Evaluating perinatal outcomes in different levels of care
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Citation for published version (APA):
Wiegerinck, M. M. J. (2018). Evaluating perinatal outcomes in different levels of care
Summary
and general discussion

10
Summary

In the first part of this thesis we presented an overview of birth outcomes when comparing different levels of care, which included care under responsibility of a community midwife (first level) and care under responsibility of an obstetrician (second and third level).

In the second part of this thesis we described the implementation of the guideline for the management of extremely premature born infants (between 24 and 26 weeks gestation). In addition, we depicted the role of guidelines in this process, in which we plead in favour of a continuous quality cycle of guideline development, implementation, evaluation and scientific studies to obviate gaps in knowledge.

Chapter 1 presented a general overview of what is known on intrapartum and neonatal mortality rates within the typical Dutch maternity care system. Furthermore, we addressed the research questions for this thesis and a summary of our findings is given below:

Part 1: Perinatal mortality in midwife-led versus obstetrician-led care

In Chapter 2 we compared intrapartum and neonatal mortality rates as well as intervention rates for women starting labour in community midwife-led- versus obstetrician-led-care (predominantly high-risk pregnancies) in the Amsterdam region of the Netherlands, by using aggregated data from the Dutch perinatal register together with hospital and midwifery record data (from 2005 to 2008). This design allowed us to make a comparison to a prior study using data from the Utrecht region in the Netherlands, which had shown a higher perinatal mortality risk in the midwife-led group compared to the obstetrician-led group (1.39‰ versus 0.60‰; relative risk (RR) 2.3; 95% confidence interval (CI) 1.1 - 4.8). Our study among 83,909 women revealed comparable intrapartum and neonatal mortality rates for women who started labour in midwife-led care (0.70‰) versus obstetrician-led care (0.80‰; Relative Risk 0.88; 95% CI 0.52-1.46). Intervention rates were significantly lower in the midwife-led group, with intrapartum caesarean section rates of 5% versus 16%, respectively (RR 0.31; 95% CI 0.30-0.32), and instrumental delivery rates of 10% versus 13%; RR 0.76; 95% CI 0.73-0.79). However, the large heterogeneity between groups caused by the difference in risk status hampered the interpretation of our findings.
In Chapter 3 we compared intrapartum and neonatal mortality, as well as intervention rates in a population of low risk term women (n=57,396; from 2005-2008) starting labour in midwife-led versus obstetrician-led care, in order to increase comparability between groups and solve the difficulties in interpretation inherent to the design of the studies described in the former chapter. Furthermore, we performed a propensity score matched analysis (matching for maternal age, birth weight, duration of pregnancy, ethnicity and socio-economic level, among others) in order to minimize confounding. After matching we found a non-significant difference in perinatal mortality between the midwife-led group and the obstetrician-led group (0.75 ‰ versus 0.19‰; matched OR 4.0; 95% CI 0.85-18.9), however the size of the odds ratio and the large confidence interval, gave rise to concern and warranted further evaluation in a larger population with more recent data. The significantly lower intervention rates in the midwife-led group were consistent with our previous study, with a caesarean section rate of 2.5% versus 8.9 % (matched OR 0.26; 95% CI 0.22-0.29).

In Chapter 4 we described the course of 32 individual intrapartum and neonatal deaths from our previously stated (chapter 3) low risk population of women, as well as the 14 stillbirths of which our classification team was unable to differentiate between antepartum and intrapartum death. Perinatal asphyxia was the most often reported relevant clinical condition, followed by infection. Furthermore, we identified recurrent themes that might benefit from improvement strategies. Regarding antenatal risk assessment, improving detection of growth restricted infants was a suggested target for improvement, as well as improvement of patient instructions on when to call the caregiver. For the intrapartum period, the frequency of ‘fetal condition monitoring’ and misinterpretation of the ‘fetal condition monitoring’ (in midwife- and obstetrician led care) were recurrent themes. Postnatally, prolonged observation of the neonate in case of risk factors could improve outcome. We endorse the recommendation of the College of Perinatal Care (CPZ) as stated in the Zorgstandaard (Standard of Care) and now advised by the KNOV (Royal Dutch Organisation of Midwives) to evaluate the fetal condition from the moment of start of labour as experienced by the pregnant woman and not so much by the caregiver, followed by continuous presence of a caregiver (if the woman so wishes)).

