaction was found between GWG categories and BMI which means that these associations were the same irrespective of women's BMI (Table 6). Regarding birth outcomes we found a significant association between GWG categories of the Tc and LGA >97.7 and between GWG categories of the IOMr and administered pain relief, caesarean delivery, LGA >97.7 and neonatal problems <24 hours (Table 5). However, after performing multiple logistic regressions adjusting for parity and BMI, these associations disappeared (Table 6).

Table 4. Indications for referral in women gaining weight below, within and above Tc and IOMr

Indications for referral	Tc GWG<Tc (n = 470) n (%)	Tc GWG within Tc (n = 597) n (%)	Tc GWG>Tc (n = 221) n (%)	*p*-Value	IOMr GWG<IOMr (n = 430) n (%)	IOMr GWG within IOMr (n = 507) n (%)	IOMr GWG>IOMr (n = 351) n (%)	*p*-Value	Total (n = 1288) n (%)
Referral in pregnancy	120 (25.5)	136 (22.8)	51 (23.1)	0.55	96 (22.3)	120 (23.7)	91 (25.9)	0.50	307 (23.8)
Hypertensive disorders	24 (5.1)	27 (4.5)	21 (9.5)	0.02*	9 (2.1)	31 (6.1)	32 (9.1)	0.000†	72 (5.6)
Postdate delivery	25 (5.3)	34 (5.7)	6 (2.7)	0.21	20 (4.7)	29 (5.7)	16 (4.6)	0.67	65 (5.0)
Abnormal fetal positions	20 (4.3)	29 (4.9)	5 (2.3)	0.26	23 (5.3)	19 (3.7)	12 (3.4)	0.33	54 (4.2)
Preterm labour	7 (1.5)	11 (1.8)	2 (0.9)	0.62	7 (1.6)	7 (1.4)	6 (1.7)	0.92	20 (1.6)
Blood loss after 20 weeks gestation	7 (1.5)	9 (1.5)	2 (0.9)	0.79	5 (1.2)	8 (1.6)	5 (1.4)	0.86	18 (1.4)
Decreased fetal movements	7 (1.5)	4 (0.7)	3 (1.4)	0.40	4 (0.9)	5 (1.0)	5 (1.4)	‡	14 (1.1)
Suspected LGA	3 (0.6)	1 (0.2)	3 (1.4)	‡	1 (0.2)	4 (0.8)	2 (0.6)	‡	7 (0.5)
Suspected fetal malformation	3 (0.6)	1 (0.2)	3 (1.4)	‡	3 (0.7)	2 (0.4)	2 (0.6)	‡	7 (0.5)
Gestational diabetes with insulin	3 (0.6)	4 (0.7)	0 (0.0)	‡	3 (0.7)	3 (0.6)	1 (0.3)	‡	7 (0.5)
Suspected IUGR	2 (0.4)	3 (0.5)	1 (0.5)	‡	3 (0.7)	1 (0.2)	2 (0.6)	‡	6 (0.4)
Other indications	19 (4.0)	13 (2.2)	5 (2.3)	0.16	18 (4.2)	11 (2.2)	8 (2.3)	0.14	37 (2.9)
Referral in childbirth	116 (33.1)	166 (36.0)	88 (51.8)	0.000†	103 (30.8)	147 (38.0)	120 (46.2)	0.001*	370 (37.7)
Meconium stained fluid	36 (7.7)	37 (6.2)	30 (13.6)	0.002*	27 (6.3)	47 (9.3)	29 (8.3)	0.24	103 (8.0)
Prolonged 1st stage	13 (2.8)	32 (5.4)	11 (5.0)	0.11	12 (2.8)	20 (3.9)	24 (6.8)	0.02*	56 (4.3)
PROM	15 (3.2)	27 (4.5)	11 (5.0)	0.43	13 (3.0)	23 (4.5)	17 (4.8)	0.37	53 (4.1)
Request pain relief	21 (4.5)	19 (3.2)	10 (4.5)	0.48	18 (4.2)	15 (3.0)	17 (4.8)	0.34	50 (3.9)
Prolonged 2nd stage	13 (2.8)	16 (2.7)	14 (6.3)	0.02*	13 (3.0)	17 (3.4)	13 (3.7)	0.87	43 (3.3)
Suspected fetal distress	4 (0.9)	8 (1.3)	3 (1.4)	0.73	6 (1.4)	5 (1.0)	4 (1.1)	0.84	15 (1.2)
Abnormal fetal positions delivery	3 (0.6)	4 (0.7)	5 (2.3)	‡	1 (0.2)	2 (0.4)	9 (2.6)	‡	12 (0.9)
Prolonged 3rd stage	3 (0.6)	7 (1.2)	2 (0.9)	‡	1 (0.2)	8 (1.6)	3 (0.9)	‡	12 (0.9)
Other indications	8 (1.7)	16 (2.7)	2 (0.9)	0.23	12 (2.8)	10 (2.0)	4 (1.1)	0.26	26 (2.0)

IOMr: IOM recommendations 2009; Tc: traditional criteria

Hypertensive disorders: hypertension (diastolic pressure ≥95 mmHG) and/or pre-eclampsia (hypertension + proteinuria)

Postdate delivery: delivery >42 weeks gestation; Preterm labour: labour <37 weeks gestation;

Gestational diabetes with insulin: a selective screening protocol was used for GDM: If indications were present, an O'Sullivan test was performed at 24-28 weeks of gestation, followed by an OGTT in the case of a value ≥7.8 mmol/l. Women with GDM and diet received shared care, women who needed insulin were referred to obstetrician-led care.

Other indications in pregnancy/childbirth: all indications with a frequency of n ≤3 or indications registered as 'other problems during pregnancy/ childbirth'.
Prolonged 1st stage: no progress in dilatation during four hours; prolonged 2nd stage: no progress in descent during pushing for one hour; prolonged 3rd stage: placenta not born within one hour after infant birth.
PROM: prelabour rupture of the membranes
*p <0.05
†p <0.001
‡ Conditions $\chi 2$ not fulfilled.

Table 5. Adverse birth outcomes in women gaining weight below, within and above TC and IOMR

	Tc				IOMr				
	GWG<Tc (n = 470)	GWG within Tc (n = 597)	GWG>Tc (n = 221)		GWG<IOMr (n = 430)	GWG within IOMr (n = 507)	GWG>IOMr (n = 351)		Total (n = 1288)
Birth outcomes	n (%)	n (%)	n (%)	*p*-Value	n (%)	n (%)	n (%)	*p*-Value	n (%)
Stillbirth	0	0	0		0	0	0		0
Induction of labour	66 (14)	70 (11.7)	26 (11.8)	0.49	41 (9.5)	71 (14.0)	50 (14.2)	0.07	162 (12.6)
Pain relief	58 (12.3)	77 (12.9)	41 (18.6)	0.07	40 (9.3)	64 (12.6)	72 (20.5)	0.000†	176 (13.7)
Instrumental delivery	44 (9.4)	50 (8.4)	26 (11.8)	0.33	36 (8.4)	48 (9.5)	36 (10.3)	0.66	120 (9.3)
Caesarean delivery	41 (8.7)	59 (9.9)	26 (11.8)	0.45	30 (7.0)	48 (9.5)	48 (13.7)	0.007*	126 (9.8)
Shoulder dystocia	7 (1.5)	15 (2.5)	6 (2.7)	0.44	5 (1.2)	11 (2.2)	12 (3.4)	0.10	28 (2.2)
SGA <2.3 centile	4 (0.9)	4 (0.7)	2 (0.9)	‡	3 (0.7)	5 (1.0)	2 (0.6)	‡	10 (0.8)
LGA >97.7 centile	13 (2.8)	24 (4.0)	15 (6.8)	0.04*	8 (1.9)	18 (3.6)	26 (7.4)	0.000†	52 (4.0)
Cong malformations	6 (1.3)	16 (2.7)	5 (2.3)	0.28	6 (1.4)	9 (1.8)	12 (3.4)	0.12	27 (2.1)
Neonat probl <24 hours	28 (6.0)	32 (5.4)	18 (8.1)	0.33	26 (6)	26 (5.1)	26 (7.4)	0.03*	78 (6.1)

IOMr: IOM recommendations 2009; Tc: traditional criteria
Stillbirth: intra-uterine death or death immediately postpartum.
Induction of labour: induction by amniotomy or medicinal induction with or without amniotomy; Pain relief: any analgesic or sedative medicine (oral, intramuscular, intravenous, spinal, or epidural) administered during labour; Shoulder dystocia: a birth requiring more than 1 manoeuvre to deliver the infant's shoulders; SGA <2.3 centile and LGA >97.7 centile: based on the 'Kloosterman centiles' which adjusted for gestational age at delivery, parity and sex of the infant. [44]
*p <0.05
†p <0.001
‡ Conditions $\chi 2$ not fulfilled

Table 6. Associations between significant indications for referral and adverse birth outcomes using Tc or IOMr according to chi-square test and relevant predictors in the final multiple log regression model

	GWG below* aOR (95% CI)	GWG above* aOR (95% CI)	BMI aOR (95% CI)	Multiparity (vs. nulliparity) aOR (95% CI)
Indications for referral using Tc or IOMr				
Hypertensive disorders Tc	0.92 (0.50-1.67)	**1.91 (1.04-3.50)**	**1.12 (1.07-1.17)**	**0.36 (0.21-0.62)**
Hypertensive disorders IOMr	**0.38 (0.18-0.81)**	1.13 (0.66-1.93)	**1.10 (1.05-1.16)**	**0.37 (0.21-0.63)**
Meconium stained fluid Tc	1.32 (0.82-2.12)	**2.22 (1.33-3.71)**	-	**0.64 (0.42-0.97)**
Prolonged 1st stage IOMr	0.79 (0.38-1.65)	1.54 (0.83-2.85)	-	**0.24 (0.12-0.46)**
Prolonged 2nd stage Tc	1.20 (0.57-2.55)	2.01 (0.96-4.22)	-	**0.19 (0.08-0.42)**
Birth outcomes using Tc or IOMr				
Pain relief IOMr	0.87 (0.56-1.34)	1.30 (0.88-1.93)	**1.08 (1.04-1.12)**	**0.17 (0.11-0.25)**
Caesarean delivery IOMr	0.82 (0.50-1.32)	1.30 (0.84- 2.01)	-	**0.23 (0.14-0.35)**
LGA >97.7 Tc	0.48 (0.23-1.00)	1.57 (0.80-3.11)	**1.14 (1.08-1.21)**	**0.54 (0.30-0.99)**
LGA >97.7 IOMr	0.58 (0.25 - 1.36)	1.67 (0.89-3.15)	**1.10 (1.05-1.16)**	**0.54 (0.30-0.98)**
Neonat probl <24 hours IOMr	1.32 (0.75-2.33)	1.31 (0.74-2.31)	-	**0.35 (0.21-0.58)**

aOR: adjusted Odds Ratio; IOMr: IOM recommendations 2009; Tc: traditional criteria.
Covariates included in the initial models were GWG below, within, above Tc or GWG below, within and above IOMr, parity, BMI (continuous variable) and interaction terms between BMI and GWG classes.
*GWG within is used as reference in log. regression

Discussion

We explored the effect of GWG on likelihood of referral to obstetric care during pregnancy and childbirth for women in primary care at the beginning of their pregnancy. The results indicated that falling outside of the IOMr for GWG was not associated with the rates of referral during pregnancy and childbirth. However, gaining weight >15 kg between 12 and 36 weeks (GWG above Tc) - irrespective BMI classification - nearly doubled the odds of being referred during childbirth.

Interpretation in light of other evidence

Our finding of no association between GWG below or above IOMr and our primary and secondary outcome measures - i.e. referral rates during pregnancy and childbirth and adverse obstetric outcomes - contrasts with international studies that found adverse outcomes - especially SGA, LGA and caesarean delivery - associated with falling outside of the 2009 IOMr. [3-13] However, our results correspond with studies that established the utility of using lower and/or wider optimal ranges than those of IOMr. [16-19] In our study we found no association between being outside the IOMr and referral for LGA and caesarean birth after correcting for BMI and/or parity. Additionally, we found that inadequate weight gain according to IOMr did not result in higher rates of referral.

Although in our study referral for preterm labour was one of the five most frequent medical indications for moving from primary to secondary care in pregnancy, rates did not differ significantly across the GWG categories. This lack of effect could be an artefact of method. As we measured weight at 36 weeks, the weights of all women who delivered before this time were considered missing. This explains the difference between our figures for referral for preterm labour of 1.6% and the 3.5% prevalence of preterm labour reported in an earlier study of this population. However, our sensitivity analysis showed no association between inadequate GWG and a higher rate of referral for this group. Our finding of no effect of GWG < IOMr on SGA <2.3 was not the result of missing data - the prevalence of SGA <2.3 in our study was 0.8 % (n = 10) and the prevalence in the former study of this population was 0.9% (n = 11) - but the null finding may be the result of lack of power. Given the size of our sample, we would expect about 30 cases of SGA according to the definition (<2.3 centile), but we observed only 10 cases, too small a number to perform a chi square test. A Fisher's exact test, however, did not show a significant difference between the amount of SGA <2.3 in the groups with or without inadequate weight gain as defined by the IOMr. Another explanation could be that whereas nearly 70% of our women fell outside of IOMr, about 21% crossed the thresholds only minimally, by 1 kg or less.

Interestingly, our findings showed that GWG >15 kg had no effect in pregnancy but almost doubled the odds of being referred during childbirth, irrespective of women's BMI category. This is consistent with the association between GWG >15kg and adverse outcomes found by several others. [4, 32, 33, 35] Exploring the underlying indications for referral and birth outcomes in relation to Tc we found that GWG >15 kg doubled the referral for hypertensive disorders and meconium stained fluid. The finding with regard to hypertensive disorders coincides with earlier studies. [4, 32, 33] To our knowledge meconium stained fluid was not included as an outcome measure in studies evaluating the 2009 IOM guidelines or in the extensive review of Viswanathan et al.. [1] The nature of the association between GWG and meconium stained fluid remains unknown and needs further investigation. Although more women with GWG >15 kg were referred during childbirth we found no association with instrumental delivery or caesarean section, a finding that contrasts with other studies. [4, 32, 33, 35]

We know that correlation does not equal causality; it may well be that associations between GWG and perinatal outcomes are not causal. Whereas the relation between excessive GWG, high food intake and a LGA baby or postpartum weight retention may be plausible, associations between GWG and outcomes such as preterm birth, hypertensive disorders, or meconium stained fluid may be more complex from a pathophysiological point of view. Disappointing results on perinatal outcomes of weight gain targeted interventions could be - at least partly - based on this complexity. [36-38]

The variation in results found in studies of GWG, including this study, might be explained by differences in study populations. Different risk profiles, maternal characteristics, socio-economic statuses and lifestyles may account for the inconsistent

findings. Differences in models of maternal care further complicate comparison between studies.

Strengths and limitations

A major strength of this study is that it yields new evidence on GWG according to IOMr and Tc in a population of healthy women cared for in primary care at the beginning of their pregnancies. Calculation of BMI and weight gain was based on objectively measured weight at fixed moments in pregnancy. Using data gathered before the implementation of guidelines on obesity we were able to study the impact of GWG in relation to BMI without distortion of referral rates caused by the implementation of these guidelines. Data were not collected for the purpose of our study hypothesis reducing the likelihood of bias caused by the focus of women or professionals on BMI or weight gain.

Our study has limitations. Whereas the IOM classification on GWG is based on a woman's prepregnancy BMI, we used a (measured) first trimester BMI. This makes comparison with other studies regarding the IOM guidelines difficult: our first trimester BMIs could be higher compared to the prepregnancy BMI used by the IOM, resulting in more women being classified as overweight or obese. Consequently, more women in our population had to fulfil restrictive weight gain recommendations, resulting in a likely overestimation of women exceeding recommended GWG. In our study most women delivered after 36 weeks. Their total GWG until delivery was thus probably higher than reported, resulting in an underestimation of exceeding IOM guidelines. This suggests that more research is needed in order to determine the usefulness of the IOM guidelines in our population. Furthermore, the missing data on GWG could be a source of bias as we lacked these data for women referred before 36 weeks of pregnancy. The reasons for these referrals might be related to inadequate or excessive GWG. About half of these missing data turned out to be based on premature labour and hypertensive disorders which are indeed explicitly associated with inadequate [1, 30] or excessive GWG, [4, 32, 33] respectively. Therefore we performed three series of sensitivity analyses: in one we added only the women with missing data on GWG based on a referral before 36 weeks because of premature labour to the analyses. We labelled all those women - pessimistically - as having an inadequate GWG. In the second series we added all women with missing data on GWG because of a referral for hypertensive disorders, labelling them all as having an excessive GWG. In the third series we added both women referred for premature labour and for hypertensive disorders. In spite of this 'pessimistic' labelling, the results supported our primary results: only GWG >15 kg between 12 and 36 weeks was associated with more referral during childbirth. Because the other 35 women with missing data on GWG were referred for of a variety of reasons without an explicit link to inadequate or excessive GWG, we do not expect an effect on our study results. Generalisability is limited: because the original study was

interested in thyroid function (which may vary between ethnic groups) we studied only Caucasian women. In this low-risk population some adverse outcomes (e.g. SGA) were rare, resulting in insufficient power to find significant associations. While we have no information on women who did not agree to participate, our data were gathered for another study purpose so we do not expect a deviation of these women on weight gain and related outcomes compared to women in this study.

Implications for practice and research

Although our findings have some limitations, they do have implications for practice. In the context of worldwide awareness of how perinatal outcomes can be affected by either inadequate and excessive weight and weight gain during pregnancy, health care professionals are advised to counsel women about healthy GWG. However, there is no consensus on optimal GWG [21] leaving professionals with empty hands regarding advice for pregnant women. Policy discussions about GWG are complicated by issues such as the contradictory effects of GWG on outcomes such as birthweight - excessive GWG is related to more LGA babies but it also protects against SGA babies and vice versa [3-7, 10, 11, 13] - and by the paucity of evidence underpinning IOM guidelines, which is limited to just a few outcomes such as birthweight and caesarean delivery. The question remains: Is this evidence thorough enough to justify the substantial impact of the implementation of a guideline for clients and professionals? In order to adequately advise pregnant women at the beginning of their pregnancy we need better information about the general effect of GWG on the course and the outcome of pregnancy and childbirth in this population. Therefore we decided to use referral during pregnancy and childbirth as our primary outcome. In Dutch midwife-led care these are proxies for adverse outcomes: Midwives refer women to obstetrician-led care not only when medical complications occur but also when the risk of a complication increases, as defined by the OIL and other guidelines. Because we are aware that the outcome is not always the same as the reason for referral - for example a woman referred for a suspected IUGR does not always deliver from a SGA-baby - we also studied the indications for referral and the actual birth outcomes. As such, we believe that our approach offers new insights about the generic effect of GWG on pregnancy and childbirth taking into account the complex of perinatal outcomes.

Our comparison of the effect of two different guidelines for GWG in a population of healthy women - IOM and 'traditional' - was revealing. We found that: 1) IOM guidelines did not have a predictive value for adverse outcomes in this population, 2) falling out the boundaries of healthy GWG as described in both guidelines had no effect on referral during pregnancy, 3) GWG >15 kg occurring between 12 and 36 weeks was associated with an almost doubled odds of referral during childbirth compared to GWG between 10 and 15 kg, and 4) no interaction was found between GWG and BMI: the effect of GWG was the same regardless the BMI category of the woman. Furthermore,

the explained variance of GWG in the model exploring the association between GWG according to Tc and referral during childbirth was 1.2%: slightly more than 1% of the variation in being referred during childbirth was explained by GWG; almost 99% was related to other factors. Does this means that GWG guidelines are less important than previously thought? Although we may conclude that for healthy women, targeting GWG as a means of preventing adverse perinatal outcomes is not very efficient, there are other reasons to be concerned with GWG. Inadequate weight loss after pregnancy is associated with an increase of complications in subsequent pregnancies [39, 40] and may cause general health problems such as diabetes type 2 for the mother [41-43]. Repetition of our research with larger samples and across different populations is needed to address the above-described limitations of generalisability, small numbers of uncommon adverse outcomes, and missing data. Including long-term outcomes such as postpartum weight retention would further enhance the ability of caregivers to give useful advice about GWG. On the basis of our findings and awaiting the results of further research we would advise midwives working with healthy women to emphasise a healthy lifestyle in order to gain a healthy weight <15 kg between 12 and 36 weeks for all women, irrespective of their BMI category. While we did not find negative consequences of gaining weight <10 kg, gaining inadequate weight during pregnancy may be a symptom of inadequate growth of the fetus, underlying pathology, or an unhealthy lifestyle of the mother and thus must be monitored.

Conclusion

Our study contributes valuable information to clinicians facing the challenge of appropriately managing weight and weight gain in obstetrics. In our population gaining weight >15 kg between 12 and 36 weeks for women in all BMI categories was found to be associated with a higher likelihood of referral to specialised care, but notably only during childbirth. Gaining weight <10 kg was not associated with a higher referral rate and thus may be acceptable in case of an uncomplicated pregnancy and healthy lifestyle. Our data - showing that nearly 70% of our population fell outside of IOM guidelines with no consequences for maternal and neonatal outcomes - underscore the importance of validation of these guidelines in a population before implementing them.

