

Implementing personalized obstetric care

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Valorisation

This chapter discusses the societal and economic relevance of this thesis. Valorisation has been defined by the Dutch National valorisation committee as *'the process of value creation from knowledge by making knowledge suitable for either economical or societal utilization and by translating knowledge into new products, services, processes, or business'*¹.

Relevance

The unique Dutch system with autonomous midwives providing primary care for pregnant women and obstetricians providing secondary, used to be an example of well-organized maternity care with low rates of medical interventions². However, this conservative approach underlying the Dutch system became subject of debate due to high perinatal mortality rates in the Netherlands as reported by two successive European perinatal health reports³⁻⁵.

A system strictly divided into two separate levels of care, such as Dutch obstetric care, may suffer from disadvantages such as insufficient risk awareness and selection, discontinuity of care, and an increased risk of inaccurate communication⁶. Due to the European perinatal health reports, there was an increasing call for a reform of obstetric care into a system of integrated client-centered care with a more proactive approach^{3,6}. In Limburg, the obstetric consortium, consisting of obstetric healthcare professionals representing the region, chose to achieve this by designing and implementing a risk-based care (RBC) approach: an obstetric healthcare system relying on an individual risk assessment with basic care pathways for low-risk women and additional recommendations for women identified with an increased risk for pregnancy related complications. Furthermore, RBC pathways might stimulate integrated care by intensifying the collaboration between autonomous midwives and gynecologists.

The majority of perinatal deaths in the Netherlands are related to either asphyxia, preterm birth (PTB), small-for-gestational-age infancy (SGA), or congenital anomalies⁷. Hypertensive disorders in pregnancy, such as pre-eclampsia (PE), are strongly associated with SGA and PTB⁸. Gestational diabetes mellitus (GDM) increases the risk of with birth injuries and asphyxia^{9,10}. Therefore, preventing these adverse outcomes could eventually lead to a reduction of perinatal mortality.

A number of interventions have shown to be effective in the prevention of adverse pregnancy outcomes, such as low-dose aspirin treatment in case of PE¹¹⁻¹³, adequate management of GDM^{14,15}, and progesterone administration in women at risk of spontaneous PTB¹⁶. Most of the interventions, however, are not suitable for all pregnant women, because of either possible adverse effects, patient burden, or costs. Consequently, healthcare professionals need a risk assessment in order to decide which women may, on average, benefit most from such preventive measurements.

In care-as-usual (CAU), the Dutch obstetric indication list is used to check whether there is a predefined risk factor present, or a complication during pregnancy that warrants transfer from primary to secondary care¹⁷. However, this list does not assess an individual woman's absolute risk and is unable to take a combination of factors into account simultaneously. Furthermore, it does not describe the contents of obstetric care that should be offered.

The Expect Study was designed to improve the risk selection of pregnant women and consists of two parts^{11,18}. Expect Study I was aimed at the external validation of in total 39 non-invasive prediction models predicting important pregnancy related complications. Expect Study II, which is reported on in this thesis, focused on the implementation and evaluation

of RBC using prediction models, combined with obstetric healthcare paths tailored to the individual risk assessments ¹⁸.

Expect Calculator

To implement RBC we designed an online prediction tool, the Expect Calculator. This tool combines the selected prediction models, risk-thresholds, and care paths to enable RBC. Risk assessment of pre-eclampsia and gestational diabetes mellitus is performed with the aid of externally validated prediction models. Risks of spontaneous preterm birth and fetal growth deviations are assessed with regional guidelines which were provided by the Limburg obstetric consortium.

To facilitate the shared decisional approach, the results of the risk assessment are visualized at a linear scale. Moreover, the tool automatically provides patient information brochures tailored to the results of the individual risk assessment. As shown in Figure Add.1, displaying the number of risk assessments made per month, the Expect Calculator was increasingly and intensively used. Although the Expect Calculator was specifically developed for healthcare professionals of Limburg, it can be easily used by any obstetric healthcare professional.

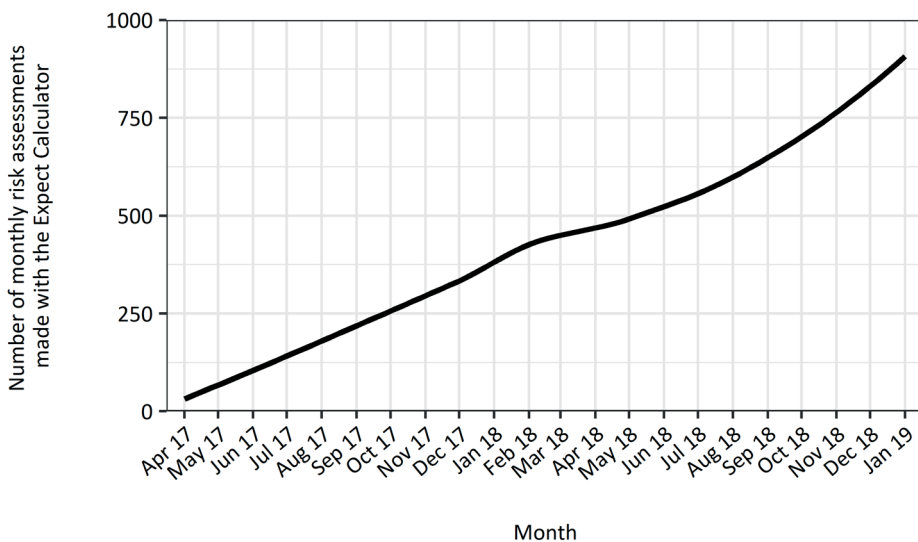


Figure Add.1 Number of risk assessments performed by the Expect Calculator per month