Moreover, we studied possible risk factors for perinatal mortality within the low-risk group of women who were in midwife-led care from the start of labour. Women with a pregnancy resulting in perinatal death were more likely to be primiparous, compared to women with a
child born in good condition (5 minute Apgar score ≥7). There were no significant differences in maternal age, ethnicity, socio economic status, gestational age, fetal birthweight, fetal sex or intended place of birth. Our study gives insight in certain pathways leading to perinatal mortality for low risk term births, and offers a focus for further strategies to improve perinatal outcomes.

In Chapter 5 we evaluated the cost-effectiveness of starting labour in midwifery-led care with an intended home birth versus obstetrician-led care for low-risk term women, with use of a decision model. Used probabilities, including mortality rates, referral rates and caesarean section rates, were calculated from the cohort of low risk women as described in chapter 3 (referring to data from 2005-2008), and were completed with data from literature. Effectiveness was defined as risk of intrapartum or neonatal mortality (<28 days of birth). We estimated direct medical costs associated with healthcare utilisation from onset of labour of the index pregnancy until 6 weeks after the birth of a subsequent pregnancy in different models, using costs of existing guidelines and literature and included outcomes for a possible subsequent pregnancy. Starting labour in obstetrician-led care for low risk women reduced perinatal mortality only at high costs as compared to midwife-led care (€ 1,060,153 to prevent one death and €1,241,242 to prevent one death in two subsequent pregnancies) with increased caesarean section rates (9% versus 4% CS, rising to 21% vs 9% when a second pregnancy was included). Whether this is considered cost-effective depends on what society is prepared to pay for this health gain, while also taking into account the disadvantages of the higher intervention risk and the preferences of the woman (not part of the study). We concluded that effort should be made to preserve an optimal balance of safety for mother and child with low intervention rates.

In Chapter 6 we repeated the study question of chapter 3 (low risk comparison midwife-led versus obstetrician-led care with a propensity score matched design), but now for a more recent cohort of 2010-2012 data collected from the Perinatal Audit in the Netherlands (PAN) together with data from the national database (PERINED). The PAN database is a prospective cohort of perinatal deaths in The Netherlands regarding data from 2010-2012. This was an initiative to learn from the audit data with the aim to improve perinatal outcome at national level. In our study we made selection of intrapartum and neonatal mortality occurring at low-risk pregnancies and children without congenital anomalies. This study demonstrated no difference in perinatal mortality between the group with midwife-led care at the start of labour and the group of obstetrician-led care (0.49‰ versus 0.44‰, respectively; OR 1.13 (95% CI
0.65-1.98)). In the midwife-led care group fewer children had low Apgar score (<7 at 5 minutes). Whether this reflects decreased morbidity should be further evaluated. Decreased intervention rates were in line with our previous studies. The results of his study may differ from previous outcomes because of more recent data (much has changed in Dutch obstetrical care in recent years) and the use of a larger cohort. We concluded that women with a low-risk pregnancy could benefit from starting labour in midwife-led care considering the lower intervention risk with a similar perinatal mortality risk.

In **Chapter 7** we described the shortcomings of the use of the variable ‘NICU admittance’ as a surrogate outcome for perinatal morbidity when comparing different levels of care. This study showed that the severity of neonatal illness after 37 weeks of gestation differed depending on the level of care in which they were born. Neonates born in secondary care consistently had the highest morbidity scores with the longest average duration of admission (106 hours), and those born in tertiary the lowest morbidity with the shortest hospital stay (22.5 hours). This can be explained by the fact that admission to the secondary care center was not sufficient and therefore an indication for tertiary care. Children referred directly from community midwife-led care had an average morbidity score in between with an average duration of admittance of 60 hours. We concluded that “NICU admittance” is not a suitable outcome measure for comparing neonatal morbidity of primary, secondary and tertiary care.

**Part 2: Translating research into clinical practice (and vice versa)**

In **Chapter 8** we described the importance of translating clinical research into guidelines, implementing these guidelines into clinical practice, and subsequently evaluating care leading to new research questions and guidelines. This can be seen as a continuous quality cycle. Examples of such studies and topics were presented.