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Chapter 6

Use of midwife-led primary antenatal care by obese women in The Netherland: an explorative cohort study

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Abstract

Objective: To study the effect of BMI on the use of antenatal care by women in midwife-led care

Design: An explorative cohort study

Setting: 11 Dutch midwife-led practices

Participants: A cohort of 4421 women, registered in the Midwifery Case Registration System (VeCaS), who received antenatal care in midwife-led practices in the Netherlands and gave birth between October 2012 and October 2014.

Findings: The mean start of initiation of care was at 9.3 (SD 4.6) weeks of pregnancy. Multiple linear regression showed that with an increasing BMI initiation of care was significantly earlier but BMI only predicted 0.2% (R^2) of the variance in initiation of care. The mean number of face-to-face antenatal visits in midwife-led care was 11.8 (SD 3.8) and linear regression showed that with increasing BMI the number of antenatal visits increased. BMI predicted 0.1% of the variance in number of antenatal visits. The mean number of antenatal contacts by phone was 2.2 (SD 2.6). Multiple linear regression showed an increased number of contacts by phone for BMI categories 'underweight' and 'obese class I'. BMI categories predicted 1% of the variance in number of contacts by phone.

Key conclusions: BMI was not a relevant predictor of variance in initiation of care and number of antenatal visits. Obese pregnant women in midwife-led practices do not delay or avoid antenatal care.

Implications for practice: Taking care of pregnant women with a high BMI does not significantly add to the workload of primary care midwives. Further research is needed to more fully understand the primary maternal health services given to obese women.

Introduction

Maternal obesity during pregnancy and childbirth presents a significant challenge to maternal health services. Obesity is associated with an increase in adverse outcomes and interventions [1-11] creating demands for additional care and resources. To address the need for maternal health care of obese women it is important to be able to estimate the magnitude of the additional health care services required. Earlier studies have identified the relationship between obesity and increased use of in-hospital facilities such as obstetrical ultrasonography and more interventions including inductions of labour, instrumental and caesarean deliveries, longer hospital stays, antenatal fetal tests, and neonatal intensive care; all of which result in higher maternity costs. [5, 12-15]

However, little is known about obese women's use of primary maternal care services: do they use more, less, or the same amount of primary care? In an earlier study we found that Dutch midwives are able to safely assign obese women who started in primary care to either midwife-led or obstetrician-led care, resulting in 62% of the obese women with a midwife-led pregnancy and 33% with a midwife-led pregnancy and childbirth. [16] This model of maternity care - providing primary care when possible and specialised care only when necessary - offers possibilities for cost reduction without losing quality of care.

Some studies suggest that obese women use *more* primary care than women with normal weight. Chu et al. [12] registered a higher amount of medication dispensed from the outpatient pharmacy, more telephone calls and more antenatal visits with physicians for US pregnant women with BMI ≥35 without high-risk conditions. Denison et al. [17] found an increase in minor complications and complaints such as symphysis pubis dysfunction, heartburn, and chest infection in pregnant women with BMI ≥30 in the UK. In a qualitative study of the impact of obesity on UK maternity services, midwives reported increased use of glucose tolerance tests, ultrasounds to determine fetal size and presentation, and more referrals to dieticians and to physiotherapists for their obese patients. [18]

On the other hand, obese women may be reluctant to access services and thus use *less* care. The qualitative study of UK primary health care users by Brown et al. [19] revealed that obese patients' feelings about their personal responsibility, their sense of stigma, and their expectation of negative stereotypes seemed to interact with their use of primary care services: a lack of services tailored to obese women and negative communication affected access to care and good experiences with primary care professionals only partly ameliorated the effects of stigma cognitions. We also know that obese white women participate less frequently in breast and cervical cancer screening. [20-23] As far as we know no studies in maternal care revealed this effect.

To further complicate this picture, there are studies that show that obese women use maternity care services at the same rate as non-obese women. Levine et al. [24] found

no difference in the initiation of care in the first trimester, in total number of antenatal visits or in adequacy of antenatal care between pregnant women with and without obesity in the US. Satisfaction with medical and emotional aspects of maternity care in general and overall satisfaction of antenatal (midwifery) care did not differ between obese and non-obese pregnant women in Sweden. [25] In a Dutch study of determinants of antenatal healthcare utilisation by women in primary midwife-led care BMI ≥30 did not predict inadequate use of antenatal care. [26]

In conclusion, the few studies carried out on the use of primary maternal care services by obese women showed contradictory results. The goal of our study of 11 midwife-led primary care practices across The Netherlands was to determine the effect of BMI on the use of antenatal care in a midwife-led care population.

Methods

Study population and data collection

An explorative cohort study was conducted based on data from VeCaS. This Dutch database initiated by the Research Centre for Midwifery Science Maastricht - Zuyd University continuously extracts digital obstetrical files from 25 Dutch midwife-led practices. [27, 28] Midwives who cooperate in the VeCaS project register their care using their own electronic patient record system (EPRS). Two different EPRS are used by the midwife practices participating in VeCaS: Vrumun and Orfeus. To optimise validity and completeness of the data a Consensus Manual for Data Registration was constructed as a guide for midwives' registrations and midwives participated in activities such as consensus meetings and feedback sessions. [29] When the midwifery practice participates in the VeCaS project, all women are asked for permission to use their anonymised records with 1 - 3 refusals per practice per year. We used data gathered between October 2012 and October 2014 of pregnant women registered using the Orfeus system because of the completeness of the required data for our study. In this study period the Orfeus system represented 11 practices which were spread across the Netherlands and differed on degree of urbanisation, size of practice and number of practising midwives. We included all pregnant women who consented, received antenatal care, and gave birth in the period of the data collection. We excluded women who were not eligible for primary care and were referred to secondary care immediately after their booking and women with missing data on prepregnancy BMI. Prepregnancy BMI was calculated as weight before pregnancy (kg) divided by squared height (m^2). Weight was self-reported by the pregnant women, height was measured by the midwives. We classified BMI according to the WHO classification. [30] The VeCaS project was approved by the regional Medical Research Ethics Committee Maastricht (no. 09-4-061) and is admitted in the public register of the Dutch Data Protection Authority (no. 1489634)

Outcome measures

To assess the use of primary maternal care services, we considered two main outcomes: the initiation of antenatal care and the total number of antenatal visits in primary care. We recorded the total number of antenatal consultations and the number of antenatal contacts by phone as secondary outcomes. We defined initiation of antenatal care as the moment (in weeks of pregnancy) of first contact with the midwife-led practice, in person or by phone. We considered an antenatal consultation as any antenatal contact between the midwife and the pregnant woman in person or by phone. We defined an antenatal visit as a face-to-face contact between midwife and woman.

Statistical analyses

To test the association between BMI and the initiation of antenatal care, the number of antenatal visits, and the number of contacts by phone we performed separate fixed effects multiple linear regression analyses with a stepwise backward predictor selection strategy. [31] BMI as a continuous variable, age, parity and socio-economic status (SES) (dummies) were included in the model for initiation of antenatal care. We used an algorithm made by the Netherlands Institute for Social Research as a proxy for SES, allowing us to correct for this variable. [32] Categories of SES were based on this algorithm. The regression model on the number of antenatal visits included BMI as a continuous variable, age, parity, SES, referral to secondary care during pregnancy, initiation of care and duration of antenatal care. We also included the interaction between initiation and duration of antenatal care because the number of visits intensifies towards the end of the pregnancy. Thus the association between duration of antenatal care and the number of visits might differ depending on initiation of care early in pregnancy versus later in pregnancy. Since the mean number of visits distributed over the BMI categories could show a U-shaped relation, we performed a multiple linear regression including BMI categories and found no significant effect of the underweight category. This allowed us to integrate BMI as a continuous variable in the regression models of initiation of care and number of antenatal visits. The regression model on the number of contacts by phone included BMI as a categorical variable (dummies), age, parity, SES, referral to secondary care during pregnancy, initiation of care and duration of antenatal care and the interaction between initiation and duration of care. To give the reader a better understanding of the clinical relevance of the result of the regressions we calculated initiation of care, the number of antenatal visits and contact by phone for two women with the same maternal characteristics but only differing on their BMI (23 versus 33) using the estimated unstandardised regression coefficients. To compare the value for practice of the different covariates in the model we used the standardised *β*'s. We defined duration of midwife-led antenatal care as the time in days between the start of the antenatal care on the one hand and the start of

birth in primary care or the moment of referral to secondary care on the other hand. All statistical analyses were done using IBM SPSS version 22. *p*-Values of 0.05 were considered statistically significant.

Findings

A total of 4770 complete cases of pregnant women receiving antenatal care between 2012 and 2014 were available of which 349 were excluded resulting in a study population of 4421 pregnant women (Figure 1). Table 1 shows the characteristics of our study population in relation to BMI classification and to the Dutch population. Across BMI classes we established that with increasing BMI class, referral during pregnancy increased. Comparing the study population and the national population, a slightly lower referral rate during pregnancy was found (38% versus 41% respectively) although a higher percentage of nulliparous women were included in our study (50% versus 45% in national population). The prevalence of prepregnancy obesity of 10% corresponds with the national population on obesity of non-pregnant women between 20 - 40 years in 2014. [33]

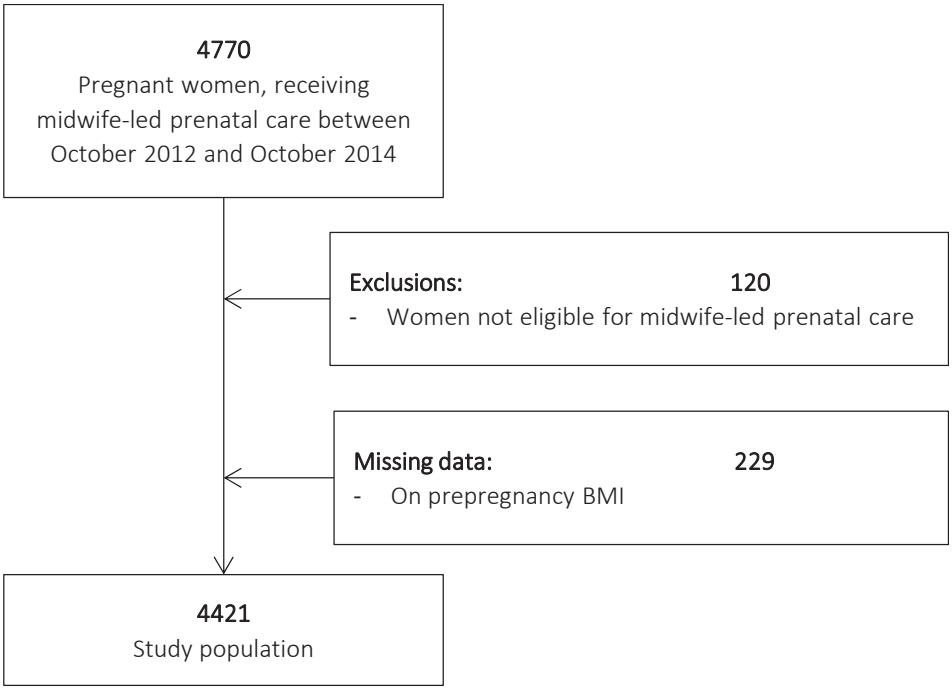

Figure 1. Flow chart study population

Table 1. Maternal characteristics by BMI classes

	Underweight n = 178 Mean (SD)/ n (%)	Normal weight n = 2872 Mean (SD)/ n (%)	Overweight n = 928 Mean (SD)/n (%)	Obese class I n = 333 Mean (SD)/n (%)	Obese class II-III n = 110 Mean (SD)/n (%)	Total n = 4421 Mean (SD)/n (%)	Dutch Population Mean (SD)/(%)
Demographic:							
Age	29.0 (5.4)	30.8 (4.6)	30.8 (4.6)	30.3 (4.8)	31.1 (4.9)	30.7 (4.7)	31.1 (4.8)*
Education†							
Low	29 (27.9)	233 (13.5)	115 (21.6)	45 (24.4)	24 (42.1)	446 (17.1)	14.7 §
Middle	33 (31.7)	474 (27.4)	172 (32.3)	70 (37.8)	17 (29.8)	766 (29.4)	40.4
High	42 (40.4)	1020 (59.1)	245 (46.1)	70 (37.8)	16 (28.1)	1393 (53.5)	44.9
Ethnicity¶							
Dutch: Yes	104 (91.2)	1803 (93.4)	568 (90.0)	226 (93.4)	68 (93.2)	2769 (92.6)	74.3*
No	10 (8.8)	128 (6.6)	63 (10.0)	16 (6.6)	5 (6.8)	222 (7.4)	25.7
Partner**							
Yes	157 (97.5)	2528 (97.6)	823 (97.5)	283 (94.0)	102 (95.3)	3893 (97.3)	90‡
No	4 (2.5)	61 (2.4)	21 (2.5)	18 (6.0)	5 (4.7)	109 (2.7)	10
BMI classification	4%	65%	21%	7.50%	2.50%	100%	2.8/59.3/26.5/ 11.4% (≥class I)§§
Obstetrical:							
Parity:							
Nulliparae	93 (52.2)	1491 (51.9)	408 (44.0)	170 (51.1)	46 (41.8)	2208 (50.0)	45*
Multiparae	85 (47.8)	1380 (48.1)	520 (56.0)	163 (48.9)	64 (58.2)	2212 (50.0)	55
Referral during pregnancy	47 (26.4)	950 (33.1)	422 (45.5)	184 (55.3)	73 (66.4)	1676 (37.9)	40.8*

* Perined 2015 [37]

† Education: low - primary education or secondary education not completed; middle - secondary education completed; high - degree at university level; missings n = 1816.

§ CBS Statline, 2016 (women between 25 and 45 years of age).[42]

¶ Ethnicity: missings n = 1336 (30.2%).

** Partner: missings n = 419 (9.5%).

‡ CBS, 2010.[43]

§§ CBS Statline, 2014 (women between 20 and 40 years of age).[33]

Initiation of antenatal care

The mean start of antenatal care in the study population was at 9.3 weeks of pregnancy (SD: 4.6). Of all pregnant women 51.7% started midwifery care within 8 weeks of pregnancy as recommended by the Dutch Organisation for Midwives in the guideline on antenatal care [34], 90% within the first trimester. Table 2 shows that, in relation to the different BMI classes, the first contact of the obese pregnant women with their midwifery practice was somewhat earlier compared to women of other BMI classes.

Multiple linear regression showed that with increasing BMI, the initiation of care was significantly earlier (Table 3). However, the difference was only small. A calculation of the initiation of care for a nullipara of middle SES and a normal weight BMI of 23 versus a woman with the same characteristics but with a BMI of 33 showed a barely relevant difference: 9.4 versus 8.9 weeks; a difference of 3-4 days. Moreover, our model did not prove to be a good predictor of the variance in initiation of care with a R^2 of 2.3%, BMI alone explaining 0.2%. The highest predicting value in our model was a high SES with a standardised β of 0.121.

Number of antenatal visits in primary care

A total of 4421 pregnant women had face-to-face contact with their midwife on 52141 occasions, a mean of 11.8 (SD 3.8) antenatal visits per woman. Of all women in our study population, 38% were referred during pregnancy and - as expected - they received on average 2.5 fewer primary care antenatal visits compared to the non-referred women: 10.3 versus 12.7. In the group of women who were not referred the increase of visits for higher BMI categories was less than 1 visit. Of the women who were referred during pregnancy especially obese class II received less visits (8.4) compared to normal weight women (10.1). Comparing referred and not-referred women within the same BMI-category showed a difference of about two visits in all categories except for obese class II-III women, the difference in this latter category between referred and not-referred women was 5 visits (Table 2).

Multiple linear regression showed that with increasing BMI, the number of antenatal visits significantly increased. Again, a calculation of the number of antenatal visits for a nullipara of middle SES, 30 years of age, who started care at 9 weeks, with a duration of antenatal care of 224 days, and a BMI of 23 compared to a woman with the same characteristics but with a BMI of 33 presented a minimal difference: 14.0 versus 14.2 antenatal visits. Although the model proves to be relevant with a R^2 of 51.5%, the contribution of BMI was only marginal with a R^2 of 0.1%. Duration of care with a standardised β of 0.761 had the highest predicting value in our model (Table 3).

Table 2. Initiation of antenatal care and number of antenatal consultations, visits and contacts by phone by BMI classes

	Underweight n = 178 Mean (SD)	Normal weight n = 2872 Mean (SD)	Overweight n = 928 Mean (SD)	Obese class I n = 333 Mean (SD)	Obese class II-III n = 110 Mean (SD)	Total n = 4421 Mean (SD)
Initiation of antenatal care*	9.9 (5.9)	9.4 (4.8)	9.1 (4.2)	8.8 (3.9)	8.8 (4.1)	9.3 (4.6)
Number of consultations	14.5 (5.3)	13.8 (5.0)	14.1 (5.1)	15.3 (6.2)	12.7 (5.9)	14.0 (5.2)
Number of antenatal face-to-face visits	11.9 (3.6)	11.8 (3.7)	11.9 (3.8)	12.1 (4.2)	10.1 (4.5)	11.8 (3.8)
Referred during pregnancy	10.0 (3.9)	10.1 (4.5)	10.7(4.3)	11.0 (4.2)	8.4 (4.1)	10.3 (4.4)
Not referred during pregnancy	12.6 (3.2)	12.6 (2.9)	12.9 (3.0)	13.4 (3.8)	13.3 (3.5)	12.7 (3.0)
Number of contacts by phone	2.6 (3.0)	2.0 (2.5)	2.2 (2.6)	3.3 (3.4)	2.7 (2.9)	2.2 (2.6)

*in weeks of pregnancy

Table 3. Multiple linear regression analysis: initiation of antenatal care and number of antenatal visits, final models.

	Model initiation of care			Model number of visits		
Predictors	*B* (unstandardised)	*β* (standardised)	*p*-Value	*B* (unstandardised)	*β* (standardised)	*p*-Value
Constant	10.609 (0.397)	-	0.000	1.772 (0.455)	-	0.000
Prepregnancy BMI	- 0.052 (0.016)	- 0.048	0.001	0.020 (0.009)	0.022	0.035
SES high	1.380 (0.177)	0.121	0.000	- 0.437 (0.104)	- 0.047	0.000
SES low	- 0.186 (0.169)	- 0.017	0.273	- 0.479 (0.099)	- 0.054	0.000
Multiparity (vs nulliparity)	- 0.622 (0.138)	- 0.067	0.000	- 0.455 (0.084)	- 0.060	0.000
Age	-	-	-	- 0.053 (0.009)	- 0.065	0.000
Initiation of care	-	-	-	0.089 (0.011)	0.108	0.000
Duration of antenatal care	-	-	-	0.056 (0.001)	0.761	0.000
R^2	2.3%			51.5%		

Covariates included in the initial model of initiation of antenatal care: BMI (continuous variable), age, parity, SES (dummies) Covariates included in the initial model of number of antenatal visits: BMI (continuous variable), age, parity, SES (dummies), referral to secondary care during pregnancy, initiation of care (in weeks), duration of antenatal care (in days) and interaction between initiation and duration of antenatal care

Number of antenatal contacts by phone and antenatal consultations.

Additionally to the face-to-face interactions, our 4421 respondents had 9590 telephone contacts with their midwives during pregnancy, a mean of 2.2 (SD 2.6) per woman. Lowest number of phone calls was made with normal weight women (2.0; SD 2.5), the highest number with obese class I women (3.3; SD 3.43) (Table 2). In total there were 62039 antenatal consultations both in person (antenatal visits) and by phone, which means a mean of 14.0 (SD 5.2) per woman with a range of a mean number of antenatal consultations of 12.7 in case of obese class II-III women and 15.3 consultations in case of obese class I women (Table 2).

Multiple linear regression showed that only BMI categories 'underweight' and 'obese class I' were significantly associated with an increase of the number of telephone contacts. The calculation of the number of contacts by phone for a nullipara of middle SES, 30 years of age, who started care at 9 weeks, with a duration of antenatal care of 224 days, no referral during pregnancy and a BMI of 23 compared to a woman with the same characteristics but with a BMI of 33 showed the difference of 1 telephone call: 1.9 contacts by phone for the woman with a BMI of 23 and 2.8 contacts for the woman with a BMI of 33. BMI categories explained 1% of the variance in the number of telephone contacts (R^2=1%). Duration of care (standardised β of 0.264) had the highest predicting value in this model (Table 4).

Table 4. Multiple linear regression analysis: number of contacts by phone, final model.

	Model number of visits		
Predictors	β (unstandardised)	β (standardised)	*p*-Value
Constant	3.070 (0.410)	-	0.000
Underweight BMI	0.492 (0.189)	0.037	0.009
Overweight BMI	0.062 (0.093)	0.010	0.507
Obese class I	0.966 (0.142)	0.097	0.000
Obese class II-III	0.432 (0.238)	0.026	0.070
SES high	-0.555 (0.097)	-0.085	0.000
SES low	0.648 (0.091)	0.104	0.000
Multiparity (vs nulliparity)	-0.212 (0.077)	-0.040	0.006
Age	-0.079 (0.008)	-0.141	0.000
Initiation of care	0.028 (0.015)	0.050	0.067
Duration of care	0.013 (0.001)	0.264	0.000
Interaction between initiation and duration of care	-0.001 (0.000)	-0.200	0.000
Referral during pregnancy	0.647 (0.091)	0.119	0.000

Covariates included in the initial model of number of contacts by phone: BMI categories (dummies), age, parity, SES (dummies), referral to secondary care during pregnancy, initiation of care (in weeks), duration of antenatal care (in days) and interaction between initiation and duration of antenatal care.

