Safe motherhood : severe maternal morbidity in the Netherlands. The LEMMoN study

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CHAPTER 1

General Introduction

Pregnancy and delivery are major life events. In high income countries, they are generally referred to as joyful events, the start of a new life being central. That pregnancy and delivery can adversely affect the mother's health is generally not the first concern. Sometimes, however, pregnancy and childbirth are severely disturbed, posing the mother's life at danger.

Severe acute maternal morbidity (SAMM) becomes more and more accepted as an important indicator of reproductive health in high income countries, in addition to existing maternal mortality statistics.[1-23] Ever since 1880, maternal mortality is registered in the Netherlands by Statistics Netherlands (CBS). Since 1983, it is more accurately registered by the Maternal Mortality Committee of the Dutch Society of Obstetrics and Gynaecology, including individual assessment of substandard care in each case.[24] The World Health Organisation facilitates international comparison of national maternal mortality ratios to assess the quality of reproductive and public health care worldwide.[25] However, since maternal mortality in high income countries has become extremely low, there is a growing interest to also include SAMM in the quality assessment process. It takes years to collect sufficient data to draw valid conclusions about trends in maternal mortality. Moreover, maternal deaths are not representative of the major problems encountered in daily obstetric practice. For instance, major obstetric haemorrhage seldom leads to maternal death nowadays, whereas it is a major cause of SAMM.[26;27] And finally, although analysing cases of maternal death is of vital importance, further reduction of maternal mortality will not likely have large effects on the quality of obstetric care anymore. In contrast, much improvement of quality of care may be gained through reduction of SAMM. Still, considering the course from normal pregnancy to maternal death as a continuum as described by Mantel et al[2], maternal mortality could further decrease by also focussing on SAMM.

There is a paucity of epidemiologic data on pregnancy and childbirth in the Netherlands. Despite a properly functioning national statistics unit (CBS) and the existence of the Dutch Perinatal Registry ('Landelijke Verloskunde Registratie', LVR), vital obstetric statistics are lacking. For instance, we do not know the exact caesarean section rate, the rate of women with a caesarean section in their obstetric history and pregnant women's body mass index. Moreover, until now the incidence of severe obstetric conditions such as eclampsia, uterine rupture and major obstetric haemorrhage in the Netherlands was unknown. As epidemiologic data serve as an important tool for signalling trends in obstetric practice, opportunities to improve the quality of obstetric care are likely missed. In the United Kingdom, a government-funded national perinatal epidemiology unit (NPEU) exists in Oxford, employing nearly 50 persons. In Scandinavian countries, national perinatal databases are kept more accurately, including linkage to the newborns and to national statistics.
There has been a growing interest in evaluating health services in recent years, clinical audit being

a vital part of this process. The awareness that quality improvement should start with quality measurement is rising. An important factor that has speed up this awareness was the Peristat-I report, in which Dutch perinatal mortality was said to be among the highest in Europe due to variations in epidemiologic registration.[28] This has led to the development of a national perinatal audit system.[29] Furthermore, improvement of the Dutch Perinatal Database is foreseen with an upcoming new set of minimally required data for each delivery, and a set of parameters is developed by the Quality Committee of the Dutch Society of Obstetrics and Gynaecology to monitor quality of obstetric care. This brings about opportunities for the implementation of the results of the study described in this thesis.

Internationally, a similar pattern can be observed in other high income countries. The United Kingdom traditionally played a leading role in assessing quality of obstetric care including maternal mortality statistics and clinical audit. They are now again leading in the development of a surveillance system for trends in obstetric practice and management. The United Kingdom Obstetric Surveillance System (UKOSS), was established in 2005 by the National Perinatal Epidemiology Unit to describe the epidemiology of a variety of uncommon disorders of pregnancy.[30] Advanced plans exist for a comparable European network to monitor even rarer conditions, but funding is still a problem. In the 2000-2002 triennial report of the confidential enquiry into the causes of maternal deaths a separate chapter dedicated to SAMM was included for the first time, based on data from the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH).[26] Various other groups internationally have investigated the rate of SAMM as a complementary marker of standards of care, including Canada, Australia and the United States.[11;20;21] The World Health Organisation is currently in the process of integrating these efforts into internationally accepted criteria for SAMM.[8] However, accurately defining SAMM appears very difficult and is of vital importance to facilitate international comparison.

The incidence of SAMM currently seems to increase in high income countries. This can be explained by various factors, including the rise in maternal age at childbirth, the rise of multiple pregnancies following assisted reproduction, the rise of caesarean section rates and the rise of pregnant mothers with complex medical conditions like cardiac disease, who did not reach reproductive age or were denied to become pregnant in the past. However, close monitoring of the incidence of SAMM is a necessary first requirement to reveal these patterns of obstetric practice and management.