In **Chapter 9** we presented the introduction of the guideline for the management of extreme premature birth (24-26 weeks gestation) in The Netherlands. The development of this multidisciplinary guideline was initiated by the Dutch Ministry of Health, Welfare and Sport (VWS) in consequence of the PERISTAT results. The aim was to reduce variation of practice between the different Dutch perinatal centers, and to get insight in perinatal outcomes of this high risk group as a basis for improvement.
Chapter 10

General discussion

During the period that the studies included in this thesis were carried out, many changes were implemented in the Dutch obstetrical health care system. An important change is the formal introduction of the ultrasound at 20 weeks of pregnancy (January 2007), therapeutic neonatal hypothermia for perinatal asphyxia (2009), the installation of the Foundation Perinatal Audit in the Netherlands (PAN) with a multidisciplinary approach to critically and systematically audit term perinatal deaths (2010)\(^4\), and the installation of the College Perinatal Care (CPZ) to implement the recommendations of the steering group "A good start" with the aim to reduce maternal and perinatal mortality (2011).\(^2\)\(^5\) The CPZ aspires and facilitates the development of an integrative obstetric network, with a central position for the wishes and needs of the pregnant woman. The CPZ developed the Standard for integral birth care (Zorgstandaard Integrale Geboortezorg), describing the optimal care from preconception to 6 weeks postnatal for all women.\(^2\) The care and future perspectives as described in the Standard will be implemented in 3 phases, from July 2017 until January 2020, in close collaboration with all stakeholders including client organisations, midwives, obstetricians and health insurance companies.

One of the recommendations of the Steering committee was that women in labour should not be alone. This is in accordance with international literature advocating continuous care during labour in order to improve patient satisfaction and maternal and neonatal outcomes.\(^6\) In 2014 the Royal Dutch Organisation of Midwives (KNOV) amended their original advise to women only to call the midwife for start of labour when predominantly objective parameters of onset of labour (e.g. interval between and duration of contractions) were present, and currently advise their members to instruct women to call when they believe or experience that labour has started, and go visit in an earlier stage.\(^3\) The aim is continuous care (if the client so wishes) starting earlier in the process, in order to increase patient satisfaction and possibly reduce referral to obstetrician-led care. It is possible that within the characteristic Dutch obstetric system an approach of continuous care from the experienced onset of labour might also address some of the recurrent notable factors that we observed in pregnancies suffering perinatal mortality, such as missing information regarding fetal condition in the earlier and even later stages of labour, risk of unplanned unattended out-of-hospital births, and certain situations in which there was insufficient time for intrapartum referral when indicated. It is unclear to what extent this positive initiative for early evaluation and
continuous care has been implemented, but the 2016 CPZ Standard issues the same advice and therefore an increase in adherence over the coming years can be expected. In addition, intrapartum and postpartum neonatal mortality is still declining.7, 8

Another recommendation of the Steering Committee was the 24/7 availability and accessibility of emergency treatment within 15 minutes. Our study shows a delay of the gynaecologist to have been an issue in 2 cases of perinatal mortality. As in all the cases we described leading to perinatal death, it is unknown what the neonatal outcomes would have been, had there not been any delay. We do agree that any delay in case of emergency is suboptimal,9 and therefore support the recommendation of 24/7 availability and accessibility of care. The CPZ Standard does not specifically mention the 15-minute interval or the full time presence of a specialist in the hospital, but recommends the 24/7 possibility of start treatment within acceptable time. No consensus was reached regarding acceptable time, but reference is made to the accessibility rule of 45 minutes for a general emergency unit, and good agreements for parallel actions in case of emergency referral from home to hospital.

This brings us back to the discussion of the risks involved in transferring care from one level to the next. The a priori risk that a woman in active labour will be referred to obstetrician led care during labour is substantial, especially for nulliparous women (up to 59% to 70%).8, 10 The Dutch system anticipates on quick referral possibilities, and although only a small portion (5%) of all intrapartum referrals are for acute fetal distress,11 it is unlikely that referral to another caregiver and possibly another location is optimal in case of acute emergencies. A Dutch study showed a positive relation between longer travel time (≥20 minutes) and total intrapartum and neonatal mortality (OR 1.17, 95% CI 1.002-1.36).9 Furthermore, a Dutch cohort study by Evers et al. showed increased risk of delivery related perinatal death in infants of women who were referred by a midwife to an obstetrician during labour compared to infants of women who started labour supervised by an obstetrician (RR 3.66, 95% CI 1.58-8.46) with a concomitant higher risk of NICU admission (RR 2.51, 1.87-3.37).1 However, the interpretation of these findings is difficult, as there was obviously a reason for referral (therefore a high-risk pregnancy), and the effect of the referral itself cannot be measured. Evers also prospectively evaluated all cases of delivery related asphyxia at term in the Utrecht region between 2007 and 2008, and identified substandard care factors in 58%, that were possibly (43%) or probably (15%) related to perinatal death or NICU admission.12 In midwife-led care, substandard care factors were mostly the low frequency of examination
Chapter 10

during labour and delay in referral to secondary care. In obstetrician-led care, misinterpre-
tation of fetal monitoring (CTG) and failure to respond adequately to clinical signs of fetal
distress were the most common substandard care factors.\textsuperscript{12}