Discussion

In this study we found that higher BMI among women eligible for primary, midwife-led care after their first antenatal visit was related to a significantly earlier initiation of care and more antenatal visits. Regarding contacts by phone, obese class I women had more contacts with their midwives than women with a normal BMI. However, the differences were so small that they mean an insignificant addition for the workload of midwives. Our findings indicate that obese women did not withhold themselves from primary antenatal care.

Interpretation in light of other evidence

In 2015 the KNOV initiated a study of time allocation of midwives among 100 midwifery practices. Our findings of a mean of 11.8 antenatal visits and 2.2 contacts by phone is slightly lower than the findings of the KNOV study of a mean of 12.8 antenatal visits and 3.2 contacts by phone. [35] Only half of the population - irrespective of women's BMI - had their first contact with their midwife at 8 weeks of pregnancy or earlier, as recommended in the guideline of the KNOV on antenatal care. This indicates that starting antenatal care earlier must be stimulated. On the other hand, our findings of a mean number of antenatal visits of 12.7 in the group of non-referred women showed an on average adequate use of antenatal care taking into account the KNOV recommendation of 10-13 individual visits up to 40 weeks of pregnancy. [34]

Women in obese class II-III had fewer antenatal consultations (12.7) when compared to women in other BMI classes (13.8 - 15.3, Table 2). This is mainly caused by fewer antenatal visits in the referred group: 8.4 visits for obese class II-III women versus 10.0 - 11.0 visits for women in the other BMI classes. This can be explained by our findings in a former study showing that obese class II-III women had significantly fewer uncomplicated pregnancies than normal weight women [16] and were thus more likely to be referred to obstetrician-led care. Moreover, a current guideline on obesity from the Dutch Society of Obstetrics and Gynaecology advises referral to obstetrician-led care in pregnancy and childbirth for all women with a BMI >40. [36] Consequently, referred women had fewer visits in midwife-led care. Fewer antenatal visits in midwife-led care for obese class II-III women - in context of the Dutch maternity care system - is not an indication of suboptimal care, but rather reflects referral to obstetrician-led care.

Our findings are in line with the studies that found that obesity was no barrier for adequate antenatal care. [24, 26] This might be influenced by the appreciation of the quality of care by obese clients: while Brown et al. [19] reported ambivalence of obese patients about the received care and the communication with health professionals, Hildingsson et al. [25] found no differences in satisfaction with antenatal care between obese and non-obese women. To our knowledge satisfaction towards maternity care in relation to BMI classes is not yet studied in the Netherlands. Dutch midwifery care is

established with 86.3% of women starting their care in midwife-led practices, [37] assessed as easy accessible and well appreciated by women. [38] This might positively influence a timely start of antenatal care and an adequate number of antenatal visits. Whereas care for obese women in primary care does not seem to challenge the available resources, we found increasing referrals to secondary obstetric care related to increasing BMI. This suggests that there is an additional demand for care in the secondary care setting as described elsewhere. [18]

Strengths and limitations

This study offers new insights on the use of antenatal care of obese women receiving care in midwife-led practices. A subject that has scarcely been studied, resulting in contradictory evidence. The prevalence of obesity in our study corresponds with the national prevalence and the number of antenatal visits found in the total study population is in line with the national guideline on antenatal care, important elements when considering generalisation of our results. An additional strength is the large sample size of this unique population of pregnant women, generally healthy and eligible for primary care after their first antenatal visit. Our study also had some limitations. Based on the evidence that women of reproductive age underestimate their weight by 0.8 kg/m^2 (SE 0.1) - resulting in a BMI classification that is 84% accurate [39] - it can be argued that self-reported weight is not a reliable measure. However, we performed multiple linear regression analyses on our primary outcomes including BMI as a continuous variable (and not in categories) and found a significant, but not clinically relevant result. We do not believe that an underestimation of weight by all women influences our findings. Because we used the VeCaS database we were limited to the aspects of the consultations which are registered in the allocated fields in the EPRS, which are all quantitative items midwives put in the woman's file. Medical notes of the midwife in the free fields cannot be anonymised and therefore not used. For example consultation of other professionals in primary care such as the general practitioner, dietician, and physiotherapist are mostly registered as such and not available for the VeCaS database. Feijen-de Jong et al. [40] found that Dutch pregnant women contacted their GP more than non-pregnant women. This could be influenced by women's BMI as suggested by Chu et al [12]. In the qualitative study of Heslehurst et al. [18] midwives reported a higher use of ultrasounds and glucose tests; it would be interesting to quantify these observations. At this moment, the VeCaS database is not yet able to provide these data. Given the evidence that midwives' communication and counselling with obese women can be enhanced, [41] research on aspects of the quality of antenatal care and on women's experiences of care will contribute to improvement of antenatal care for obese women. Furthermore, we were not able to identify and exclude women who left the midwifery practice because of their removal to another area or women who came in because of their removal to the area of the midwifery practice. Nationally,

4% of the women shift between practices due to removals (Perined 2015, not published). Although this could influence the mean number of antenatal visits we expect an equal distribution of this phenomenon over the BMI categories.

Conclusion

Obese women in primary care have a similar number of antenatal visits and initiation of care as normal weight women. They do not withhold themselves from adequate antenatal care. Moreover, the care for obese women does not require additional workload for the midwives as compared to normal weight women. Future research on this topic should address other aspects of antenatal care such as the number of consultations to other professionals in primary care, the time spent on the visits and contacts by phone, the difference between scheduled and extra consultations, diagnostic tests in relation to BMI. Only half of our total study population initiated their care at 8 weeks or earlier as recommended by the national guideline on antenatal care. A timely initiation of antenatal care may be a point of attention for every pregnant woman.

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Chapter 7

Factors influencing the clinical decision-making of midwives: a qualitative study

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Submitted

Abstract

Background: Although midwives make clinical decisions that have an impact on the health and well-being of mothers and babies, little is known about *how* they make those decisions. Wide variation in intrapartum decisions to refer women to obstetrician-led care suggests that midwives' decisions are based on more than the evidence based medicine (EBM) model - i.e. clinical evidence, midwife's expertise, and woman's values - alone. In this study we explore the factors that influence clinical decision-making of midwives who work independently.

Methods: We used a qualitative approach, conducting in-depth interviews with a purposive sample of 11 primary care midwives. Data collection took place between May and September 2015. The interviews were semi-structured, using written vignettes to solicit midwives' clinical decision-making processes (Think Aloud method). We performed thematic analysis on the transcripts.

Results: We identified five themes that influenced clinical decision-making: views of the pregnant woman, sources of knowledge, the midwife herself, the collaboration between maternity care professionals, and the organisation of care. Regarding the midwife, her decisions were shaped not only by her experience, intuition, and personal circumstances, but also by her attitudes about physiology, woman-centredness, shared decision-making, and collaboration with other professionals. The nature of the local collaboration between maternity care professionals and locally-developed protocols dominated midwives' clinical decision-making. When midwives and obstetricians had different philosophies of care and different practice styles, their collaborative efforts were challenged.

Conclusion: Midwives' clinical decision-making is a more varied and complex process than the EBM framework suggests. If midwives are to succeed in their role as promoters and protectors of physiological pregnancy and birth, they need to understand how clinical decisions in a multidisciplinary context are actually made.

Background

A defining feature of midwifery care is the promotion and protection of physiological reproductive processes. [1] During the course of pregnancy and childbirth, midwives are constantly weighing the appropriate care for each individual woman, including when the assistance of specialised caregivers is needed (referral decisions). This assessment demands well-developed competencies for clinical decision-making. [2] Ideally, midwives provide evidence-based care, using the best available clinical evidence, their own clinical expertise, and the situation and values of the pregnant women. [1, 3] However, we know that midwives' intrapartum referral decisions differ and that this cannot be explained by medical circumstances or women's characteristics alone. [4-6] This suggests that other factors may be involved in the clinical decision-making process.

Cheyne et al. [5] identified three elements in the decision-making process: the *assessment* (the professional's judgement of the level of risk), the *decision* (the choice between possible courses of action) and the *decision threshold* (the professional's threshold when linking the judgment and the decision). They found that although midwives and obstetricians made similar case *assessments*, there was great inconsistency with regard to referral *decisions* within the groups. This suggests that the main source of variation is not in the *assessment* but in the personal *decision thresholds* of professionals. [5] Several studies suggest that factors related to the individual midwife contribute to the variation in decisions, such as: experience of earlier adverse events, definition of the boundaries of physiological birth, perceptions of risk, methods of managing the uncertainty during the childbirth process, practice philosophy, attitude towards collaboration with other professionals, and interaction with the woman. [4, 7-11] Intrapartum referral rates are also affected by features of the midwife-led practices such as number of midwives working in the practice and the distance to the hospital. [5, 9, 12] Studies among other health professionals confirm the diversity of factors affecting a clinical decision: knowledge, previous experiences and intuition of the professional, woman and caregivers beliefs and values, interdisciplinary professional relationships, clinical facilities and resources. [13, 14] Clinical decision-making thus seems to be a more complicated and less rational process than suggested by the definition of evidence based medicine (EBM).

Most research on decision-making in midwife-led care is done quantitatively with a focus on the intrapartum decision and not on *how* the decisions were made. Our research addresses this lacuna, offering insight into factors that influence midwives' clinical decision-making in pregnancy and childbirth by means of in-depth interviews with practicing midwives.

Methods

Design

We undertook a qualitative study using in-depth interviews. Each interview started with the exploration of authentic written cases, vignettes, followed by a semi-structured interview. The Vignette Method is especially suited to explore people's judgements, perceptions, attitudes, potentially sensitive topics, accounts of practice, and influencing factors. [15, 16] Midwives were invited to come to a clinical decision in each vignette and to verbalise their thoughts. This approach, the "Think Aloud" method, allows description of the points of information that are concentrated on and how information is structured during a problem-solving task [17] and provides rich and extensive data for analysis. [18] Because clinical decision-making is, in part, an unconscious process [19] we continued the appraisal of vignettes using a semi-structured interview in order to make explicit all of the influencing factors. We choose for individual interviews to avoid peer influence on a midwife's answers and to allow fundamental exploration of an individual midwife's perceptions and motives. The research team included 5 members: 2 professors of midwifery science, 1 master in health promotion (PhD) and 2 midwives (1 PhD and 1 PhD student). The interviews were done by the PhD student, who has a long history in midwifery education and guideline development.

Setting and participants

A total of 11 interviews were conducted between May and September 2015 with midwives working in primary care, midwifery practices across the Netherlands. Since midwife and practice characteristics may influence the clinical decision process, [4, 5, 7-10, 12] we choose purposive sampling to achieve representative variation with gender, age, years of midwifery experience, highest level of education, practice characteristics, and features of the practice population as main criteria. Midwives were invited to participate by e-mail followed by a phone call. We began with six midwives and continued recruitment until saturation was reached. [20, 21] Only one midwife declined to participate because of workload.

Data collection

The three vignettes included situations in pregnancy, childbirth, and puerperium. Two vignettes consisted of two or more phases (Figure 1).

Vignette	Phase	Content
1	1	**Pregnancy** Gravida 2, para 1, aged 35, BMI 36, 28 weeks gestation, caesarean section in history. Obstetrician decides on a referral to obstetrician-led care after a routine consult at 30 weeks because of caesarean section in history. Obstetrician's ground: obesity
	2	**Puerperium** 2 days postpartum: the woman asks the midwife to inject a thromboprophylacticum prescribed in the hospital.
2	1	**Pregnancy** Gravida 2, para 1, aged 32, BMI 32, 20 weeks gestation, under care of a neighbouring midwifery practice where homebirth is no option although this is the woman's preference. The woman is discontented and asks for a switchover to your practice and your opinion of a homebirth.
3		**Birth** GI, PO, aged 26, 40 weeks 3 days gestation.
	1	Partner is calling: his wife has contractions
	2	First visit of the midwife
	3	10 hours after the first contact (partogram)

Figure 1. Vignettes

Obesity was introduced in the vignettes because this characteristic challenges midwives' clinical decision-making on medical and psychosocial levels. Obese women experience stigma, which may threaten the bond of trust between midwife and woman [22] and in the Netherlands, there is scant evidence on the best care for obese women in midwife-led care, clear national guidelines are lacking, and local protocols are ambiguous. [23] Based on discussions with practising midwives (other than the ones interviewed), we identified typical clinical dilemmas associated with supporting obese women and incorporated these in the vignettes.

For the second part of the interview, a semi-structured interview guide was developed (Figure 2), based on the theoretical framework of EBM (Figure 3).

Interview guide of the semi-structured interview
1. You must make a clinical decision in your care for a specific woman: What do you take into account? Which aspects do you consider?
2. What sources of knowledge do you draw on in making your clinical decisions?
3. What is the role of a woman's characteristics in your clinical decision-making?
4. Do you explore women's preferences and how do you manage them in your clinical decision-making?
5. How does your clinical expertise influence your clinical decision-making?
6. Are there specific features of your personality that may influence your clinical decisions?
7. What is your attitude towards midwifery and how does that attitude influences your clinical decision-making?
8. Are there aspects of your clinical decision-making that we have not discussed and that are important to add?

Figure 2. Interview guide semi-structured interview

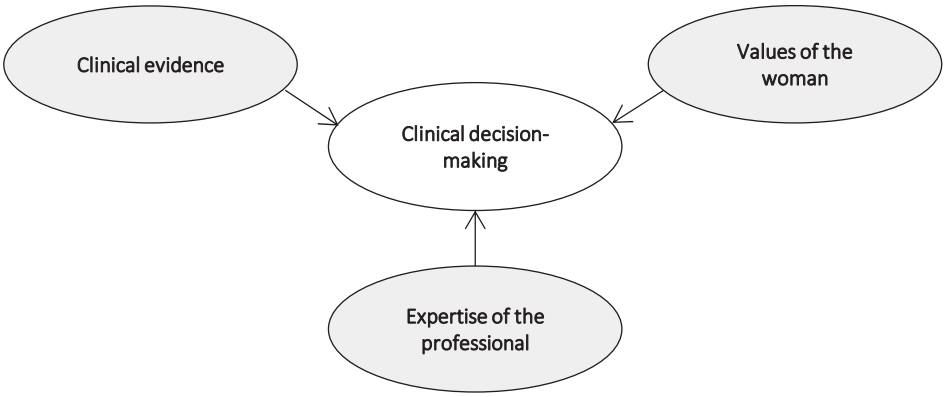

Figure 3. Evidence based medicine

The internationally recognised model of EBM is defined as the conscientious, explicit, and judicious use of best available evidence in making decisions about the care of individual patients. In its ideal form, the practice of evidence based medicine integrates the clinical expertise of the professional with the best available external clinical evidence from systematic research while taking into account an individual patient's situation, predicaments, rights, preferences and values (Figure 3). [3]

Before the interview, participants filled out a short questionnaire on their demographic characteristics. The interview was conducted by the first author at the participant's preferred location (home or in the midwifery practice). It started with a short introduction of the vignettes and the Think Aloud Method. The vignettes were presented to the midwives one by one and phase by phase and interaction was limited to clarifying questions and encouragement to think aloud. Subsequently, the interview continued based on the semi-structured interview guide, and midwives were encouraged to introduce any issue related to the topic of the study. The interview was concluded with a short evaluation and field notes describing the context of the interview and the participant. The interviews lasted between 1 hour 20 minutes and two hours.

Data analysis

All interviews were audiotaped and transcribed verbatim by the first author and an assistant. A thematic analysis was performed using QSR NVIVO 8. [24, 25] A preliminary coding scheme was developed by the first (DD) and second author (EvL) based on the framework of the interview guide and the data of three, randomly chosen, interviews, that were, coded by the first and second author independently. The final coding scheme emerged during further analysis based on consensus. Transcripts were coded by the first author who presented her analysis to the research team. Codes were grouped into

subthemes and themes by examining the commonalities, differences and relationships within and among the interviews and through reflective discussion with the research team. [26]

We used the following strategies to ensure the rigour of our study: Vignettes were made in accordance with recommendations for vignette construction [15, 16, 27] and were reviewed by four midwives working in the field of education, research, and midwifery practice. After every interview we asked the participants to comment on the content and authenticity of the vignettes. The first interview was organised as a pilot followed by an extensive evaluation of the process and the content of the interview with the interviewee and an observing researcher (HW). The combination of the Vignette method, Think Aloud procedure, and semi-structured interview aimed to obtain a complete range of data on the topic (methodological triangulation). Throughout the study several researchers reflected on the analytic process (investigator triangulation). Research team meetings were organised regularly to discuss the scientific and organisational aspects of the study (peer debriefing). The translation of the quotes was assisted by a native English speaker. The whole procedure of the study is recorded in a logbook. The writing of this article was guided by the consolidated criteria for reporting qualitative research (COREQ).[28]

Results

After nine interviews we reached saturation on the level of themes and subthemes, but we did two additional interviews for confirmation. [21] Table 1 shows characteristics of the participants. Ten midwives worked in midwife-led practices. One midwife worked in an integrated care system where a midwife-led care unit exists alongside the obstetrician-led care unit and where all midwives work in both settings during the same shift.

We identified five themes that influenced everyday clinical decision-making: the pregnant woman as a whole person, sources of knowledge, the midwife, collaboration between maternity care professionals, and organisation of care. Looking more closely at the midwife, we found five characteristics that shaped her decisions (Figure 4).

Table 1. characteristics of the participants

Characteristics	n = 11
Gender	
Male	1
Female	10
Age (mean and range)	43.8 (28-54)
Year of graduation	1983-2012
Years of experience (mean and range)	19.6 (2-32)
Highest level of midwifery education	
Bachelor in midwifery 3 years	5
Bachelor in midwifery 4 years	4
Bachelor of science in midwifery	1
Master of science in midwifery	1
Midwifery-related responsibilities outside of the practice	
Yes	7
No	4
Characteristics of the practice*	
Number of registered women yearly	40-525
Number of midwives	1-6
Number of registered women per midwife	98 (40-158)
Duration of being on call	24-56 hours, 1 caseload midwife
Mean working hours per week**	30-60
Practice population mainly typified as	
- regarding level of education-:	
Low	1
Middle	6
High	2
Mixed	2
- regarding ethnicity-:	
Dutch	6
Dutch and Western immigrants	3
Dutch, Western and non-Western immigrants	2

*1 additional midwife works in an integrated care system in a hospital together with 9 colleagues in 8 hours shifts; about 550 women are registered yearly

** also including not-woman related tasks

The pregnant woman as a whole person

During the interviews it became clear that midwives used a whole person approach in their work with women. All gathered relevant physical information of the pregnant woman described in the vignettes through history taking, observation, conversation, exploration of woman' symptoms and diagnostic tests.

> *Of course, I'm going to sit quietly together with them [woman and partner], observe the nature of the contractions, let them hear the heartbeat, external examination, vaginal examination: what is the dilatation (…) (Midwife10)*

But midwives also paid attention to the woman's psycho-social context: her thoughts and feelings, the relationship with the partner, the socio-economic situation, the

supportiveness of the woman's social network, her lifestyle, and the media influencing women's opinions.

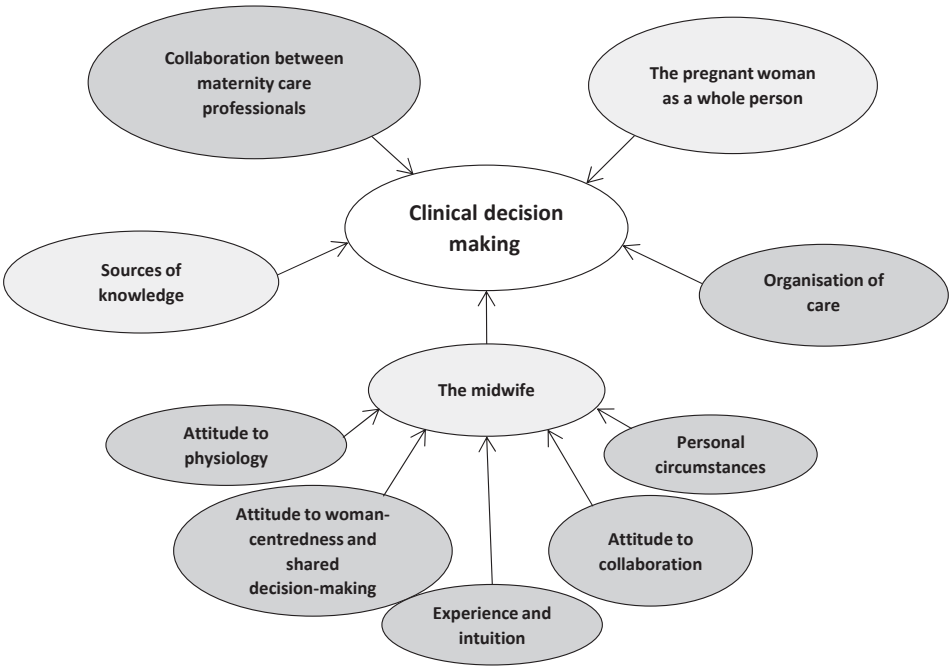

Figure 4. Clinical decision-making process: emerging themes and subthemes

Psycho-social context:

> *Woman's characteristics, I think that everything about the woman is important for decision-making, the total picture counts (Midwife6)*
>
> *How she's handling the contractions (…), you make an estimation of what women feel (…) your first impression when you enter someone's house (…) the questions you ask to determine …for example: does someone have a lot of pain or how is it going on with someone (…) is someone still properly approachable, is someone totally introverted (…) one knows his women but: how is it going with someone now? (…) disadvantaged social environment, low intellectual abilities, hypochondriac, women with anxiety disorders, you take that all into account. Women who had a very traumatic experience the first time (Midwife1)*

Relationship to the partner:

> *If partners sometimes have no connection with each other and are getting in each other's way, that makes me sometimes think: I need some help here [=reason for moving from home to hospital setting] (…) (Midwife9)*

The media:

> *A lot of people were highly influenced by journalism (…) when there was almost weekly in the papers that, um, homebirth was irresponsible, that [promoting physiology] was a very difficult message (Midwife5)*

Midwives reported that they took into account the preferences of the women and that they strived for satisfied women with good childbirth experiences. As result midwives made efforts to balance their basic attitude towards guarding physiological birth and the wishes of women for medical interventions, such as the use of epidural anaesthesia for pain relief.