Societal impact

Merely explaining the societal relevance of improving obstetric healthcare would quickly result in stating the obvious. However, when accompanied with some statistics it may be easier to realize the potential societal impact of it. RBC focuses on early detection and prevention of pregnancy related complications with the aid of prediction models. The studies in this thesis indicate that implementation of RBC resulted in an increased usage of preventive measurements and a reduction of neonatal adverse outcomes. The following paragraphs discuss the potential societal impact of these improvements in Dutch obstetric care.

Roughly 8,500 women give birth in Limburg annually ¹⁹. Applying the incidence rate of PE, approximately 3% ⁸, to this number, means that every year 255 women in Limburg suffer from PE. Fortunately, the majority of the women PE will be manifest term or near-term. In these cases labor will be induced and often further adverse events are either prevented or remain manageable. However, for a minority PE truly becomes a life threatening disease, either for the mother or for the neonate ²⁰. Preterm PE, especially extremely preterm PE, frequently results in preterm birth and is often combined with low birthweight and prolonged hospitalization of the mother and the neonate. Although the management of PE has improved, a cure that would preserve the pregnancy and thereby diminishing the sequelae accompanied with preterm birth remains unavailable. Therefore, preventive measures play a pivotal role in decreasing the burden of PE ⁸. The absolute reduction of PE depends upon the combined effectiveness of low-dose aspirin prophylaxis and adequate calcium intake. A recent meta-analysis examining the effectivity of aspirin solely, indicated a relative risk of 0.56 (95% confidence interval, 0.43-0.75) if aspirin was initiated at ≤ 16 weeks of gestation ²¹. This would mean that, if all women at risk were identified and used low-dose-aspirin as recommended, 112 of the 255 annual cases could be prevented.

In this thesis, a composite outcome was used for the evaluation of the neonatal outcome. Interpreting a composite outcome may be somewhat complicated. Still, the relevance of the reduction of this outcome is clear since all components of the composite outcome are important determinants of child mortality and morbidity. The results of chapter 8 in this thesis indicate that RBC was associated with a 44% reduction of the adverse neonatal composite outcome in nulliparous women. In the Netherlands, excluding multiple pregnancies, roughly 161,000 children are born annually. Of these children, 71,000 (44%) are born to nulliparous women ¹⁹. Assuming a 6% prevalence rate of the adverse neonatal composite outcome, the observed prevalence rate observed in nulliparous women receiving CAU, means 4.260 neonates in the Netherlands suffer from such an adverse outcome. Applying the 44% reduction rate as indicated by the analyses of chapter 8, would mean nationwide implementation of RBC in the Netherlands could prevent 1,874 new-borns having an adverse outcome. This number is equal to the number of children of roughly seven averaged sized elementary schools.

Economic impact

Ideally, decisions regarding recommendations and preferred follow-up in general are primarily based on clinical arguments. However, the potential costs associated with provided healthcare services cannot be neglected as resources, be it healthcare costs or trained staff, are not infinite. The Dutch government, as most governments of developed countries, struggles with increasing healthcare expenditures that threaten the sustainability of the healthcare system. When healthcare expenditure remains to increase at the same speed as it did during 2006-2016, a household would spent half of its income on healthcare by 2040 ²². As a result, reformation of a healthcare system should be accompanied with an economic evaluation. This evaluation should firstly answer whether the reform results into increased healthcare costs. If so, the next question is whether the reform is cost-effective, or in other words, whether the degree of improved outcomes justify the increased costs. Chapter 8 of this thesis describes the economic evaluation of RBC in detail. The results indicate that RBC is cost-effective and result in a substantial direct cost reduction of approximately €2,700 per pregnant woman. This would mean that nationwide implementation, taking into account

163.826 pregnant women¹⁹, may result in a cost saving of 442 million euro per year.

Future implications

The studies in this thesis provide useful insights regarding the potential impact of RBC relying on a prediction tool that enables an individual risk assessment. Before a prediction model can be put to practice thresholds should be selected that indicate which risks are considered as increased²³. This thesis covers how the obstetric consortium of Limburg handled this process and tried to incorporate all stakeholders. Although there are many different strategies imaginable to accomplish the implementation of a prediction model into daily practice, our study design may serve as an example for others.

Dissemination of guidelines or stating recommendations does not automatically result in adherence by healthcare professionals. Implementation of effective preventive interventions often suffers from low adherence rates²⁴⁻²⁶. The research in this thesis gives a first glance of the uptake of recommendations that emerged from an individual risk assessment provided by a prediction tool. Furthermore, a first insight of potential barriers that may hamper the uptake is provided.

By using a qualitative study design, the potential barriers and opportunities involved in this process could be evaluated in depth. Such a study, with the aid of focus groups, is currently performed regarding the recommendations of adequate calcium intake during pregnancy. Further research like this, will be necessary to improve the utilization of recommended preventive measures. This would increase our insight how to optimize the implementation of RBC, increase the uptake of preventive interventions, and how RBC could be implemented best in other regions.