These findings are in line with our results and emphasize the need for close collaboration
with clear protocols within the obstetric network, as recommended by the CPZ Standard of
integral birth care 1.1. Necessity for interdisciplinary teamwork and integration of facilities
and community settings is also highlighted in the United Kingdom as stated in the British
quality framework for maternal and newborn care.\textsuperscript{13}

Considerations for the future

Although there has been a substantial improvement in the decline in perinatal mortality
over the years, the 2010 ranking relative to other European countries showed only modest
progression and need for further for improvement.\textsuperscript{14, 15} The CPZ has initiated an important
process with the effectuation of the recommendations of the Steering Group for improve-
ment of perinatal and maternal health in the Netherlands.\textsuperscript{2} There is a clear implementation
plan and the intention to update the Standard at least every two years. Furthermore, the
CPZ plans to evaluate the implementation process and the impact of the application of the
Standard on quality, efficiency and effectiveness of care with use of indicators. Based on
the findings of our study, we emphasize the need for accurate and reliable registrations of
perinatal data as we met a considerable number of missing and incorrect registered data.

Based on this thesis we specifically recommend evaluation of:

1. the early assessment of fetal condition, from the moment labour has started
   according to the mother
2. continuous presence of a caregiver from the start of labour
3. the increasing\textsuperscript{16} intervention rates in obstetrician-led care in order to achieve a
   well-balanced reduction.
4. the accepted time between referral and treatment in case of an emergency situation
We conclude that, based on our most recent (2010 up to 2012) data, the at term intrapartum and neonatal (<28 days) mortality in low risk pregnancies in The Netherlands is low in absolute terms with an incidence of less than 0.5‰, with a comparable perinatal mortality risk for women starting labour in midwife-led care and in obstetrician-led care. However, the intervention risk is consistently and significantly lower in women in the midwife-led care group, which is in line with other studies.\textsuperscript{10,17,18} The cost-effectiveness analysis in which data were used based on cohort data from 2010-2012 showed a reduction of perinatal mortality in obstetrician-led care from the start of labour but only at high cost and high intervention risk. Based on the results of our propensity score matched study, using data from 2010-2012, it is plausible that with the use of these more recent data the cost-analysis will no longer show an advantage in effectiveness but still an advantage in costs and intervention risk. Consequently, there is a potential advantage for women with low risk pregnancies to be in midwife-led care from the start of labour. The increased and further increasing\textsuperscript{16} intervention rates in obstetrician-led care should be subject of future study in order to achieve a well-balanced reduction. Results of this thesis do not allow for conclusions regarding differences in place of birth (home, birth center, hospital) or the period of antenatal care.

What we have learned from the description of mortality is that our recommended strategies for improvement are in agreement with the already implemented and still to implement recommendations by CPZ to reduce mortality. It is important that we will find a suitable balance between safety and intervention risks, while taking women’s (and partner’s) preferences into account.

**Collaboration**

The sensitivity of the subject of this thesis is an important issue. It creates discussions in which emotions and alternative interests are involved. Everyone involved in research must be aware of her or his background and the risk of confirmation bias (evaluating evidence that supports one's preconceptions differently from evidence that challenges these convictions).\textsuperscript{19} We have carried out these studies with the intention of optimal collaboration with all parties involved, including community midwives, hospital appointed midwives, obstetricians and paediatricians, to ensure a broad scope. During this project many interesting discussions evolved, but unfortunately we could not always come to an agreement and shared interpretation of a study could not always be realized. In view of the complementary competences
Chapter 10

of the caregivers involved, all aiming for the same goal (a healthy mother with a healthy child and a positive experience of the delivery), it is paramount to invest in a sound relationship between all parties. Existing hurdles, among which regulation of autonomy and financial issues, should be removed.

Integration of obstetric care, using the specific qualities of midwives and obstetricians, is vital in view of the high referral rates, the undesirable break in continuity of care, the increasing intervention rates in obstetrician-led care, attaining clear communication, uniform registration and efficient use of obstetrical manpower and means. Above all we have a joint responsibility towards mother and child.
References