> *Yes, I want to give everyone the opportunity for a natural, healthy, good childbirth: that is my aim. But (…) if you need a medical intervention to, um, have a satisfying and good experience, and of course to have a healthy child, yes that also fits in and in that process I am the one who has to support, who has to perform an appropriate risk assessment. Yes I hope that the woman connects with me during pregnancy and childbirth; that she trusts me and, um, that we together make the best choices and that the birth goes well and is safe (Midwife11)*

Sources of knowledge

Midwives indicated that they initially gathered their professional knowledge, the ground for clinical decision-making, during their midwifery education. They also pointed to their preceptors as important role models.

> *[I gathered my professional competencies] during my education (…) I think that the examples I had were the midwives who very much went into conversation with the women (Midwife3)*

Midwives updated their basic competencies in different ways: by reading the national midwifery journal, by attending continuing education courses, by using the internet, by consulting colleagues, by participating in working groups. Primary care midwives identified the limited access to academic libraries as a barrier for doing their own literature research.

> *Of course you read your literature. I really find that as a [primary care] midwife you are limited with [only] the national midwifery journal (…) I want to have more*

> *access to evidence, to scientific articles (…) that you would be able to do your own search, in an academic library, on a certain topic (Midwife2)*

(Inter)national guidelines were reported as sources of knowledge but almost all midwives emphasised their use of the local protocols. Regarding obesity, these protocols vary in their determination of when a midwife-led hospital birth is appropriate.

> *That is a strict policy here (…) with a BMI of 32, a midwife-led hospital birth is advised (…) (Midwife8)*

> *A midwife-led hospital birth [is advised] for a BMI of 35 or greater (…) a BMI of 32 is for us no reason to advise a birth at the hospital (Midwife7)*

Midwives varied in their adherence to the guidelines: from strict use to a critical appraisal of the applicability of the guideline together with the woman. This variation was also visible in their role regarding the construction of the local protocols: from an implicit faith in the quality of the protocols to an active and critical contribution to the content of the protocols.

> *We are rather strict, um, in the adherence to the guidelines, um, yes we find that important (…) we agreed with the recommendation, um, certainly when there are risks (…) (Midwife8)*

> *I really see them as guidelines (…) that you can deviate in individual cases in agreement with the obstetricians, on the condition that you communicate well and report everything, I make the decisions but I confer on everything [with the obstetrician] (Midwife3)*

> *No, I trust that the protocols (…) really are well-founded (…) and if there is a concept, then I read it and I think: yes, that looks good, I can work with this, I agree with this but the evidence behind it? No, I'm honest: I never did ask for or look at it (Midwife1)*

In addition, some midwives mentioned local perinatal audits - meetings where maternity caregivers critically analyse the care given in cases of perinatal morbidity or mortality [29] - as an important source of knowledge.

> *I have to say that the audits (…) very much help me (…) that you think differently, work differently, [I learned] that you must be able to justify all the decisions you make (Midwife11)*

The midwife

Several characteristics of the midwife - both personal and professional - play a role her decision making, including: her attitude towards physiology, woman-centredness and

shared decision-making; her experience and intuition; her attitude toward collaboration; and her personal circumstances (Figure 4).

Attitude to physiology:
All interviewees said it was important to guard the physiology of pregnancy and childbirth. The midwives informed women that pregnancy and childbirth are natural and normal processes. They also described a number of interventions to support physiological pregnancy and childbirth, focussing on the empowerment of the woman in order to reinforce her capacity to give birth. These interventions included supporting the woman with a quiet environment, breathing techniques, varying positions and different tools in labour and childbirth. Midwives also explained that efforts to protect a physiological approach to birth may require profound discussions with obstetricians, as in the case of differing opinions on the necessity of a transfer of a woman to obstetrician-led care

> *I don't do much, I, um, especially try to help to relax, um, that there is no stress, that women surrender themselves to the birthing process. I try to avoid stimuli in the woman's environment: I darken the room, make it quiet, I try to talk quietly. I try to help her with breathing quietly, with avoiding resistance to the process, with finding relaxation between the contractions. I suggest to take a bath, to shower, yes, you don't do very much (…) if she has a lot of pain, yes, we give sterile water injections (…) we have good experiences with this, very good (Midwife11)*

> *That women must trust their body (…) and that I can give them that trust through my information, my attitude, my things, that I can help them the best with that (Midwife7)*

Responding to one of the vignettes that described a transfer to obstetrician-led care at 28 weeks (Figure 2, vignette 1, phase 1), one midwife said:

> *The local agreement is that she [pregnant woman] is referred to the care of an obstetrician at 36 weeks of pregnancy because of a caesarean section in history, thus [an obstetrician- initiated] takeover of care at 28 weeks is not needed (...) thus I certainly would bring this up with the obstetrician, I would make a phone call (Midwife3)*

One the other hand, the interviews also revealed fundamental differences between midwives in the extent of their support for protecting the physiology of pregnancy and childbirth. We found differences in: the use of interventions which are proven to support physiological birth such as continuous support in labour; attitudes towards applying diagnostic tests or interventions in general such as ultrasonography or rupture of the membranes; perceptions of certain situations or women's characteristics as risky and in the handling of those perceived risks; appraisals and application of guidelines;

support for homebirth. This results in a variation from midwives who are always looking for the most physiological approach possible - irrespective of guidelines or organisational hindrances - to midwives who use extra diagnostic tests or are quick to consult secondary care in order to reassure themselves or the women and their partners.

> *Yes, we give continuous support - if a person prefers that - in the active phase (Midwife11)*

> *What we do with continuous support? Honestly, we are not so used to that in our practice I must confess and, um, if women indicate: gosh this is too much for me (…) then I stay with them [in their home] but it is not a standard procedure to say: Ok, you are in the active phase now; I will stay with you (Midwife9)*

> *I very often get women from other practices who are not allowed to have a homebirth because there is no elevator on their floor in the apartment building and, um, I inspect the accommodation because it must be free and accessible in my opinion, but yes maybe I consider the risk of referral less and that I think: if I'm going to support a homebirth, I will support homebirth (Midwife6)*

> *Of course I try to reassure them but if persons stay worried then I offer: 'if you prefer then I arrange something, then you can undergo a CTG in the hospital, they check your blood pressure or whatever - depending what is going on - (…) then you are totally reassured'. Yes, I take care that women and their partners leave the practice satisfied and if that means a consultation with the obstetrician: fine (Midwife4)*

Midwives experienced dilemmas in their pursuit of physiological birth. They struggle with the changing cultural ideas about birth over time.

> *[Earlier] I sometimes worked with a woman during 3 or 4 days, with a prolonged labour, because I was afraid that if I should refer her, I was told that I did not coach her enough (…). Now it is the opposite situation, I got a complaint because she was unsatisfied because she did not get pain reduction. 'Did you have a bad experience?' 'No, I just wanted to have that pain reduction' (Midwife11)*

In this context, the most important dilemma that midwives experienced was how to deal with the difference in opinion about the nature of physiological obstetrics between midwives and obstetricians. Midwives felt pressured to refer to secondary care earlier. This was demonstrated by the differing opinions on guidelines between primary and secondary care and by discussions about how to make room for a more physiological approach.

> *We think (...) that the process of the development of care pathways is guided too much by secondary and even tertiary care [professionals], yes, um, we think that*

physiology has been lost sight of. We [midwives in that working group] have tried very hard to have an approach based on the practice of homebirth. And physiology, um, yes, on little components we succeeded somehow but that has been a really tough process (…) that means that a mother's third child of 3000 grams - born at home - should be admitted to the hospital for a 24-hours-glucose-protocol. That's going much too far for me and I will not go along with that (Midwife7)

Yes, I think that the pressure by the secondary care plays a big part in clinical reasoning and decision-making. Um, the pressure you feel from the rules, from the disciplinary tribunals that have been, that has resulted in more constraint within our profession, I think. Due to this you are even more inclined to call the obstetrician for certainty, do a consultation for safety's sake (…) but I do not want to go along with this (Midwife6)

Attitude to woman-centredness and shared decision-making

While all midwives in our study sought to consider the preferences and needs of women in their decision-making, they varied in the extent to which they put woman-centredness into practice. For example, midwives differed in the way they involved the woman in making decisions. This ranged from those who discussed everything with the woman and offered her real and acceptable choices to midwives who used the guidelines to direct decision-making. In between these extremes were midwives who relied on their intuition and their knowledge of the woman in assessing how to support her or what to do.

That is what I tell to women: concerning your BMI, this is the guideline: what do you think of it? What do you want? If it concerns a BMI ≥40, I say: following the guideline, I have to refer you to the obstetrician. There are two different women: one says OK. The other says: I don't need this, I'm healthy, I feel healthy, I'm pregnant, I don't want to go to the obstetrician. In that case, we are going to talk (…)(Midwife6)

I think I do it more intuitively, yes and (...) I know my women, I saw them throughout pregnancy. Then you do it intuitively: what kind of woman is this? Um, I look at the situation when they are in labour; um, I also sense a bit of what is possible (…) (Midwife2)

No, we try to adhere to the guidelines, um, you are part of [local collaboration between midwives] and you all want to handle patients equally. It cannot be possible that the patient can go 'shopping' [between midwifery practices] and thinks: 'in that practice I can have a homebirth'. I wonder: if you are stretching your boundaries, where is the end? (Midwife8)

Midwives experienced another dilemma in this context: as long as the preferences of a pregnant woman could be achieved within the boundaries of primary care as locally agreed upon, midwives were willing to meet them. If a woman's preferences exceeded the responsibility and scope of primary care midwives, they were less willing to oblige. Because local protocols are created in dialogue between local primary and secondary care professionals, they often differ between localities, and therefore midwives' dilemmas regarding this issue also differ by location.

Experience and intuition

All midwives agreed about the important - but sometimes unconscious - role of experience in clinical decision-making. Their experience provided know-how and routine (pattern recognition) and made them feel certain. Midwives with a long career have seen a lot of trends and opinions, have learned from it and remain nuanced in the face of a new 'hype'. Experience also has another dimension: midwives sometimes keep negative experiences in mind, resulting in more defensive management when similar situations arise.

> *I think I do not know [the effect of experience] very well; you are not even aware of it; you only notice it (…)when you are supervising a student (…)that you have so much experience that it is very easy to assess situations, that you know the natural course of things (Midwife11)*

> *We had a lot of referrals for pain relief (…) at that time we were very busy with the concept of active support of labour: all women had an amniotomy at a dilatation of 3-4 cm. I thought: Yes, of course, those women are in the beginning of labour, it is tense for them; they have contractions every 3 or 4 minutes. You rupture the membranes and they experience acceleration, women are scared to death, no wonder that they ask for pain relief. Thus we don't do that anymore (…) I think that I very often allow my experience to play a part especially in the 'grey area' [boundary between physiology and pathology]. You know: maybe I am somewhat less cautious, um, that indeed I more easily can deviate from the guidelines because of my experience (Midwife2)*

> *That is particularly with postpartum haemorrhage (pph): if you just experienced 2 pph, with woman number three you are more likely to give extra oxytocin…. So yes…clinical management based on the past (Midwife10)*

A midwife reported that she was influenced by her own childbirth experience in making clinical decisions.

> *It has (…) lasted a year before I regained a bit of confidence um (…) but I took it some time with me and referred women for pain relief that, when thinking later, it was probably not needed, but yes, these are things you have to learn from, where you take your own experiences with you, yes (Midwife5)*

All midwives stated that intuition plays a part in clinical decision-making, especially in combination with a gut feeling that something is wrong. In exploring the phenomenon of intuition with the interviewees we learned of situations where small deviations in the physiological process combined with their professional expertise and their in-depth knowledge of the pregnant woman enabled them to perceive 'other' behaviour or subtle symptoms. Although the midwife could not (yet) transform the deviations into a diagnosis, she took action.

> *Midwife (M): was this woman going to have a pph? My feeling said: give her 5E Oxytocin extra (…) but I had nothing to go on, that was purely my feeling (…)*
>
> *I: (…) but what do you take into account?*
>
> *M: (…) the course of the delivery, the amount of blood loss until now, the time between the birth of the placenta and the blood loss, the quality of the contractions of the uterus, is there perineal damage, do I expect a rupture of the cervix, did I have incidentally another two pph today, that I surely consider and um perhaps also a bit: it doesn't hurt to try in this case (Midwife10)*

Attitude towards collaboration:
All midwives endorsed the importance of a good collaboration with obstetricians but the personality of the midwife determined how they approached that collaboration. This was illustrated by the difference in midwives' communication during interprofessional consultation. Ranging from handing over control to a constructively critical dialogue with obstetricians when needed. On one hand, some midwives seek dialogue-based consensus, and on the other hand, some aim to please women and colleagues and avoid discussion. In this example, a midwife cedes control to the obstetrician by asking for permission to keep the woman under her care:

> *Then I would consult the obstetrician (…): <u>may</u> I wait and see or do you prefer the referral now? (Midwife1) [emphasis added]*

While this midwife challenges the advice of the obstetrician:

> *For example, the guideline on diabetes: all the different reference values [in the different (inter)national guidelines], makes it clear to me that (…) if the obstetrician says very definitely: this woman has diabetes and needs to be referred, I say: but this is not so definite, there is room here and this woman has a special wish and she wanted to do this in her way, can we collaborate on this? (…) I try it every time (Midwife6)*

Personal circumstances
Finally, midwives described how personal characteristics, feelings and conditions can influence clinical decision-making.

> *If I have had a tough shift then my perception at the end of this shift is different, I take that into account, (…) yes, you are influenced by your own state of mind and the things you find very thrilling, these also influence you (Midwife9)*

Collaboration between maternity care professionals

Midwives working within one practice aim for continuity of care for pregnant women. However, individual midwives may differ from their colleagues in their clinical decision-making in particular situations. Midwives' response within-practice variation is to make general agreements and/or to discuss individual cases.

> *We have a colleague who sometimes finds it [homebirth] hard and the agreement is clear that we do not decide upon a homebirth in advance. The midwife who is responsible during childbirth decides if she feels up to the task (Midwife5)*

Midwives and obstetricians cooperate locally and the nature and quality of this cooperation influence midwives' clinical management. Midwives described this local collaboration as positive when it was respectful and based on equality; when their view of physiological pregnancy and childbirth was assessed at its true value by obstetricians; when primary and secondary care professionals did not have strongly divergent perceptions of risk; when well-reasoned deviation from the guidelines was accepted; and when dialogue was possible in situations where pregnant women challenged the primary care boundaries. Personal relationships between professionals or groups of professionals also determined the nature and the quality of the collaboration. Importantly, when midwives worked with two different hospitals they were able to use the professional and personal differences between the institutions to their advantage.

> *I'm thinking in terms of cooperation, to have respect for each other's responsibility and way of working. We have to strive for more joint policy making and I accept that with open arms (…) it is fine to me that an obstetrician calls me and asks 'why you did this?', I find this pleasant, we can learn something from that (…) but not pointing the finger or um that is not a pleasant collaboration to my opinion (Midwife11)*

> *It is convenient to have different hospitals [to work with, with different protocols] which enable you to advise women: I would do that in hospital X and that in hospital Y (Midwife5)*

In this theme, the other themes we observed converged: in positive collaborations there seemed to be more room for physiological aspects of birth and woman's preferences. In case of difficult collaborations, medical thinking and local protocols dominated and midwives had to have a more assertive personality and good scientific

knowledge in order to realise women's preferences and physiological birth

Organisation of care

The interviews revealed how the organisational aspects of care influenced clinical decision-making. For example, legislation regarding the working conditions for ambulance drivers forbids lifting persons above a certain weight. This limits homebirth and was explicitly taken into account in midwives' clinical decision-making.

> *In our area it is above 100 kg (…) if they live in an apartment building [with no elevator] than they have to give birth on the ground floor (…) that is the local agreement because of the lifting of women [by the ambulance drivers] (Midwife9)*

Considerations of competition between midwifery practices also play a part in decision-making. Where midwifery practices offer non-medically indicated ultrasounds to women, other practices in the area feel pressured to do the same. Also the quality of medical facilities, financial considerations, the hour of the day, and busy shifts in a midwifery practice or in the referral hospital influenced decision-making.

> *Sometimes you enclose the hour of the day in your decision (...) or the weekend (…) or if you live somewhere um a quarter of an hour driving um you include that in your decision (Midwife4)*

Care for obese women

The care for obese women proved to be a good example of the way the above described different elements work together. When responding to the vignettes, midwives aimed to treat these women as they would other women, supporting them in a healthy lifestyle and striving for a pregnancy and a birth that are as physiological as possible.

> *My experience is that most of the women with overweight or obesity like it to be in primary care because we approach them physiologically just as any other woman. (M3)*

> *We see more and more women with overweight and I don't have a value judgement on that (…) we have a dietician who gives the first advice for free as a service and if women want she can support during pregnancy (…) we can try together to prevent a high gestational weight gain (…) but sometimes women find it very stressful because they do not manage (…) I try to reassure them: it [managing an optimal weight gain] is not the most important thing, you know (…) (M11)*

But at the same time, regional guidelines for the care of obese women set the boundaries of primary care and these boundaries differed between regions. Furthermore, in their practice with obese women, midwives differed in how they respected the boundaries found in the guidelines.

> *In case of a BMI ≥35 we advise a midwife-led hospital birth; when women want to have a homebirth we explain that there are some risks such as more blood loss (…) but if women really want a homebirth despite the information (…) if someone gave birth the first time without any blood loss problem, I do not expect a postpartum haemorrhage just because of a BMI of 37 (…) it is no problem for me to support this homebirth (M5)*

Discussion

This study gives us a more complete view of the factors driving the clinical decisions of midwives. Theoretically, evidence based decision-making rests on three pillars: clinical evidence, the expertise of the professional, and the values of the woman. In our study, we found these pillars did play a role in the themes 'sources of knowledge', 'the midwife' and 'the pregnant woman as whole person'. With regard to the midwife, however, clinical decisions were influenced by far more than her expertise (e.g. her education, experience, and intuition). Her attitude towards physiology of birth, woman-centredness, shared decision-making, and collaboration, as well as her personal circumstances, helped to shape her decisions. Two additional factors - 'collaboration between maternity care professionals' and 'organisation of care' - also played a role. Our findings correspond with those from other studies, confirming that clinical decision-making is a more varied and complex process than the EBM framework suggests. [4-14, 30]

We also found that the clinical decision-making of midwives was influenced by the nature and content of the local collaboration with maternity care professionals. Although midwives and obstetricians share the goal of providing the best care for mother and child, their collaborative efforts to achieve this goal are challenged by their different philosophies of care and different practice styles. [31-33] Downe et al. [34] suggest that the trend toward risk aversion and the medicalisation of childbirth may exacerbate this polarisation between obstetricians (who typically support this trend) and midwives (who typically resist it). We observed that midwives struggled with this inter-professional tension in their collaborations with obstetricians. Like O'Connell et al. [35] we found their reactions to the tension varied from acquiescing to the system, to living with the conflict, to rebelling against the norms of practice.

In cases of referral or consultation with an obstetrician, midwives felt the need to account for their interventions, and even more, for their decisions to *withhold* an intervention, a phenomenon observed by others among midwives working in hospital

settings and among community midwives, whose independent clinical decision-making is often challenged. [36-38] Since a well-defined philosophy of care and a supportive environment are described as major factors contributing to effective and respectful clinical decision-making, it is the responsibility of both midwives and obstetricians to create the kind of collaborative relationships that will safeguard the rights of women. [39]

In 2009, the Dutch government published a report 'On safe care of pregnancy and childbirth' [40] in response to a perceived problem of high perinatal mortality rates in the Netherlands. [41] An important recommendation was to reinforce local collaboration among primary, secondary and tertiary maternity caregivers. A few years later, the Ministry of Health proposed a reorganisation of the 'stratified' - i.e., primary and secondary - model of care into an 'integrated' system. This development - which presented both new opportunities and new threats for midwifery care - forms an important backdrop for our study and helps to explain our findings.

Local protocols - which were a key factor in shaping our respondent's clinical decision-making - are a product of this newly intensified local collaboration. As we noted in our study, the recommendations regarding care for obese women are different in different localities, since in the absence of evidence, protocols are established based on consensus between professionals. At this point, differences in risk perception and in philosophy regarding physiological childbirth between obstetricians and midwives and *among* midwives play an important role in prescribed pathways for care.