This thesis describes the various aspects of SAMM in the Netherlands. During a two-year period, all cases of SAMM were collected in a nationwide design. The study was called LEMMoN, a Dutch

acronym for Nationwide study into Ethnic determinants of Severe maternal morbidity in the Netherlands [Landelijke studie naar Etnische determinanten van Maternale Morbiditeit in Nederland]. It was initiated by the Maternal Mortality Committee of the Dutch Society of Obstetrics and Gynaecology to extend the assessment of cases of maternal mortality to also include SAMM. As ethnicity appears to be a significant risk factor for maternal mortality and seems to be a risk factor for SAMM, special attention was paid to the ethnic background of women. A qualitative study on the patient-related perspectives of the experienced SAMM among immigrant women was embedded in this study, but detailed results are outside the scope of this thesis.

Aim of the studies presented in this thesis
The studies address the following questions:

1. What is the **incidence and case fatality rate** of SAMM in the Netherlands, overall and for different subgroups?
2. What are the **determinants** of SAMM in the Netherlands, overall and for different subgroups?
3. Is the incidence of SAMM, overall and for different subgroups, elevated in **non-Western immigrants** in the Netherlands, and if so, what is the additional risk and its determinants for different ethnic minority women?
4. What is the level of **substandard care** in the reported cases of SAMM and is substandard care assessment through audit meetings instructive and feasible at a national, regional and local level?
5. Is **ongoing registration** of SAMM for the purpose of reproductive health care quality measurement necessary and feasible, and if so, how can it best be implemented?

Outline of the thesis

Chapter 2 highlights some methodological considerations involved in the design of the LEMMoN study. While general methods were described in the respective chapters, some important aspects deserved a more detailed description than was possible in the published manuscripts. Additional information regarding definitions, selection of inclusion criteria and selection of denominator data is included. Furthermore, the actual performance of the LEMMoN study and results of sub analyses that are specific to the Netherlands, are also described in more detail.

Chapter 3 describes the general results of the LEMMoN study. All cases of SAMM that occurred during the two-year period from August 2004 until August 2006 in the Netherlands are summarised,

along with incidence figures and case fatality rates overall and for different subgroups of severe maternal morbidity. Risk factors are assessed as compared to the general pregnant population in the Netherlands, and substandard care analysis is described for a subgroup of women.

Chapter 4 addresses the differences between non-Western immigrant women and Western women in experiencing severe acute maternal morbidity. Population based relative risks are shown for each type of morbidity and for each of the larger ethnic minority groups in the Netherlands. By comparing Western and non-Western women with SAMM in a multivariable model, explanatory factors for the difference in SAMM are identified. Additionally, to obtain qualitative data related to immigration and acculturalisation, a subgroup of women were interviewed.

Chapter 5 presents an analysis of all intensive care unit admissions during the study period in the Netherlands. Risk factors and case fatality rates are assessed, reasons for admission are summarised and women admitted to intensive care are compared to women with SAMM not requiring intensive care.

Chapter 6 presents an analysis of all uterine ruptures during the study period in the Netherlands. Incidence and risk factors are assessed in women with scar rupture and rupture of the unscarred uterus. Risk of use of uterotonic agents for trial of labour after caesarean section is assessed and discussed. A comparison is made with previous recent findings in the Netherlands.

Chapter 7 presents an analysis of all cases of eclampsia during the study period in the Netherlands. The elevated incidence as compared to other Western European countries is described, and the reasons for the large difference are discussed. Substandard care was assessed in a subset of women.

Chapter 8 presents an analysis of the severest cases of major obstetric haemorrhage in the Netherlands: those necessitating arterial embolisation and/or peripartum hysterectomy.

Chapter 9 presents all cases of severe maternal morbidity and maternal mortality in women who are Jehovah's witnesses.

Chapter 10 presents the results of our efforts to quantify underreporting to the LEMMoN study. As underreporting is inevitable in large observational multicentre studies like LEMMoN, we

searched for possibilities to quantify this. Underreporting appeared to be especially significant in case of major obstetric haemorrhage. For this reason, we conducted a national survey of cases of major obstetric haemorrhage through blood banks in the Netherlands.

Chapter 11 describes the introduction of audit of SAMM in the Netherlands.

Chapter 12 contains the general discussion. Results and conclusions are summarised.

Chapter 13 contains a list of recommendations.

Chapter 14 summarises the thesis. This chapter also includes a summary in Dutch.

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