Midwives are involved in both the creation and the implementation of these protocols. Some, but not all, of participants were actively involved in the - interdisciplinary - writing of protocols. Those who were involved were not always pleased with the quality of the process or the results. We discovered that the nature of the collaboration played an important role in shaping the local protocols: when there was an equal and constructive collaboration, a positive attitude toward promoting physiology, and little interprofessional difference in the perception of risk, there was more room for a physiological approach to care. In addition, the midwife's professional knowledge (EBM) and personal skills (communication, negotiation), in combination with a positive attitude towards physiological birth, helped to realise the goal of developing protocols that supported physiological approaches to care. Our research confirms the finding that midwives feel empowered to withstand a medical approach and a non-supportive professional environment when they can rely on 'physiological' guidelines. [33] Because guidelines reflect the views of their creators - on care and risk - and are not just products of evidence, midwives must be involved in the development of national and local guidelines in order to insure the incorporation of their physiological orientation.

Corresponding with the findings of Porter et al. [30], characteristics of the midwife played an important role in how the protocols were used in everyday practice. Midwives with strong and positive attitudes toward the promotion of physiological birth and woman-centredness invested more in empowering women to make their own choices. They applied the guidelines on a case-by-case basis instead of a "one size fits

all" approach and were more willing to discuss women's preferences with obstetricians when relevant. On the other hand, we also observed that midwives may be 'medicalised' by their environment, [8, 35] underscoring the importance of a continuous and critical reflection on one's attitude toward, and knowledge of, physiological birth.

The variety of factors influencing decision-making and the complex relation between them may explain the variation in intrapartum referral rates as found (inter)nationally. [4-6] Variation in clinical decisions is inevitable if care is tailored to the specific circumstances and preferences of women. However, different studies have shown that the complexity of decision-making may contribute to unwanted variation in clinical decisions, limiting a woman's opportunity for physiological pregnancy and childbirth. [5, 6, 8] We found that the treatment of pregnant and birthing women varied between locations and between professionals within each location, as did the promotion and protection of physiological birth. Midwives are often regarded as the protectors of physiological birth and our study provides insight in how different midwives experience and execute that role in everyday clinical decision-making. Given the strong evidence that the increasing medicalisation of birth does not necessarily contribute to better outcomes for women and their babies - and may even do harm [42-47] - midwives should reconsider and strengthen their role of the protectors of physiological childbirth.

Strengths and limitations of the study

This was a study of eleven midwives working in primary care, so our results may not be generalisable for all midwives working in primary and secondary care. However, as with all qualitative research, our goal was not statistical representation, but a rich understanding of the behaviour of our participants. It may be that social desirability influenced midwives' responses, although in their evaluations of the interviews, all participants indicated that they felt safe to speak freely. Our study is based on self-reports. Studies using observations are required to confirm that what midwives reported is actually what they do. A strength of this study is the use of the vignettes and the Thinking Aloud Method in the context of a semi-structured interview, a combination that enabled us to obtain a broad and in-depth perspective on clinical decision-making.

Conclusion

Our study contributes to the understanding of how decisions are made in the everyday clinical practice of midwives. Although the model of EBM informs midwives' clinical decision-making, it does not fully explain the result and process of their decisions. The professional and personal skills and the attitudes of the midwife in interaction with women and with the other members of the caregiving team and the organisation of care, play an important role in decisions that help to realise the goals of evidence-based care.

Results of this and future research on the non-clinical factors that influence the clinical decisions of midwives should be used to educate and empower (student) midwives. If midwives want to succeed in promoting and protecting physiological birth they need to understand how clinical decisions in the context of a multidisciplinary collaboration are actually made. In particular, our finding that constructive collaboration is critical for the promotion of physiological childbirth, underscores the responsibility of maternity care professionals to create an authentic collaborative culture.

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Chapter 8

General discussion

That is a strict policy here (…) with a BMI of 32, a midwife-led hospital birth is advised'

'BMI of 32 is for us no reason to advise birth at the hospital'

The general aim of this thesis was to learn more about the distribution of weight and weight gain among Dutch pregnant women and to better understand the results of midwife-led primary care related to women's weight and weight gain. The research described in this thesis contributes to the body of knowledge on these issues and provides relevant information to guide the clinical decision-making of primary care midwives.

We first investigated the prevalence of obesity as well as the patterns of gestational weight gain in relation to BMI among women eligible for primary midwife-led care after antenatal booking. We then explored the impact of obesity on the likelihood of remaining in midwife-led care throughout pregnancy and childbirth and the effect of parity on the association between BMI and perinatal outcomes. We compared the likelihood of referral from midwife-led to obstetrician-led care among women eligible for primary midwife-led care after antenatal booking between the various GWG classes using two different GWG guidelines. We went on to explore whether obese pregnant women in midwife-led practices delayed or avoided prenatal care. Finally, we studied factors that influence midwives' clinical decision-making in their care for the individual obese woman.

In this chapter, we summarise and reflect on the main study results, review the strengths and limitations of our study, and present recommendations for maternity care practice and for future research.

Main findings

Prevalence of obesity and pattern of GWG

We performed a secondary analysis of a prospective cohort study among pregnant women, eligible for midwife-led care after the first antenatal visit and found that 29.6% were overweight and 15.1% were obese according to the WHO BMI classification of their first trimester BMI. The mean gestational weight gain between 12 and 36 weeks of pregnancy was 11.3 kg (SD 4.2). Applying the 2009 IOM recommendations for GWG to this population, we find that 60 % deviate from the recommended GWG: 33.4 % of the women gained too little weight and 26.7 % gained too much (chapter 2).

Impact of high BMI on perinatal outcomes

With this study among 1369 women eligible for midwife-led care after the antenatal booking appointment, we aimed to assess the impact of obesity on outcomes of midwife-led pregnancy and midwife-led childbirth. Although the percentage of women remaining in midwife-led care during pregnancy declined across weight classes - from 75.4% of normal weight women to 54.7% of women in obesity classes II-III - multiple regression analysis showed that only obese class II-III women had significantly fewer midwife-led *pregnancies* than normal weight women. All overweight classes had fewer midwife-led *childbirths* than normal weight women (64% normal weight, 61.9% overweight, 52.2% obese class I en 54.3% obese class II-III women). Obese women who completed a midwife-led birth had no more adverse outcomes than overweight and normal weight women, with the exception of higher rates of LGA >97.7 centile (12.1% versus 1.9% in normal weight and 3.3% in overweight women) (chapter 3). In our regression model, parity and BMI proved to be independent predictor variables of midwife-led pregnancy and childbirth (chapter 3) however, multiparity counterbalanced the effect of BMI: multiparous obese class II-III women had a higher likelihood of a physiological childbirth than nulliparous normal weight women (chapter 4).

Effect of a deviating GWG on perinatal outcomes

Subsequently we explored the effect of a deviating GWG using two different guidelines - a 'traditional' GWG guideline (optimal GWG between 10 and 15 kg) and the IOM guideline giving GWG advice in relation to BMI classification - on the likelihood of being referred from primary to secondary care. Only GWG above 15 kg (between 12 and 36 weeks of pregnancy) proved to be associated with a significant increase (almost double) in the odds of referral to obstetrician-led care. Gaining weight outside the IOM guidelines and GWG <10 kg did not predict referral to obstetrician-led care. Regarding indications for referral and birth outcomes, GWG >15 kg was associated with higher risks of referral for hypertensive disorders and for meconium stained amniotic fluid (chapter 5).

Obesity and the use of prenatal care

In order to examine the effect of BMI on the use of antenatal care, we performed an exploratory study among a cohort of 4421 women in midwife-led care who received antenatal care and gave birth between October 2012 and October 2014. On average women initiated care at 9.3 (SD 4.6) weeks of pregnancy, had a mean of 11.8 (SD 3.8) face-to-face antenatal visits and a mean of 2.2 (SD 2.6) contacts by phone. With increasing BMI women started their care somewhat earlier, and had more antenatal visits and contacts by phone. However, the differences were not clinically relevant and

BMI explained only a small amount of the variance *(R^2)* of initiation of care (0.2%), antenatal visits (0.1%) and contacts by phone (1%). These findings indicate that obese pregnant women in midwife-led practices do not delay or avoid prenatal care and that taking care of pregnant women with a high BMI does not substantially add to the workload of primary care midwives (chapter 6).

Clinical decision-making in midwife-led practice

In individual interviews midwives were asked to verbalise their thoughts while coming to clinical decisions in specific, written situations concerning obese women during pregnancy, childbirth, and puerperium. Five themes emerged that influenced midwife's decisions: views of the pregnant woman, sources of information, attitudes and characteristics of the midwife herself, the nature of the collaboration between maternity care professionals, and the organisation of care. The midwife herself played a crucial role in the final clinical decision: besides her expertise, other factors - including her attitude towards physiology, woman-centredness, shared decision-making and collaboration with other professionals - and her personal circumstances played a part in the outcome of the decision-making process. Clinical decisions of midwives were greatly influenced by locally-developed protocols for care and by the nature of the collaboration with obstetricians in their local area (chapter 7).

Reflection on the findings

At the outset of our study we stated that there was only scarce knowledge to underpin primary care midwives' risk assessment and care according to weight and weight gain in pregnancy and childbirth. Internationally perceived risks of poor perinatal outcomes in women with obesity, lead to the question of whether elevated BMI should be treated as an indication for referral to obstetrician-led care or as a risk modifier of obstetric pathology that can be timely detected in midwife-led care.

Research into midwife-led primary care

An adequate evaluation of midwife-led care requires more than defining women who are registered in midwife-led care practice at the outset of their pregnancy and investigating their perinatal outcomes after birth. [1] Dutch midwife-led care is based on a system of ongoing risk assessment from the first antenatal visit to the last visit of the woman in the puerperium. [2] Consequently, the risk profile of the woman may change throughout pregnancy and childbirth and, as a consequence, the appropriate setting of care - including facilities to diagnose and intervene and the lead maternity caregiver - may also change. To evaluate midwife-led care properly the complete care pathway of

women through midwife-led and obstetrician-led care in pregnancy and childbirth must be considered. [1] To study the outcomes of women in midwife-led care with regard to BMI and weight gain we therefore started our study among women eligible for midwife-led care after antenatal booking. We followed this group of women and studied the population of women remaining in midwife-led care at the outset of labour, and the women who actually delivered in midwife-led primary care. In the obesity study, we also considered both referred and non-referred women during pregnancy and childbirth since striking results across BMI classes in the referred group may be influenced by the preceding midwife-led care and may, therefore, provide valuable information for improving care.

In the obesity study we chose to use salutogenically-focused outcomes namely 'the completion of a midwife-led pregnancy' and the 'completion of a midwife-led childbirth' as primary outcome measures. Salutogenically- focused outcomes reflect health and well-being rather than illness or adverse events. [3] From a midwifery perspective, we were interested to learn if obese women could experience the benefits of a physiological childbirth and we wanted to weigh the evidence of increased risks of adverse outcomes. Our choice was also based on the need to contribute to the ongoing debate on the best outcome measures to evaluate maternity care. [1, 4] In general, outcome measures to evaluate maternity care reflect the assessment of safety and are operationalised as adverse outcomes or required interventions (i.e., the pathogenic paradigm). [4] But safety is an ambiguous concept that lacks an agreed-upon definition and interpretation may depend on differences in professional interests and philosophies. [4, 5] We recognise that 'maintaining a healthy pregnancy for mother and baby (including preventing and treating risks, illness and death)' is important for healthy pregnant women, but following Downe et al.[6], we are aware that other outcomes matter to women such as 'maintaining physical and sociocultural normality, effective transition to positive labour and birth and achieving positive motherhood' (i.e., the salutogenic paradigm). In 2016, the working group Pregnancy and Childbirth of the International Consortium for Health Outcomes Measurement (ICHOM) published a standard set of outcomes to be used in research that takes into account the broader spectrum of what matters to women, and it includes some salutogenically-focused outcomes. The working group recognises the complexity of gathering data in maternity care systems with distinct care providers and settings but leaves the initiative to deal with this issue to the researchers. [7]

In the GWG study we decided to use 'referral to obstetrician-led care in pregnancy' and 'referral to obstetrician-led care in childbirth' as primary outcomes. In midwife-led primary care and registration, referral is a principal outcome since it reflects the transfer to obstetrician-led care and - therefore - is a logical choice for primary outcome. Referral is a composite outcome and can serve as a proxy measure for adverse outcomes that requires higher level care: Midwives refer women to obstetrician-led care when risk factors or complications - as defined by national and regional guidelines - arise. [2] The use

of this composite outcome fits well with our purpose to study the overall perinatal effect of different GWG classes, which are known to have differing effects on perinatal outcomes for mother and child. [8] By using referral we were able to balance these effects in a way they were only considered relevant if they required referral. Moreover, using a composite outcome may help to overcome the power problem when studying individual adverse outcomes in primary care populations with a low prevalence of some of these outcomes. On the other hand, our experiences taught us that referral is a difficult outcome measure to interpret by professionals who are not familiar with the Dutch maternal care system. Because this outcome is so strongly linked with the Dutch 'dual' system, it does not enable easy comparability with international research. [1, 7] Furthermore, and importantly, as we showed in chapter 7, 'referral' may not be the objective measure we thought it was. We found that clinical decisions are influenced by a number of factors - not all of which are rational - such as views of clients and professionals on maternity care, perceptions of risk, attitude of the midwife in local multidisciplinary collaboration, and (different) local protocols. This finding suggests an explanation for the considerable variation in intrapartum referral rates between midwife-led primary care practices described by Offerhaus et al. [9]

Evidence on weight and weight gain to found midwife-led primary care

Obesity

Our studies reveal that a high BMI does impact the pregnancy and childbirth of healthy women without comorbidities at the outset of pregnancy. With increasing BMI class there is a decrease in the likelihood of physiological pregnancy and childbirth. In general, these findings are in line with international evidence indicating higher risks of adverse perinatal outcomes for obese women. [10-23] But our results also provide us with more detailed and nuanced information that can be helpful in designing midwife-led care.

We began by examining the magnitude of the 'problem' of obesity in primary midwife-led care. Because the prevalence of first trimester obesity (15%) in our midwife-led care population was nearly the same as the prevalence reported in national figures (10.8 - 12.1% for women 20 years and older in 2002-2004) [24] and our data came from an average Dutch population, we can assume that the majority of obese women who become pregnant do not have comorbidities that require referral to obstetrician-led care. In light of this fact - that most obese pregnant women are considered healthy at the outset of their pregnancy and start their care in midwifery practices - our research is especially important.

We subsequently investigated the results of women in primary midwife-led care in relation to their BMI class between 2002 and 2004. In this period guidelines made no distinction in care pathways for women in different BMI categories. We found that while women in the highest obese class (BMI ≥35 kg/m^2) were *more* likely to be referred

during pregnancy and childbirth, more than half experienced an uncomplicated pregnancy and - in the group that experienced a physiological pregnancy - 54.3% had an uncomplicated childbirth. Second, we found that multiparity positively counterbalanced the adverse effects of higher BMI classes, with the result that obese multiparae in class II-III had a higher likelihood of a physiological childbirth than nulliparae with normal weight. Third, BMI had a stronger impact during childbirth than during pregnancy. While only women with BMI ≥35 were significantly less likely to remain in midwife-led care during pregnancy, women of *all* higher BMI classes (BMI ≥25 kg/m^2) were significantly less likely to experience an uncomplicated childbirth. Fourth, for women who were referred during pregnancy, BMI had no effect on the moment of referral. Fifth, although BMI class negatively influenced the likelihood of physiological pregnancy and childbirth, it only explained 1.5 % of the variance of the outcome 'midwife-led pregnancy' and 1.7% of the variance of the outcome 'midwife-led childbirth'. This finding puts the importance of BMI class in relation to the outcomes of women in primary midwife-led care into perspective. As far as we know, these effects of BMI have never been investigated in the context of the 'dichotomous' model of the Dutch maternity care system.

Our analysis of secondary outcomes - the specific indications for referral and birth outcomes - provide further information about the results of midwives' risk assessment in relation to women's BMI. Although our study in chapter 3 lacked the power required to study the effect of BMI class on all individual indications for referral and all birth outcomes, we were able to study the effect of obesity on the eight most frequent reasons for referral to obstetrician-led care. We found an association only between obesity and referrals for hypertensive disorders, prolonged labour, and request for pain relief. These findings are consistent with the results of international studies [12, 16] and, in the context of the Dutch maternity care system, are all considered deviations from the physiological process of pregnancy and childbirth. These deviations are addressed in the established risk assessment guidelines and are therefore part of the usual care delivered by midwives. [2]

Additionally, we thoroughly studied birth outcomes in women from different subgroups, namely women in the whole study population, women referred and not referred during pregnancy, women referred during childbirth, and women with a physiological pregnancy and childbirth. In analysing these outcomes, we found no indication of unfavourable outcomes in relation to BMI class that were traceable back to inadequate midwife-led risk assessment. In the subgroups we saw the same pattern of unfavourable outcomes: obesity was associated with a higher risk of induction of labour, pain relief, caesarean section and LGA >97.7 centile which - again - corresponds with international findings. [16-18, 22, 23] Finally, we found a 5.5% urgent referral rate during midwife-led childbirth which was not affected by BMI class.

Based on all this information we believe that obesity can be considered as a risk modifier of obstetric pathology and not as a medical condition that, in itself, requires

obstetrician-led care. The usual risk assessment by midwives, based on agreed-upon guidelines, proved to safely assign obese women to either midwife-led or obstetrician-led care.

Our findings provide information that can be used to optimise care for obese women in both midwife-led and obstetrician-led care. A notable outcome of our study is the association of obesity with prolonged labour and request for pain relief, a finding that has been reported elsewhere.[16] This suggests the need for counselling that will help pregnant women prepare for childbirth both physically and mentally and for continuous support during labour based on a woman-centred approach that empowers women to realise optimal birth experience and outcome. [25, 26]

In the total study population, the rate of LGA >97.7 centile babies for obese women was 10.5 %, compared with 2.5% in normal weight and 4.1 % in overweight women. Because LGA and macrosomia (15% of the newborns in our study had birth weights of >4000 g) are related to both short and long term complications, finding ways to prevent this is needed from an obstetric and public health point of view [27-37]. One way might be addressing excessive weight gain as international literature suggests a possible influence of excessive GWG on LGA (chapter 3). [38] However, we found no association between excessive GWG and LGA >97.7 centile after adjusting for BMI and parity in our study of GWG (chapter 5). Preventing excessive GWG did not guarantee a smaller number of LGA babies in our study population. An alternative way to reduce the rate of LGA babies is a stricter GDM screening protocol among obese women. Maternal GDM increases the risk of macrosomia and LGA in the offspring [39-42] and exacerbates some of the short- and long term complications related to LGA and macrosomia. [27, 30, 34, 35, 43] A stricter GDM screening protocol may find more women with GDM and the subsequent control of maternal glucose levels may result in fewer LGA and macrosomia. [40-42, 44] In the Netherlands, a variety of methods of GDM screening have been used in midwife-led as well as in obstetrician-led care.[45] In this study a selective screening protocol was used among women who met the criteria, including high maternal weight and excessive weight gain, LGA in history, and suspected LGA in the target pregnancy. In 2010 the NVOG published a new guideline with the advice to screen women with a higher risk of GDM at the outset of pregnancy and again between 24 and 28 weeks of pregnancy. [46] Strikingly, a secondary analysis of the HAPO study revealed that high birthweight (>90 centile) was strongly associated with higher maternal BMIs independent of variations in glycaemic exposure. [47] This finding indicates that the pathophysiology of LGA in relation to obesity is a complex phenomenon which complicates the implementation of adequate preventive measures.

The use of prenatal care

Having found that the quality of midwife-led care could be guaranteed for obese women compared to normal weight women, we became interested in the association between BMI class and the use of prenatal care. Although we did not find indications

that obesity may be a barrier to use maternity care [48, 49], there are signals in literature that obese women are more likely to withdraw from care. [50-53] In our study, we looked at the timing of the initiation of care and the number of face-to-face visits and contacts by phone and found that obese women are not more likely to drop out of midwife-led primary care (chapter 6). On the contrary, they start care somewhat earlier and have somewhat more visits and phone calls compared to normal weight women. While significant, these differences were too small to be clinically relevant and too small to conclude that they were an extra burden on midwives. Using R^2, BMI class explained just 0.2% variance in the initiation of care, 0.1% for prenatal visits and 1% for phone calls. Although we can conclude that taking care of obese women does not challenge midwives' workload, we know from our obesity study that especially the increased referral during childbirth may impact the organisation of acute obstetrician-led care in hospitals (chapter 3). We were not able to study use of primary care offered by professionals other than midwives, but we expect more use of diagnostics (e.g. ultrasound, glucose screening tests) and treatment (e.g. dietician, physiotherapist) of obese women. [54]

Gestational weight gain

Our study of the patterns of GWG provided us with updated knowledge on the physiological process of gaining weight in pregnancy. Our findings - that women gained on average 11.3 kg of weight between 12 and 36 weeks of pregnancy, [55, 56] that nulliparous women gained more weight than multiparous women, that with increasing BMI women gained less weight, [56-60] and that overweight and obese class I women had a higher risk of exceeding GWG (chapter 2) - can be applied to tailor care on GWG for individual women. Remarkably, we found that if the 2009 IOM guidelines on GWG were to be implemented in our population, 60% of the women would have deviated from the guidelines. Moreover, the prevalence of falling out of the IOM recommendations in our study differed substantially from US figures: we found twice as many women with *insufficient* GWG (33.4% versus 16.7%) and half of the number with *excessive* GWG (26.7% versus 52,6%). [61] These findings lead us to question the validity and applicability of the IOM guidelines for the Dutch midwife-led care population. Our study of the effect of GWG on perinatal outcomes - in a period (2002-2004) when there were no guidelines for (referral because of deviating) GWG - confirmed our doubts about the usefulness of the IOM guidelines. We found no association between insufficient or excessive GWG according to the 2009 IOM guidelines and adverse perinatal outcomes. A result that contrasts with international studies confirming the effectiveness of the 2009 IOM guidelines [62-72] but agrees with studies that propose lower and/or wider optimal ranges than those of the IOM guidelines. [73-76]

We compared IOM guidelines with a Dutch 'traditional' recommendation for optimal GWG between 10 and 15 kg (measured between 12 and 36 weeks of pregnancy) and found that only GWG >15 kg was associated - irrespective of women's

prepregnancy BMI - with almost doubled odds for referral during childbirth. Looking at the reasons for referral in the group with GWG >15 kg, we found a higher risk of referral because of hypertensive disorders in pregnancy and for meconium stained amniotic fluid in childbirth. These findings, however, must be carefully applied as GWG categories explained only 1.2% of the variance in the outcome 'referral in childbirth'. GWG did not affect pregnancy outcomes.

Overall, based on these findings we may conclude that for healthy women, targeting GWG as a means of preventing adverse perinatal outcomes is not very efficient. However, there are still some reasons to be concerned with GWG. Women with excessive GWG have a higher risk to permanently end up with an increased BMI after pregnancy which is associated with an increase of complications in subsequent pregnancies [77, 78] and may cause general health problems. [79-82] Although BMI and GWG class are independent determinants of adverse perinatal outcomes, in practice the effects of both - especially regarding referral during childbirth - may add up in individual women.

Taking this all into account, in our midwife-led care population a general GWG recommendation of not gaining more than 15 kg between 12 and 36 weeks seems - at the moment - to be more appropriate advice than the use of the 2009 IOM guidelines.

The use of evidence in clinical decision-making

In our contacts with professionals caring for women with a higher BMI we noticed the differences in clinical decisions. This made us curious about the use of evidence based medicine (EBM) in the care of individual women. We performed a qualitative study and observed that midwives' clinical decision-making seems to be a much more variable and complex process than the EBM framework suggests.

This framework describes a rational process where autonomous professionals critically evaluate the research evidence and apply it to their care for individual women. In this model the context of the clinical decision-making process is not mentioned, but we found a significant influence of context on clinical decisions. While midwives are an independent medical profession, they function within a collaboration of maternity care professionals and organisations. In the Netherlands, these collaborative relationships are becoming more institutionalised with the movement toward more integrated maternity care. In our study, we found midwives experiencing tension within this collaboration as a result of differences between caregivers in philosophies of care, in perceptions of fear and risk, and in levels of trust in normal childbirth. We also found that difficulties within interprofessional relationships - generated by differing levels of institutional power and control, lack of trust between professionals, and conflicting professional interests - threaten constructive collaboration. [5, 83, 84]

This tension between professionals also impacts the content of care. Ideally, local protocols are based on (inter)national guidelines or research findings. However, there is

not always evidence to underpin aspects of care that matter in daily practice. Regarding care for obese women, there is a lot of evidence of higher risk of adverse outcomes, but not much on the best care to support pregnancies and childbirths of low-risk obese women in the context of the Dutch 'dual' maternal care system. This is reflected in the low levels of evidence (D-Level) of the few recommendations in the NVOG guideline 'Pregnancy and Obesity' that are relevant for midwife-led care. [85] In the absence of convincing evidence, local protocols are constructed based on consensus agreements between maternity care professionals. In this situation, the above-described collaborative tensions will influence the outcome of the consensus procedures and can lead - despite midwives' involvement - to protocols that do not (fully) correspond to midwives' views of best care. Although professionals can deviate from guidelines based on well-considered arguments, [86] midwives did not always feel free or capable to do so. Thompson et al. [87] found that Dutch community midwives feel they have to fully explain their decisions to obstetricians and obstetric nurses, even when these decisions are about their own field of expertise. In sum, midwives' clinical decision-making is significantly affected by the colleagues they collaborate with and by their own professional and personal skills to adequately interact with those colleagues.

Internationally, there is a growing critique of the model of EBM based on - amongst other arguments - an unmanageable number of guidelines, with recommendations that are not always tuned to the (complex) situation of the individual client, [88] and often based on low levels of evidence. [89] Most protocols do not clarify a woman's role in decision-making and do not take into account women's preferences or needs. [90]

A return to the 'real' evidence based medicine has been proposed. This approach puts the client at the centre of the model by asking: 1) what does the woman wants? 2) what is the evidence? and 3) what is the professional's experience with similar clients? [88, 91] Most women want to have an active role in their care during pregnancy and childbirth. Being involved in decision-making contributes to a woman's sense of control and a more positive birth experience. [92] Interestingly, we found that midwives with strong and positive attitudes towards the promotion of physiological birth invested more in empowering their clients to make their own choices and were more willing to fit the guidelines to the needs of their clients and to negotiate women's preferences with obstetricians. Hall et al. found an association between professionals' different attitudes to shared responsibility with women and their ability to relinquish control. Those who were confident in sharing power and responsibility with women were more likely to be able to resist unnecessary interventions. [93]

Trusting relationships between women and professionals are crucial to the realisation of true partnerships with women. [93, 94] In the Netherlands where 86.3% of women start their care in midwife-led practices [95] and midwife-led care is well appreciated by women, [96] a substantial basis for 'real' evidence based medicine is already in position. Dutch women trust their maternity caregivers, but do maternity caregivers trust their clients enough to share responsibility and control?

Strengths and limitations

This thesis contributes new evidence to the body of knowledge on weight and weight gain of pregnant women in the context of the Dutch maternity care system. By studying outcomes of women eligible for midwife-led care at the outset of their pregnancy until the puerperium - whether they remained in midwife-led care or were referred to obstetrician-led care - we got valuable information about the results of midwives' risk-assessment - based upon agreed risk assessment tools - in relation to women's BMI and GWG. Furthermore, we gained useful insights about the use of evidence and the influence of other factors in determining appropriate care for an individual woman in daily midwifery practice. These topics had not been the subject of extensive studies to date, especially not in the context of the Dutch maternity care system.

We were able to examine the impact of obesity itself on the course of pregnancy and childbirth by using data from a period before the implementation of guidelines on obesity that continues to influence risk assessment and outcomes. Calculation of BMI and weight gain was based on objectively measured weight at fixed moments in pregnancy. By using referral in pregnancy or childbirth as primary outcomes in the GWG study we were able to provide insight into the overall - and sometimes opposite - effect of GWG classes on adverse perinatal outcomes. The multimethod approach of our qualitative study enabled us to obtain a broad and rich perspective on clinical decision-making.

For our studies of obesity and GWG, we performed secondary analyses of a prospective cohort study which allows findings of associations but not judgements of causality. By doing secondary analyses we might have overlooked biases and confounders in the primary study that we were unaware of. [97] Because we used data from existing databases we lacked data on issues that were interesting in relation to our research questions, such as information on women referred to obstetrician-led care before 36 weeks of pregnancy because of preterm birth (in the GWG study -chapter 5) or the amount of care provided by primary care professionals - other than midwives - to obese women (chapter 6). The generalisability of our study is limited because only Dutch speaking women of Northern European descent were included. As known in studies of low-care populations, some adverse outcomes were too rare to have enough power to be able to detect significant associations. We dealt with this by using the composite outcome of referral in pregnancy or childbirth: a relevant outcome in Dutch maternity care, but difficult to interpret in the international context.

Implications for practice

Based on the findings of this thesis we can conclude that obesity in healthy women is not a medical condition that requires significant adaptations in daily midwifery practice.

We did not find a reason to consider obesity in itself as an indication for referral to obstetrician-led care: midwives proved to be able to safely assign obese women to either midwife-led or obstetrician-led care, using customary risk assessment tools. Obese women did not delay or avoid prenatal care. Midwives aimed to treat obese women the same way as their other clients, to support their lifestyle and to strive for a pregnancy and childbirth as physiological as possible.

Considering the current guidelines and local protocols on obesity we advise the removal of explicit thresholds for obstetrician-led care and for homebirth. The current move towards integrated maternity care opens the door to a more woman-centred, tailor-made approach of supporting woman with higher BMI's in relation to these topics. Professionals need to include the broader perspective of woman's preferences and characteristics, such as parity, in the consideration of best care or preferred place of birth.

Regarding GWG we learned that it is important to valorise guidelines before implementing them. Based on our findings, striving for a GWG of not more than 15 kg proves to be good advice and gaining less than 10 kg may be acceptable in case of an uncomplicated pregnancy and healthy lifestyle.

On a more detailed level, our findings provide tools for midwives. Our findings can be used for tailor-made prevention programs, and for information and support on weight and weight gain with special attention to the support of obese women regarding labour pain and the duration of labour and how these are shaped by parity and BMI class.

Regarding clinical decision-making, midwives need to be aware of the complexity of the clinical decision-making process in a multidisciplinary context and the variety of factors that are involved. Every midwife needs to be conscious of her EBM skills, her attitude towards physiology of childbirth, woman-centred care and shared decision-making and collaboration with other professionals. Critical review of these important aspects of care will allow midwives to the skills and attitudes that protect and promote physiological pregnancy and birth. All midwives should actively take up their role in the development of guidelines and protocols - in both the construction itself and the critical appraisal of the concepts - in order to support the physiological approach of childbirth and to make room for clients' perspectives in clinical decision-making. Midwives need to contribute to the implementation of the 'renewed' model of EBM, respecting women's preferences and using the available evidence critically to achieve best care from the perspective of the client and the professional.

Since constructive collaboration is critical for the promotion of physiological childbirth, every maternity care professional must take responsibility for creating an authentic collaborative culture.

Educational programmes should be directed at empowering (student) midwives in their clinical decision-making in a multidisciplinary context, especially considering the current move to integrated maternity care.

Implications for future research

Regarding obesity and GWG we recommend repetition of our research with larger samples of women eligible for midwife-led care at the outset of pregnancy and across different subpopulations (ethnicity, lifestyle, socio-economic status). This repetition will address the above-described limitations of generalisability, small numbers of uncommon adverse outcomes, and missing data. A larger study would enable a more detailed evaluation of care for women in higher obesity classes. Regarding GWG, repeated research to validate our recommendations is needed. Studies including research on long-term outcomes such as postpartum weight retention, health outcomes of women and children will enhance the ability of caregivers to give useful advice about GWG. Studies focusing on gestational weight loss in obese women of different categories would complete our knowledge in this area. Research on perinatal outcomes of underweight women including the effect of different categories of GWG for this population will provide important knowledge regarding women in all BMI categories.

In the context of integrated care it would be interesting to evaluate new models of care in relation to obesity based on protocols without thresholds for obstetrician-led care or place of birth and including a more woman-centred and tailor-made approach on these topics.

Regarding the use of prenatal primary care by obese women, future research should address additional aspects of prenatal care such as the number of consultations with other professionals in primary care, the time spent on visits and phone contact, the difference between scheduled and extra consultations, and diagnostic tests in relation to BMI. Only half of our total study population initiated their care at 8 weeks or earlier as recommended by the national guideline on prenatal care, thus it would be interesting to do a more detailed study of this topic. Research on aspects of the quality of prenatal care and on women's experiences of care will contribute to improvement of prenatal care for obese women.

Our study of clinical decision-making shows the need for further research on the topic. Knowledge of the association between midwives' attitudes - including their perceptions of risk and attitudes towards physiology of birth - and their decisions to refer will provide insight into the observed variation of referral rates. In the context of the move to integrated care, new models of clinical decision-making, including a more prominent place for pregnant women's perspectives, must be developed and their implementation will require further research. If we are to fit educational programs to the need of students and midwives, we must better understand what midwives need to be adequately equipped for clinical decision-making in an integrated care context.

General conclusion

Most obese women are eligible for midwife-led practice at the outset of their pregnancy. Although obesity adversely impacts pregnancy and childbirth, a considerable number of obese women experience normal pregnancy and childbirth. BMI class explains only a small amount of the variance in the occurrence of a midwife-led pregnancy and childbirth. Obesity in and of itself should not be considered an indication for referral, midwives are able to safely assign women to either midwife-led or obstetrician-led care using the agreed upon risk assessment tools. A GWG of not more than 15 kg is useful advice for all women regardless of BMI class. Obese women in midwife-led primary care are not more likely to delay or avoid prenatal care when compared to women who are not obese.

Although the model of EBM informs midwives' clinical decision-making, a variety of additional factors are involved in their decisions. Professional and personal skills as well as the attitudes of the midwife regarding physiology of birth, woman-centredness, shared decision-making, and collaboration with the local maternity care team, play an important role in clinical decision-making. A return to the 'real' EBM, by putting the client at the centre of the model, is needed.

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Summary

Chapter 1
General introduction

At the beginning of the twenty first century obesity entered Dutch maternity care as a 'new illness' challenging maternity care professionals in providing optimal care for women with higher BMI's. International research revealed that obese women had more perinatal problems than normal weight women. However, the effect of higher BMIs on perinatal outcomes had never been studied in women eligible for midwife-led primary care at the outset of their pregnancy. In the context of the Dutch maternity care system, it was not clear if obesity should be treated as a high-risk situation always requiring obstetrician-led care or as a condition that may lead to problems that could be detected in a timely manner in midwife-led care using the usual risk assessment tools.

With the increased attention on obesity in maternity care there was also increased interest in GWG. Regarding GWG in the Netherlands, the effect of insufficient or excessive GWG on perinatal outcomes had never been studied and there were no validated guidelines for GWG.

A midwife's care for the individual woman in the context of the Dutch maternity care system - characterised by 'midwife-led care if possible, obstetrician-led care if needed' - is hampered by the lack of national multidisciplinary consensus regarding obesity and weight gain. Obesity has not yet been included in the OIL and local protocols contain varying recommendations. To enable sound clinical decisions and to offer optimal individual care for pregnant women in the Netherlands more insights in weight and weight gain in relation to perinatal outcomes are required.

With this thesis we intend to contribute to the body of knowledge on weight and weight gain to enhance optimal midwife-led primary care for the individual woman and to guide midwives' clinical decision-making.

Chapter 2
Patterns of gestational weight gain in healthy, low-risk pregnant women without co-morbidities.

This chapter presents the findings of a secondary analysis of a prospective cohort study among 1449 pregnant women, eligible for midwife-led care after the first antenatal visit, from five midwife-led practices. We aimed to examine the prevalence of obesity and the distribution of GWG in relation to the 2009 IOM guidelines for GWG. Weight was measured at 12, 24 and 36 weeks. We found that 1.4% of the women were underweight, 53.8% had a normal weight, 29.6% were overweight and 15.1% were obese according to the WHO BMI classification of their first trimester BMI. The mean

gestational weight gain between 12 and 36 weeks of pregnancy was 11.3 kg (SD 4.2). Nulliparous women gained on average 2 kg more than multiparous women (p <0.000). If the 2009 IOM recommendations for GWG were to be implemented in this population, 60% would have had a GWG outside the recommendations: 33.4 % of the women had insufficient weight gain, and 26.7 % gained excessive weight. With increasing BMI women had a decreasing mean GWG. Overweight and obese class I women had a higher risk of excessive GWG than normal weight women. Normal weight women had a higher risk of inadequate GWG than overweight and obese class I women. Obese women classes II and III were at risk for both over- and undergaining. Since our data show that most women deviated from the recommended GWG ranges according to the IOM guidelines, research on the effect of insufficient and exceeding GWG on perinatal outcomes is required before implementing them.

Chapter 3
The impact of obesity on outcomes of midwife-led pregnancy and childbirth in a primary care population: a prospective cohort study

In this study we aimed to assess the impact of obesity on the likelihood of remaining in midwife-led care throughout pregnancy and childbirth. We analysed data of a prospective cohort study among 1369 pregnant women from Northern European descent, eligible for midwife-led care after the first antenatal visit, from five midwife-led practices. Data were collected between 2002 and 2004, a period before the implementation of national or local guidelines on obesity that nowadays influence risk assessment and outcomes; this enabled us to examine the impact of obesity itself on the course of pregnancy and childbirth.

Although the percentage of women remaining in midwife-led care during pregnancy showed a declining trend from 75.4% of normal weight women to 54.7% of women in obesity classes II-III, a considerable number of obese women remained in midwife-led care. Multiple logistic regression analysis showed that only obese class II-III women had significantly fewer midwife-led *pregnancies* than normal weight women (aOR 0.38; 95% CI 0.21 - 0.69). All overweight classes had fewer midwife-led *childbirths* than normal weight women (64% normal weight, 61.9% overweight (aOR 0.63; 95% CI 0.44 - 0.90), 52.2% obese class I (aOR 0.49; 95% CI 0.29 - 0.84) en 54.3% obese class II-III women (aOR 0.48; 95% CI 0.21 - 1.12)). Obese women had higher referral rates for hypertensive disorders (4% versus 14%; p <0.001), prolonged labour (4.6% versus 10.4%; p <0.05) and request for intrapartum pain relief (4% versus 10.4%; p <0.05) than normal weight women. During midwife-led childbirth, overweight or obese women received no more urgent referrals than women with normal weight. Obese women who completed a midwife-led birth had no more adverse outcomes than overweight and normal weight

women, except for higher rates of LGA >97.7 centile (12.1% versus 1.9% in normal weight and 3.3% in overweight women; p <0.001).

Although fewer women remained in midwife-led care during pregnancy and childbirth, there was no increased risk of unfavourable birth outcomes for obese women eligible for a midwife-led birth when compared with women of normal weight. This indicates that primary care midwives are able to safely assign women who are obese to either midwife-led or obstetrician-led care using the agreed upon risk assessment tools.

Chapter 4
Pregnant and overweight: at home in midwife-led primary care? Multiparity positively affects outcomes of obese pregnant women

In this chapter we used two scientific publications on the association between higher BMIs and perinatal outcomes of low-risk women to provide advice to Dutch midwives on appropriate care for obese women, especially multiparous women. We hypothesised that multiparous obese women would have less adverse outcomes than normal weight nulliparous women. First, we provided a summary of our obesity study described in chapter 3. Second, we presented a summary of a secondary analysis of the English Birthplace study, a prospective cohort study. This secondary analysis among 17,230 women who were low-risk at the start of their birth, aimed to explore the effect of maternal BMI on intrapartum interventions and on adverse maternal and neonatal outcomes. This study also examined whether parity influenced the effect of BMI on the outcomes. Low-risk obese pregnant women had an increased risk of interventions during birth. However, in absolute terms, these interventions occurred less in class II-III obese multiparous than in nulliparous women with normal weight. This study concluded that the risk of interventions in class II-III obese multiparous women is lower than previously assumed.

Inspired by this study we calculated the OR based on the logistic model of our obesity study (chapter 3) for remaining in midwife-led care during childbirth for class II-III obese multiparous versus nulliparous women with normal BMIs (equal characteristics apart from this). We found an OR of 2.19 which means that in our study, class II-III obese multiparous women had a greater possibility of a physiological childbirth than nulliparous women with normal BMIs. In absolute numbers, 84% (n = 16) of class II-III obese multiparous women who started their births in primary care also completed these in primary care, compared to 42.6% (n = 110) of nulliparous women with normal weight.

During pregnancy, the interplay of the factors 'parity' and 'class II-III obesity' worked out differently. We calculated an OR of physiological pregnancy of 0.90, which indicates that class II-III obese multiparous women had a smaller possibility of a physiological pregnancy than nulliparous women with normal weight. In absolute numbers, 56% (n =

19) of class II-III obese multiparous women had a physiological pregnancy, compared to 67% (n = 258) of nulliparous women with normal weight. Based on the two studies, we conclude that a referral indication for childbirth in multiparous women solely based on class II-III obesity appears to be unnecessary. A review of this policy in clinical pathways is recommended.

Chapter 5
The effect of gestational weight gain on likelihood of referral to obstetric care for women eligible for primary, midwife-led care after antenatal booking

This chapter describes a study we performed to examine the effect of GWG on likelihood of referral from midwife-led to obstetrician-led care during pregnancy and childbirth. In a secondary analysis of a prospective cohort study among 1288 pregnant women from Northern European descent, eligible for midwife-led care after prenatal booking, we explored the effect of deviating GWG according to two different guidelines. We compared the effect of a 'traditional' GWG guideline (optimal GWG between 10 and 15 kg) and the IOM guideline (GWG advice in relation to BMI classification) on the likelihood of being referred from primary to secondary care. Only GWG above 15 kg (measured between 12 and 36 weeks of pregnancy) proved to be associated with the likelihood of referral to specialist care (aOR 1.88; 95% CI 1.22 - 2.90). Gaining weight outside the IOM guidelines and GWG <10 kg did not predict referral to specialised care. Regarding indications for referral and birth outcomes, only GWG >15 kg was associated with higher risks of referral for hypertensive disorders (aOR 1.91. 95% CI 1.04 - 3.50) and for meconium stained amniotic fluid (aOR2.22, 95% CI 1.33 - 3.71).

Based on these findings we advise a GWG of less than 15 kg (between 12 and 36 weeks) for all pregnant women irrespective their BMI category.

Chapter 6
The use of midwife-led primary antenatal care by obese women in The Netherlands: An explorative cohort study

This chapter addresses the question whether BMI affects women's use of prenatal midwife-led care. We performed an explorative cohort study of 4421 women, registered in the Midwifery Case Registration System (VeCaS), who received antenatal care in 11 midwife-led practices in the Netherlands and gave birth between October 2012 and October 2014. Women initiated their care on average at 9.3 (SD 4.6) weeks of pregnancy. Multiple linear regression analysis showed that with an increasing BMI

initiation of care was significantly earlier. However, this difference was too small to be clinical relevant and BMI only explained 0.2% (R^2) of the variance in initiation of care. The mean number of face-to-face prenatal visits in midwife-led care was 11.8 (SD 3.8). Linear regression showed that with increasing BMI the number of prenatal visits increased significantly but that increase was not considered clinically relevant. BMI explained 0.1% (R^2) of the variance in number of prenatal visits. The mean number of prenatal contacts by phone was 2.2 (SD 2.6). Multiple linear regression analysis showed an increased number of contacts by phone for BMI categories 'underweight' and 'obese class I'. BMI categories explained 1% (R^2) of the variance in number of contacts by phone.

This study revealed that BMI was not a relevant predictor of variance in initiation of care and in number of prenatal visits. The findings indicate that obese pregnant women in midwife-led practices do not delay or avoid prenatal care and that taking care of pregnant women with a high BMI does not substantially add to the workload of primary care midwives.

Chapter 7
Factors influencing the clinical decision-making of midwives: a qualitative study

This chapter provides insight in factors influencing midwives' clinical decision-making in everyday practice. Ideally, midwives provide evidence-based care, using the best available clinical evidence, their own clinical expertise, and the situation and values of women. However, the wide variation of Dutch midwives' intrapartum referral decisions suggests that other factors may be involved in clinical decision-making. To learn more about how midwives make clinical decisions, we undertook a qualitative study between May and September 2015, conducting in-depth interviews with a purposive sample of 11 independent midwives. Midwives were asked to verbalise their thoughts (Think Aloud Method) while coming to clinical decisions in specific, written situations during pregnancy, childbirth, and puerperium involving obese women (Vignette Method). The interview continued using a semi-structured list of questions. We performed thematic analysis on the transcripts. We found five themes that influenced midwife's decisions: views of the pregnant woman, sources of knowledge, attitudes and characteristics of the midwife herself, the nature of the collaboration between maternity care professionals, and the organisation of care. The midwife herself played a crucial role in the final clinical decision; in addition to her experience, intuition, and personal circumstances, her decisions were shaped by her attitudes about physiology, woman-centredness, shared decision-making, and collaboration with other professionals.

Midwives' clinical decision-making appeared to be a more variable and complex process than the EBM framework suggests. Clinical decisions of midwives were greatly

influenced by locally-developed protocols for care and by the nature of the collaboration with obstetricians in their local area. If midwives are to succeed in their role as guardians of physiological birth, they need to understand how clinical decisions in a multidisciplinary context are actually made.

Chapter 8
General discussion

This chapter presents an overview of the main findings and discusses them in the overall context of the dissertation. Implications for practice and future research are outlined.

Research into midwife-led care

Dutch midwife-led care is based on a system of ongoing risk assessment. Consequently, the risk profile of the woman and - related to this - the setting of care and the lead maternity caregiver may change throughout pregnancy and childbirth. To thoroughly evaluate the results of midwife-led care of women regarding their weight and weight gain, we studied outcomes of the group of women eligible for midwife-led care at the outset of pregnancy, outcomes of the group of women eligible for midwife-led care at the start of labour and outcomes of women with a midwife-led birth, in both referred and non-referred women. In the obesity study we used salutogenically-focused outcomes ('completion of a midwife-led pregnancy' and 'completion of a midwife-led childbirth') as primary outcome measures. We choose these outcomes - which reflect aspects of health and well-being - to counterbalance the overwhelming evidence on higher risks of obesity on adverse perinatal outcomes. To gather evidence on optimal GWG to underpin advice for women at the beginning of the pregnancy, we studied the composite outcomes 'referral in pregnancy' and 'referral in childbirth'. By using these outcomes we aimed to give an insight in the overall effect of GWG on perinatal outcomes rather than the sometimes opposite effects of GWG on individual adverse outcomes. We used composite outcomes to overcome the power problem when studying individual adverse outcomes with a low prevalence in primary care populations. Both salutogenically-focused outcomes and 'referral' are not commonly used in international literature which makes it difficult to compare our results with international studies.

Weight and weight gain

Based on our findings we can conclude that obesity is not a medical condition requiring significant adaptations in daily midwifery practice. We did not find evidence in favour of

considering obesity, in itself, as an indication for referral to obstetrician-led care: midwives were able to safely assign obese women to either midwife-led or obstetrician-led care based on agreed-upon guidelines. Midwives aimed to treat obese women the same way as their other clients, to support a healthy lifestyle, and to strive for a pregnancy and childbirth as physiological as possible. Obese women did not delay nor avoid prenatal care. Considering current guidelines and local protocols for the care of obese women, we advise the removal of explicit recommendations for referral to obstetrician-led care and for hospital birth. The current move in the Netherlands towards integrated maternity care opens the door for a more woman-centred and tailor-made approach to supporting woman with higher BMIs. Professionals need to include the broader perspective of a woman's preferences and characteristics such as parity in the consideration of best care or preferred place of birth.

Regarding GWG, we learned that it is important to validate guidelines before implementing them. Based on our findings, striving for a GWG ≤15 kg is advisable. On a more detailed level, our findings provide tools for tailor-made prevention, information-giving, and support for weight and weight gain.

The use of EBM in clinical decision-making

Although we recognised the three pillars of the EBM model (evidence, midwife's expertise and women's needs) in midwives' clinical decision-making, this proved to be a much more complex and irrational process than the model suggests. Not only midwife's knowledge and experience played an important role in clinical decision-making, but also her professional and personal skills as well as her attitudes regarding physiology of birth, woman-centredness, shared decision-making, and collaboration with the local maternity care team. In the EBM model the context of the clinical decision-making process is not mentioned, while our findings indicate a significant influence of local maternity care collaborations on midwives' decision-making. In our study, we found midwives experiencing tension within this collaboration based on differences between (and within) obstetricians and midwives in philosophies of care, in perceptions of fear and risk, and in trust in normal childbirth. Tensions were also exacerbated by difficulties within the interprofessional relationships, such as differences in institutional power and control, lack of trust between professionals and conflicting professional interests. These differences and difficulties influenced consensus procedures used to develop protocols and midwives' clinical decisions for individual women. A return to the 'real' EBM is proposed by putting the woman at the centre of the model. Educational programs for (student) midwives are needed to provide them with competencies necessary for clinical decision-making in the complex context of current maternity care.

To conclude, this thesis contributes to the body of knowledge on the effects of weight and weight gain on outcomes for women in midwife-led primary care, and provides

insight into how midwives weigh the evidence on these topics in their care for women. However, more research is needed. Regarding obesity and GWG we recommend the repetition of our research with larger samples of women and across different subpopulations (ethnicity, lifestyle, socio-economic status) to address the limitations of generalisability, small numbers of uncommon adverse outcomes, and missing data. International GWG recommendations need to be validated in the target population before implementation is considered. In the context of integrated care, it is important to explore new models of care with protocols for obesity that adopt more woman-centred and tailor-made approaches and do not include fixed thresholds for obstetrician-led care or place of birth. Finally, we need more research on how educational programs can be modified to give midwives what they need in order to be adequately equipped for clinical decision-making in an integrated care context.

Samenvatting

Hoofstuk 1
Algemene inleiding

In het begin van de eenentwintigste eeuw werd de Nederlandse verloskundige zorg geconfronteerd met de 'nieuwe aandoening' obesitas; een uitdaging voor verloskundige zorgverleners om optimale zorg voor zwangere vrouwen met hogere BMIs vorm te geven. Internationaal onderzoek toonde aan dat vrouwen met obesitas meer perinatale problemen hadden dan vrouwen met een normale BMI. Echter, het effect van hogere BMIs was tot nu toe niet onderzocht bij vrouwen die in aanmerking kwamen voor eerstelijns verloskundige zorg. Binnen het Nederlandse verloskundige systeem was het hierdoor niet duidelijk of obesitas behandeld moest worden als een hoog-risico situatie die per definitie tweedelijns zorg vereist of als een conditie die weliswaar kan leiden tot problemen, die echter tijdig door verloskundigen gedetecteerd kunnen worden op basis van de geldende richtlijnen voor risicoselectie.

Met de toegenomen aandacht voor obesitas in de verloskunde ontstond er ook een toegenomen interesse voor gewichtstoename in de zwangerschap. Het effect van onvoldoende of teveel gewichtstoename op perinatale uitkomsten was in Nederland niet eerder bestudeerd en hierdoor waren er geen gevalideerde richtlijnen over gewichtstoename in de zwangerschap voorhanden.

Zorg door eerstelijns verloskundigen voor vrouwen in de context van het Nederlandse verloskundige systeem - gekarakteriseerd door 'zorg door verloskundigen indien mogelijk, zorg door gynaecologen indien noodzakelijk' - wordt belemmerd door het ontbreken van nationale, multidisciplinaire consensus over obesitas en gewichtstoename in de zwangerschap. Obesitas is niet opgenomen in de Verloskundige Indicatielijst (VIL) en hierdoor bevatten lokale protocollen uiteenlopende aanbevelingen. Om juiste klinische besluitvorming en optimale zorg voor elke zwangere vrouw in Nederland mogelijk te maken zijn meer inzichten nodig in gewicht en gewichtstoename in de zwangerschap en hun effect op perinatale uitkomsten.

Met dit proefschrift beogen we bij te dragen aan de kennis en inzicht over gewicht en gewichtstoename in de zwangerschap om eerstelijns verloskundige zorg voor de individuele vrouw te versterken en om als leidraad te dienen bij klinische besluitvorming.

Hoofdstuk 2
Gewichtstoename in de zwangerschap bij gezonde, laag-risico vrouwen zonder co-morbiditeit.

Dit hoofdstuk behandelt de resultaten van een secundaire analyse van de data van een prospectieve cohortstudie bij 1449 zwangere vrouwen afkomstig uit vijf verloskundige praktijken, die na de eerste prenatale controle in aanmerking kwamen voor eerstelijns

zorg. We beoogden de prevalentie van obesitas en de gewichtstoename van zwangeren in kaart te brengen, waarbij gebruik werd gemaakt van de IOM richtlijnen over gewichtstoename tijdens de zwangerschap uit 2009. Gewicht werd gemeten bij 12, 24 en 36 zwangerschapsweken, BMI werd berekend bij 12 weken en geclassificeerd volgens de WHO classificatie van BMI. Het bleek dat 1,4% van de zwangeren ondergewicht had, 53,8% had een normaal gewicht, 29,6% had overgewicht en 15,1% had obesitas. Tussen 12 en 36 weken kwamen de vrouwen gemiddeld 11,3 kg (SD 4,2) bij. Nullipara kwamen gemiddeld 2 kg meer bij dan multipara (p <0,000). Indien de IOM richtlijnen in deze populatie geïmplementeerd waren geweest dan zou 60% van de zwangeren niet hebben voldaan aan de aanbevelingen: 33,4% van de vrouwen zou een te lage gewichtstoename hebben gehad en 26,7% een te hoge. Met een toenemende BMI hadden vrouwen gemiddeld een afnemende totale gewichtstoename tijdens de zwangerschap. Vrouwen met overgewicht en obesitas klasse I hadden een hoger risico op teveel aankomen dan vrouwen met een normale BMI. Vrouwen met een normale BMI hadden een hoger risico op te weinig gewichtstoename dan vrouwen met overgewicht of obesitas klasse I. Vrouwen met obesitas klasse II en III hadden een verhoogd risico op zowel teveel als te weinig aankomen.

Omdat onze data aantonen dat de meerderheid van de zwangere vrouwen afweken van de IOM richtlijnen, is onderzoek naar het effect van een te lage of een te hoge gewichtstoename op perinatale uitkomsten noodzakelijk alvorens implementatie van deze richtlijnen te overwegen.

Hoofdstuk 3
De invloed van obesitas op uitkomsten van zwangerschap en baring van vrouwen begeleid door eerstelijns verloskundigen: een prospectieve cohort studie

Met deze studie beoogden we de invloed van obesitas op de kans op een fysiologische zwangerschap en bevalling, begeleid door eerstelijns verloskundigen, te beoordelen. We analyseerden hiervoor data van een cohort van 1369 zwangere vrouwen van West-Europese herkomst, afkomstig uit vijf verloskundige praktijken. Zij kwamen allen in aanmerking voor eerstelijns zorg na de eerste prenatale controle. Data werden verzameld tussen 2002 en 2004, een periode waarin de implementatie van nationale of regionale richtlijnen over obesitas nog niet had plaatsgevonden. Hierdoor waren we in staat de impact van obesitas op het verloop van zwangerschap en bevalling te onderzoeken zonder dat BMI hierbij a priori als risicofactor werd meegenomen.

Hoewel het percentage vrouwen met een ongecompliceerde, fysiologische zwangerschap afnam van 75,4% vrouwen met een normale BMI naar 54,7% vrouwen met obesitas klasse II-II, bleef een aanmerkelijk deel van de vrouwen met overgewicht of

obesitas toch in zorg bij eerstelijns verloskundigen. Meervoudige logistische regressie analyse toonde aan dat alleen vrouwen met obesitas klasse II-III significant minder fysiologische *zwangerschappen* doormaakten dan vrouwen met een normale BMI (aOR 0,38; 95%CI 0,21 - 0,69). Alle vrouwen met een BMI klasse ≥ overgewicht hadden minder fysiologische *baringen* dan vrouwen met een normale BMI (64% normaal gewicht, 61,9% overgewicht (aOR 0,63; 95% CI 0,44 - 0,90), 52,2% obesitas klasse I (aOR 0,49; 95% CI 0,29 - 0,84) en 54,3% obesitas klasse II-III (aOR 0,48; 95% CI 0,21 - 1,12)). Zwangeren met obesitas werden meer verwezen voor hypertensieve aandoeningen (4% versus 14%; p <0,001), niet vorderende ontsluiting (4,6% versus 10,4%; p <0,05) en sedatiewens (4% versus 10,4%; p <0,05) dan zwangeren met een normale BMI. Zwangeren met overgewicht en obesitas hadden durante partu niet meer spoedverwijzingen dan vrouwen met een normaal gewicht. Bovendien hadden obese zwangere bij een baring in de eerste lijn geen slechtere uitkomsten dan vrouwen met normaal gewicht en overgewicht. Wel bleek het percentage LGA >p 97,7 hoger (12,1% versus 1,9% bij vrouwen met normaal gewicht en 3,3% bij vrouwen met overgewicht; p <0,001).

Hoewel minder vrouwen met obesitas een fysiologische zwangerschap en baring doormaakten dan vrouwen met een normale BMI, hadden ze - in geval van een fysiologische baring in de eerste lijn - geen verhoogd risico op ongunstige uitkomsten. Dit toont aan dat eerstelijns verloskundigen in staat zijn vrouwen met obesitas veilig te selecteren voor eerste dan wel tweedelijns verloskundige zorg op grond van de geldende richtlijnen voor risicoselectie.

Hoofdstuk 4
Zwanger en te zwaar: thuis in eerste lijn?
Multipariteit heeft positieve invloed op uitkomsten van zwangere vrouwen met obesitas.

In dit hoofdstuk gebruikten we twee wetenschappelijke publicaties over de associatie tussen hogere BMIs en perinatale uitkomsten van laag-risico zwangeren om Nederlandse verloskundigen te adviseren over passende zorg voor vrouwen met obesitas, in het bijzonder multiparae. Onze hypothese was dat multiparae met obesitas minder ongunstige uitkomsten hebben dan nulliparae met een normale BMI. Eerst vatten we onze studie, beschreven in hoofdstuk 3, samen. Daarna behandelden we een secundaire analyse van de Engelse Birthplace studie, een prospectieve cohort studie. Deze secundaire analyse bij 17.230 vrouwen met een laag risico ten tijde van de start van hun baring, exploreerde het effect van de maternale BMI op intrapartum interventies en op ongunstige maternale en neonatale uitkomsten. Bovendien werd onderzocht of pariteit het effect van BMI op de uitkomsten beïnvloedde. Laag-risico zwangeren met obesitas hadden een verhoogd risico op interventies tijdens de baring.

Echter, absoluut gezien kwamen deze interventies minder voor bij multiparae met obesitas klasse II-III dan bij nulliparae met een normale BMI. In deze studie werd geconcludeerd dat het risico op interventies bij multiparae met obesitas klasse II-III lager was dan eerder werd aangenomen.

Geïnspireerd door deze studie, berekenden we de OR - gebaseerd op het logistisch model van onze obesitas studie (hoofdstuk 3) - voor het doormaken van een fysiologische, eerstelijns baring voor multiparae met obesitas klasse II-III versus nulliparae met een normale BMI (en verder dezelfde kenmerken). De gevonden OR van 2,19 betekent dat multiparae met obesitas klasse II-III een grotere kans hadden op een fysiologische baring dan nulliparae met een normale BMI. In absolute getallen had 84% van de multiparae (n = 16) met obesitas klasse II-III een eerstelijns baring vergeleken met 42,6% nulliparae met een normale BMI (n = 110).

Gedurende de zwangerschap bleken de resultaten voor het samenspel tussen 'pariteit' en 'obesitas klasse II-III' anders. De OR voor fysiologische baring was 0,90, wat betekent dat multiparae met obesitas klasse II-III een kleinere kans hadden op een fysiologische zwangerschap dan nulliparae met een normale BMI. In absolute getallen, hadden 56% multiparae met obesitas klasse II-III (n = 19) een fysiologische zwangerschap vergeleken met 67% nulliparae met een normaal gewicht (n = 258). Gebaseerd op deze twee studies, concluderen we dat een verwijzing durante partu enkel op indicatie 'obesitas klasse II-III' bij multiparae niet nodig is en bevelen we een herziening van dit beleid in de klinische zorgpaden aan.

Hoofstuk 5
Het effect van gewichtstoename tijdens de zwangerschap op de kans op verwijzing naar tweedelijns zorg in een eerstelijns populatie zwangere vrouwen.

Dit hoofdstuk beschrijft een studie naar het effect van gewichtstoename tijdens de zwangerschap op de kans op verwijzing van eerste- naar tweedelijns zorg zowel ante als durante partu. Een secundaire analyse van een prospectieve cohort studie bij 1288 zwangeren van West-Europese oorsprong die na de eerste prenatale controle in aanmerking kwamen voor eerstelijns verloskundige zorg, vergeleek het effect van afwijkende gewichtstoename volgens twee verschillende richtlijnen: de 'traditionele' richtlijn voor gewichtstoename (optimale gewichtstoename tussen 10 en 15 kg) versus de IOM richtlijn (advies over gewichtstoename gerelateerd aan BMI klasse). Alleen een gewichtstoename boven 15 kg (gemeten tussen 12 en 36 zwangerschapsweken) bleek geassocieerd met een hogere kans op verwijzing naar tweedelijns zorg (aOR 1,88; 95% CI 1,22 - 2,90). Een gewichtstoename buiten de IOM richtlijn en een gewichtstoename van <10 kg hadden geen voorspellende waarde ten aanzien van verwijzing naar tweedelijns

zorg. Met betrekking tot indicaties voor verwijzing en baringsuitkomsten bleek dat alleen gewichtstoename >15 kg geassocieerd was met hogere risico's op verwijzing voor hypertensieve aandoeningen (aOR 1,91; 95% CI 1,04 - 3,50) en voor meconiumhoudend vruchtwater (aOR 2,22; 95% CI 1,33 - 3,71).

Gebaseerd op deze resultaten, lijkt een gewichtstoename van minder dan 15 kg (tussen 12 en 36 zwangerschapsweken) voor alle zwangere vrouwen ongeacht hun BMI klasse een plausibel advies te zijn.

Hoofdstuk 6
Prenataal zorggebruik door een eerstelijns populatie zwangere vrouwen met obesitas in Nederland: een explorerende cohort studie.

Dit hoofdstuk behandelt de vraag of BMI een invloed heeft op het prenataal zorggebruik door vrouwen begeleid door eerstelijns verloskundigen. We voerden een exploratieve cohort studie uit bij 4421 vrouwen, geregistreerd in het Verloskundig Casusregistratie Systeem (VeCaS), die prenatale zorg kregen in 11 Nederlandse eerstelijns verloskundige praktijken en tussen oktober 2012 en oktober 2014 bevallen zijn. Vrouwen startten hun prenatale zorg bij gemiddeld 9,3 (SD 4,6) zwangerschapsweken. Meervoudige lineaire regressie analyse toonde aan dat met toenemende BMI, vrouwen hun zorg significant eerder startten. Echter, het verschil was te klein om klinisch relevant te zijn en BMI verklaarde slechts een marginale 0,2% (R^2) van de variatie in start zorg. Het gemiddeld aantal persoonlijke, prenatale consulten door verloskundigen was 11,8 (SD 3,8). Meervoudige lineaire regressie analyse toonde aan dat ook met toenemende BMI het aantal prenatale consulten significant toenam maar we beschouwden deze toename niet klinisch significant. BMI verklaarde 0,1% (R^2) van de variatie in aantal prenatale consulten. Het gemiddelde aantal prenatale telefonische contacten was 2,2 (SD 2,6). Meervoudige lineaire regressie analyse toonde een toename in telefonische contacten bij de vrouwen met de BMI klassen 'ondergewicht' en 'obesitas klasse 1' aan. BMI klassen verklaarden 1% (R^2) van de variatie in aantal telefonische contacten.

Deze studie toont aan dat BMI geen relevante voorspeller was van variatie in start zorg en in het aantal prenatale consulten. De resultaten geven aan dat zwangere vrouwen met obesitas eerstelijns verloskundige zorg niet mijden en dat de zorg voor vrouwen met obesitas niet wezenlijk bijdraagt aan een toename van de werkbelasting van eerstelijns verloskundigen.

Hoofdstuk 7
Factoren die de klinische besluitvorming van verloskundigen beïnvloeden: een kwalitatieve studie.

Dit hoofdstuk geeft inzicht in factoren die de klinische besluitvorming van verloskundigen in de dagelijkse praktijk beïnvloeden. Idealiter bieden verloskundigen evidence-based zorg, gebruikmakend van het beste, beschikbare wetenschappelijke bewijs, hun eigen klinische ervaring, en de omstandigheden en de waarden van de zwangere vrouwen. Echter, de grote variatie in intrapartum verwijzingspercentages tussen Nederlandse verloskundige praktijken suggereert dat mogelijk ook andere factoren betrokken zijn bij klinische besluitvorming. Om meer te leren over hoe verloskundigen tot klinische besluiten komen, voerden we een kwalitatieve studie uit waarbij we, tussen mei en september 2015, diepte-interviews hielden met een gerichte steekproef van 11 zelfstandig werkende verloskundigen. Verloskundigen werden gevraagd hardop hun gedachtes te verwoorden (Think Aloud methode) bij het komen tot een klinisch besluit over specifieke, beschreven casus van obese vrouwen tijdens zwangerschap, baring en kraambed (Vignette methode). Het interview werd vervolgd met een gesprek op basis van een semi-gestructureerde vragenlijst. De thematische analyse van de transcripten leverde vijf thema's op die de besluitvorming van verloskundigen beïnvloedden: opvattingen van de zwangere vrouwen, kennisbronnen, attitudes en kenmerken van de verloskundige, de aard van de samenwerking tussen professionals in de geboortezorg en de organisatie van de zorg. De verloskundige zelf speelde een cruciale rol in het uiteindelijk klinisch besluit; naast haar ervaring, intuïtie en persoonlijke omstandigheden werden haar besluiten ook bepaald door haar attitude ten aanzien van fysiologie, ten aanzien van het centraal stellen van de vrouw en gezamenlijke besluitvorming, en ten aanzien van samenwerking met andere professionals.

Klinische besluitvorming van verloskundigen bleek een veelzijdiger en complexer proces dan het EBM model suggereert. Klinische besluiten van verloskundigen werden in belangrijke mate beïnvloed door lokaal ontworpen protocollen en door de aard van de lokale samenwerking met gynaecologen. Willen verloskundigen succesvol zijn in hun rol als bewaker van de fysiologie dan dienen ze te begrijpen hoe klinische besluiten in een multidisciplinaire context daadwerkelijk tot stand komen.

Hoofdstuk 8
Algemene discussie

Dit hoofdstuk beschrijft een overzicht van de belangrijkste resultaten en bespreekt deze in de algemene context van het proefschrift. Implicaties voor de praktijk en voor toekomstig onderzoek worden geschetst.

Onderzoek van zorg door verloskundigen

Eerstelijns verloskundige zorg in Nederland is gebaseerd op een systeem van voortdurende risicoselectie. Als gevolg hiervan kan het risicoprofiel van de vrouw en - hieraan gerelateerd - de setting van de zorg en de verantwoordelijke verloskundig zorgverlener tijdens de zwangerschap en baring veranderen. Om de resultaten van eerstelijns verloskundige zorg in relatie tot gewicht en gewichtstoename van zwangeren grondig te evalueren, bestudeerden we uitkomsten van de groep vrouwen die in aanmerking kwamen voor eerstelijns zorg in het begin van hun zwangerschap, uitkomsten van de groep vrouwen die in aanmerking kwamen voor eerstelijns zorg bij de start van de baring en uitkomsten van de groep vrouwen met een eerstelijns baring. En dit zowel bij vrouwen die in de eerste lijn bleven gedurende de zorg als bij vrouwen die verwezen werden naar de tweede lijn. In de obesitas studie gebruikten we salutogenetische uitkomsten - die aspecten van gezondheid en welbevinden reflecteren - als primaire uitkomstmaten, om tegenwicht te bieden aan de overweldigende hoeveelheid wetenschappelijke informatie over hogere risico's van obesitas op ongunstige perinatale uitkomsten. Om wetenschappelijke kennis over optimale gewichtstoename tijdens de zwangerschap te verzamelen, bestudeerden we de samengestelde uitkomstmaat 'verwijzing tijdens de zwangerschap' en 'verwijzing tijdens de baring'. Met het gebruik van deze uitkomstmaten beoogden we inzicht te bieden in het totale effect van gewichtstoename tijdens de zwangerschap op perinatale uitkomsten, eerder dan in de soms tegengestelde effecten van gewichtstoename op specifieke ongunstige uitkomsten. We gebruikten de samengestelde uitkomstmaten eveneens om het powerprobleem dat ontstaat bij het bestuderen van specifieke ongunstige uitkomsten met een lage prevalentie in eerstelijns populaties, op te lossen. Zowel de salutogenetische uitkomstmaten als 'verwijzing' worden niet algemeen gebruikt in de internationale literatuur wat de vergelijking van onze resultaten met internationale studies bemoeilijkt.

Gewicht en gewichtstoename

Gebaseerd op onze resultaten kunnen we concluderen dat obesitas geen risicofactor is die wezenlijke aanpassingen vergt in de dagelijkse verloskundige praktijk. We vonden geen wetenschappelijk bewijs voor het beschouwen van obesitas - op zichzelf - als een indicatie voor verwijzing naar tweedelijns zorg: verloskundigen waren in staat om vrouwen met obesitas veilig te selecteren voor eerste dan wel tweedelijns verloskundige zorg op grond van de geldende richtlijnen voor risicoselectie. Verloskundigen beoogden vrouwen met obesitas op dezelfde wijze te behandelen als hun andere cliënten, hen te ondersteunen in een gezonde leefwijze, en ook voor hen te streven naar een zo fysiologisch mogelijke zwangerschap en baring. Vrouwen met obesitas vermeden de eerstelijns verloskundige zorg niet. Met betrekking tot de huidige richtlijnen en lokale

protocollen over zorg voor obese vrouwen, adviseren we expliciete aanbevelingen over verwijzingen naar de tweede lijn en over plaats van bevalling op grond van obesitas te verwijderen. De huidige ontwikkeling naar integrale geboortezorg in Nederland opent deuren voor de ondersteuning van vrouwen met hogere BMIs gekenmerkt door het meer centraal stellen van de vrouw en door zorg op maat. Hulpverleners dienen het bredere perspectief van voorkeuren en kenmerken van de vrouw, zoals pariteit, mee te nemen in hun overwegingen over de best mogelijk zorg of plaats van bevalling.

Wat gewichtstoename tijdens de zwangerschap betreft leerden we dat het belangrijk is richtlijnen voor een bepaalde doelgroep eerst te valideren alvorens ze te implementeren. Gebaseerd op onze resultaten adviseren we het nastreven van een gewichtstoename in de zwangerschap van <15 kg. Op een meer gedetailleerd niveau bieden onze resultaten handvaten voor preventie, informatievoorziening en begeleiding van gewicht en gewichtstoename op maat.

Het gebruik van EBM in klinische besluitvorming

Ondanks het feit dat we de drie pijlers van het EBM model (wetenschappelijk bewijs, ervaring van de verloskundige en behoeften van de vrouw) herkenden in de klinische besluitvorming van verloskundigen bleek dit proces veelzijdiger en complexer te zijn dan het model suggereert. Niet alleen de kennis en ervaring van de verloskundige bleek een belangrijke rol te spelen in de klinische besluitvorming maar ook haar professionele en persoonlijke vaardigheden en attitudes ten aanzien van fysiologie, van het centraal stellen van de vrouw en gezamenlijke besluitvorming, en ten aanzien van de lokale samenwerking met andere verloskundige hulpverleners. In het EBM model wordt de context van het klinisch besluitvormingsproces buiten beschouwing gelaten terwijl onze resultaten aantonen dat de lokale verloskundige samenwerkingsverbanden in belangrijke mate van invloed zijn op de besluitvorming van verloskundigen. In onze studie vonden we dat verloskundigen spanning ervaren in deze samenwerking gebaseerd op verschillen in visie op zorg, in risico- en angstperceptie en in vertrouwen in fysiologie van zwangerschap en geboorte tussen gynaecologen en verloskundigen maar ook tussen verloskundigen onderling. Spanningen werden versterkt door factoren in de interprofessionele relatie zoals verschillen in macht- en gezagspositie tussen betrokken partijen, gebrek aan vertrouwen tussen professionals en conflicterende professionele belangen. Deze verschillen en moeilijkheden waren ook van invloed op de consensus-procedures tijdens de ontwikkeling van protocollen en op de klinische besluiten van verloskundigen in hun zorg voor individuele vrouwen. Een terugkeer naar de ‘echte’ EBM kan gerealiseerd worden door de zwangere een prominente plaats in het centrum van het EBM model te geven. Onderwijsprogramma’s dienen ontwikkeld te worden om verloskundigen (in opleiding) te voorzien van competenties nodig voor klinische besluitvorming in de complexe context van de huidige geboortezorg.

Samenvattend, dit proefschrift draagt bij aan de kennis over het effect van gewicht en gewichtstoename op uitkomsten van vrouwen in de eerstelijns verloskundige zorg en biedt inzichten in hoe verloskundigen wetenschappelijke kennis over deze onderwerpen afwegen in hun zorg voor vrouwen. Echter, meer onderzoek is nodig. We bevelen herhaling van ons onderzoek over obesitas en gewichtstoename aan, met grotere steekproeven en in verschillende subpopulaties (etniciteit, leefstijl, sociaaleconomische status) om de beperkingen van generaliseerbaarheid, lage prevalentie van bepaalde ongunstige uitkomsten en missende waarden aan te pakken. Internationale richtlijnen over gewichtstoename dienen gevalideerd te worden alvorens implementatie in een bepaalde doelgroep overwogen wordt. In de context van geïntegreerde geboortezorg is het van belang nieuwe zorgmodellen te exploreren met protocollen over obesitas die geen vaste afspraken over plaats van bevalling en tweedelijns zorg bevatten maar gekenmerkt worden door het meer centraal stellen van de vrouw en door zorg op maat. Tot slot is er meer onderzoek nodig over hoe onderwijs, initieel en postinitieel, het beste vorm gegeven kan worden om verloskundigen te voorzien van datgene wat nodig is voor adequate klinische besluitvorming in de context van integrale geboortezorg.

Valorisation

This valorisation addendum completes the dissertation: 'Calibrating care in midwifery: Weighing the evidence on weight and weight gain for pregnant women'. In this addendum we explain the societal value of our studies and describe how the findings can be used to benefit (inter)national maternity care.

Relevance

Obesity

Given the already high, and increasing, prevalence of obesity in the Netherlands and in the world - and the negative health consequences of being overweight [1, 2] - there can be no doubt about the relevance of our research. We know that obese women face more reproductive problems than normal weight women, [3, 4] and there is growing evidence of an association between obesity in pregnancy and the health of future generations. [5] Although myriad studies report adverse outcomes for obese women in pregnancy and childbirth, there is only limited evidence on what the appropriate care for obese pregnant women should be, and this is especially true in the context of the Dutch dual maternity care system. Obesity is not included in the OIL. [6, 7] In their 2009 guideline, 'pregnancy and obesity', the NVOG defines class-III obesity (BMI ≥40 kg/m2) as a medical condition requiring obstetrician-led care, but this recommendation was based on professional opinion and not on evidence. [8] The research questions examined in this dissertation originated in daily midwifery practice and were explored in order to contribute to the knowledge necessary to provide optimal care for women with obesity.

Being able to safely assign women to primary care, referring to secondary care only when necessary - as described in chapter 3 - is critical for the provision of the best possible care for mother and child. Adequate risk assessment avoids the problems that occur when a woman is improperly labelled as being at 'high risk', including unnecessary interventions, negative psychological sequelae, [9] and reduced choices throughout pregnancy and around the birth. [10]

The impact of maternal BMI on perinatal outcomes has implications for the use of obstetric resources, [11] underscoring the economic relevance of having a clear view of what is needed to address the needs of pregnant women who are obese. We found, for example, that midwives play a prominent role in the support of obese women (chapter 3), leading us to study how the use of antenatal care by obese women (chapter 6) influences the workload of primary care midwives.

Weight gain

Like obesity, weight gain in pregnancy is related to perinatal outcomes: insufficient or excessive GWG is harmful to women and babies. [12] Excessive GWG may result in

inadequate weight loss after pregnancy, which is associated with an increase of complications in subsequent pregnancies [13, 14] and may lead to higher BMIs and general health problems for the mother later on in life. [15-17] There is no consensus, internationally, on optimal weight gain, resulting in a great variation in formal and informal policies for the management of GWG. [18] In the Netherlands, there are no national-level guidelines for GWG in primary care, leaving midwives on their own when advising women about GWG. In our first study on patterns of GWG (chapter 2) we found that if the 2009 IOM guidelines were to be implemented in primary care settings, a substantial personal, organisational, and financial investment would be needed. Our research and the research of others confirms the social, scientific, and economic relevance of the study of the effects of too much or too little GWG on perinatal and health outcomes in low-risk populations.

Target groups

Because our research focused on the results of primary care midwifery in relation to weight and weight gain, our findings are, first and foremost of interest to primary care midwives. This group of health care providers should critically appraise our results, using them to update local protocols for their practices and their collaborations with other providers. Our study of the factors influencing midwives' clinical decision-making will inspire midwives to reflect on their professional and personal skills and attitudes in the context of local multidisciplinary maternity care collaborations and can empower them to explore the 'new' EBM model by realising a more woman-centred approach.

Of course, primary care midwives do not work alone and cannot change care pathways on their own. Therefore, our findings are also of interest to midwives working in secondary care, and to obstetricians and obstetric nurses. Our studies are also of interest to an international audience. In several countries around the world midwives work autonomously - in midwife-led units or in the community - and take care of low-risk pregnant women. In our review of international studies of clinical decision-making by midwives we learned about the many dimensions of this process and the challenges midwives must meet in multidisciplinary collaboration. With adjustments for local contexts, our findings can be applied to their populations and their work settings.

Our studies contribute to the body of knowledge on weight and weight gain and are therefore interesting for the developers of national guidelines and for the teachers of midwifery, who should incorporate this new knowledge in their midwifery programs.

Our study of clinical decision-making is especially useful for the creation of educational programs for (student)midwives, and will provide them with the competencies needed for clinical decision-making in the context of the integrated maternity care movement. The KNOV should encourage this kind of education, which

will empower midwives by developing the skills and attitudes needed to succeed in their role as promoters and protectors of physiological pregnancy and birth.

Finally, our findings will be of interest to insurance companies, providing the basis for the purchase of appropriate care for the group of overweight women. Our work can be used to support the development and evaluation of new models of care that put women at the centre of evidence-based integrated maternity care.

Innovative character of the study

The innovative character is evidenced in its choice of subjects and in the design of the studies, done in the context of Dutch midwife-led primary care. Obesity and GWG - in relation to risk assessment done by primary care midwives and to the outcomes of midwife-led primary care - have not yet been studied in the Netherlands.

Regarding the design of the studies, it was important for us to consider the complete care pathway of women through midwife-led and obstetrician-led care in pregnancy and childbirth. [19] Therefore, to study the outcomes of women in primary care with regard to BMI and weight gain, we began our research with women eligible for midwife-led care after antenatal booking. We followed this group of women and studied the population of women remaining in midwife-led care at the onset of labour and the women who delivered in midwife-led primary care. In the obesity study (chapter 3), we examined both referred and non-referred women during pregnancy and childbirth.

In line with the ongoing discussion of relevant outcome measures of midwife-led care [20-22] we chose to use salutogenically-focused outcomes in our obesity study (chapter 3). These outcomes reflect health and well-being rather than illness or adverse events. [23] We did this because we were especially interested to learn if obese women could experience the benefits of a physiological childbirth. In the GWG study (chapter 5) we used referral in pregnancy and in childbirth as primary outcomes. The use of this composite outcome allowed us to study the overall perinatal outcomes for different GWG classes, which are known to have differing effects for mother and child. [24] Using a composite outcome also helped us to overcome the power problem of low prevalence of some adverse outcomes in primary care populations.

Activities

As mentioned earlier, we initiated our research because of the need for better insights into the subjects of weight and weight gain in midwife-led primary care. That is why, beginning in the early stage of our research activities, we disseminated the knowledge we had gathered. We presented our findings at a variety of national and international

conferences and also in meetings of local maternity care collaborations. We reached a multidisciplinary audience of (student) midwives, obstetricians, professionals in the field of public health and health promotion, policy makers in maternity care and public health, and professionals involved in education in these domains. We did poster presentations at conferences, and four of the five studies of this dissertation are published and available for an (inter)national audience. The fifth study has been submitted to an international journal. Details of these activities are listed below.

After the publication of the dissertation, we will continue to disseminate the findings by including the newly gathered insights into the midwifery educational program and by looking for (financial) opportunities to study the topics we identified as important subjects for future research. We will also use what we have learned to develop and evaluate a 'new' EBM model in the context of integrated maternity care. In the most recent KNOV factsheet on obesity our research project is referenced and we expect that our results will be used to update guidelines on obesity in pregnancy and GWG. [25]

Publications

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Curriculum vitae

Darie Daemers was born in Ghent (Belgium) on 21st November 1961. She finished her nursing and midwifery training at the Higher Institute of Paramedical Professions (HIPB - Ghent, Belgium) in 1982 and 1983 respectively. Between 1983 and 1987 she worked as a lecturer in nursing (Institute for Nursing - Ghent, Belgium), as a co-founder of an organisation providing care by maternity nurse assistants (VZW Kraamzorg - Ghent, Belgium) and as a midwife in a hospital setting (OCMW - St Amandsberg, Belgium). In 1984 she obtained a teaching qualification for higher education (HIPB - Ghent, Belgie). She continued her midwifery training in Amsterdam at the Midwifery School (The Netherlands) in 1987 and received her diploma in 1989. Following graduation, she worked as a primary care midwife in midwifery practices in Ijmuiden and Ermelo. From 1990 she worked at the Midwifery School Heerlen/Kerkrade, first as a primary and secondary care midwife, with the responsibility for educating student-midwives. She was also involved in the theoretical component of midwifery education, including the development of the 4 year-midwifery curriculum. In 1997 she took up a post at the Royal Dutch Organisation of Midwives (KNOV - Bilthoven) were she was responsible for the foundation of the guideline department. Between 1997 and 2005, she co-authored several guidelines as well as initiating collaboration with relevant other professional associations and guideline-developers (Dutch Society of General Practitioners, Institute for Quality of Health Care, Dutch Society for Obstetrics and Gynaecology. As a KNOV staff member she was involved in various national maternity care issues and developments.

In 2005, she was re-employed by the Institute for Midwifery Education and Studies, Zuyd in Maastricht. As coordinator of the Life Long Learning department she is responsible for acquisition, programme planning, development and organisation of educational activities for maternity care professionals. As a member of the Research Centre Midwifery Science she took the opportunity to undertake a PhD, of which the result is before you.

Darie Daemers werd geboren in Gent (België) op 21 november 1961. Ze rondde haar opleiding tot verpleegkundige en vroedvrouw af aan het Hoger Instituut voor Paramedische Beroepen (HIPB - Gent, België) in 1982 en 1983, respectievelijk. Tussen 1983 en 1987 werkte ze als verpleegkundig docent (Instituut voor Verpleegkunde - Gent, België), als medeoprichter van een organisatie die kraamzorg verleende (VZW Kraamzorg - Gent, België) en als klinische vroedvrouw (OCMW - St Amandsberg, België). In 1984 behaalde ze de bevoegdheid tot docent (HIPB - Gent, België). In 1987 werd ze toegelaten tot de opleiding tot verloskundige op de Kweekschool voor Vroedvrouwen in Amsterdam (Nederland) en behaalde haar diploma in 1989. Na haar afstuderen, werkte ze als eerstelijns verloskundige in verloskundige praktijken in IJmuiden en Ermelo. Vanaf 1990 werkte ze op de Vroedvrouwenschool Heerlen/Kerkrade, eerst als verloskundige in eerste en tweede lijn met een opleidingsopdracht (student-verloskundigen). Later was ze voornamelijk betrokken bij het theoretische gedeelte van de opleiding waaronder de ontwikkeling van het vierjarige curriculum. In 1997 maakte ze de overstap naar de Koninklijke Nederlandse Organisatie voor Verloskundigen (KNOV - Bilthoven) waar ze verantwoordelijk was voor de oprichting van de afdeling richtlijnen. Tussen 1997 en 2005 was ze medeauteur van diverse richtlijnen en startte ze de samenwerking op dit gebied met aanpalende beroepsgroepen en andere richtlijnmakers (NHG, CBO, NVOG). Tevens was ze als KNOV-stafmedewerker betrokken bij allerlei nationale verloskundige vraagstukken en ontwikkelingen.

In 2005 kwam ze opnieuw in dienst van de Academie Verloskunde Maastricht (Zuyd Hogeschool). Als coördinator Leven Lang Leren is ze verantwoordelijk voor acquisitie, programmering, ontwikkeling en organisatie van bij- en nascholingsactiviteiten voor professionals in de geboortezorg. Als lid van het lectoraat Midwifery Science werd ze in de gelegenheid gesteld een promotietraject te starten waarvan het resultaat voor u ligt.

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