

# BMJ Open Variations in childbirth interventions in high-income countries: protocol for a multinational cross-sectional study

Anna Seijmonsbergen-Schermerms,<sup>1</sup> Ank de Jonge,<sup>2</sup> Thomas van den Akker,<sup>3</sup> Katrien Beeckman,<sup>4</sup> Annick Bogaerts,<sup>5,6,7</sup> Monalisa Barros,<sup>8</sup> Patricia Janssen,<sup>9</sup> Lorena Binfa,<sup>10</sup> Eva Rydahl,<sup>11</sup> Lucy Frith,<sup>12</sup> Mechthild Gross,<sup>13</sup> Berglind Hálfhánsdóttir,<sup>14</sup> Deirdre Daly,<sup>15</sup> Jean Calleja-Agius,<sup>16</sup> Patricia Gillen,<sup>17</sup> Anne Britt Vika Nilsen,<sup>18</sup> Eugene Declercq<sup>19</sup>

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## ABSTRACT

**Introduction** There are growing concerns about the increase in rates of commonly used childbirth interventions. When indicated, childbirth interventions are crucial for preventing maternal and perinatal morbidity and mortality, but their routine use in healthy women and children leads to avoidable maternal and neonatal harm. Establishing ideal rates of interventions can be challenging. This study aims to describe the range of variations in the use of commonly used childbirth interventions in high-income countries around the world, and in outcomes in nulliparous and multiparous women.

**Methods and analysis** This multinational cross-sectional study will use data from births in 2013 with national population data or representative samples of the population of pregnant women in high-income countries. Data from women who gave birth to a single child from 37 weeks gestation onwards will be included and the results will be presented for nulliparous and multiparous women separately. Anonymised individual level data will be analysed. Primary outcomes are rates of commonly used childbirth interventions, including induction and/or augmentation of labour, intrapartum antibiotics, epidural and pharmacological pain relief, episiotomy in vaginal births, instrument-assisted birth (vacuum or forceps), caesarean section and use of oxytocin postpartum. Secondary outcomes are maternal and perinatal mortality, Apgar score below 7 at 5 min, postpartum haemorrhage and obstetric anal sphincter injury. Univariable and multivariable logistic regression analyses will be conducted to investigate variations among countries, adjusted for maternal age, body mass index, gestational weight gain, ethnic background, socioeconomic status and infant birth weight. The overall mean rates will be considered as a reference category, weighted for the size of the study population per country.

**Ethics and dissemination** The Medical Ethics Review Committee of VU University Medical Center Amsterdam confirmed that an official approval of this study was not required. Results will be disseminated at national and international conferences and published in peer-reviewed journals.

## Strengths and limitations of this study

- The use of crude data at the level of individual women.
- The use of strict definitions of variables.
- Multivariable analyses to make more valid comparisons between countries.
- Missing variables in multivariable analyses.
- Different quality standards for data across countries.

## BACKGROUND

There are growing concerns about the increase in rates of commonly used childbirth interventions. When indicated, childbirth interventions are crucial for preventing maternal and perinatal morbidity and mortality, and medical technology has led to improved maternal and perinatal outcomes in the last decades.<sup>1</sup> However, the routine use of these interventions in healthy low-risk women and children leads to avoidable maternal and neonatal harm and rising healthcare costs.<sup>2-7</sup> The rate of childbirth interventions varies both geographically and over different time periods,<sup>3 8-10</sup> even within groups of women with identical risk profiles, and has risen for some interventions and declined for others.<sup>8 10-13</sup> In low-income countries, a very low caesarean section (CS) rate has been reported with a high risk of maternal mortality. Due to inadequate access to high-quality intrapartum care in these countries, most stillbirths in these countries are preventable.<sup>14</sup> CS and labour induction rates have shown a steady increase since the 1970s in high-income countries.<sup>8 10 12 15 16</sup> However, CS rates higher than 10% are not associated with lower maternal and perinatal mortality.<sup>17 18</sup> In contrast to the increase of CS rates, the episiotomy rate has declined in many countries



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For numbered affiliations see end of article.

### Correspondence to

Anna Seijmonsbergen-Schermerms;  
a.seijmonsbergen@vumc.nl



since the 1980s.<sup>8 19 20</sup> WHO has stated that episiotomy rates should be no higher than 10%.<sup>21</sup>

While establishing ideal rates of childbirth interventions is a challenge,<sup>22 23</sup> high rates of interventions should be avoided, especially among low-risk women, because of the risk of adverse effects. CSs are associated with adverse perinatal outcomes,<sup>24</sup> postoperative complications<sup>25 26</sup> and avoidable maternal and fetal risks in subsequent pregnancies.<sup>27</sup> Therefore, CSs should only be performed for strict medical and obstetric indications. Other interventions, such as induction of labour, augmentation of labour, epidural anaesthesia, instrument-assisted birth and episiotomy, if performed without medical indication, can lead to avoidable adverse maternal and perinatal outcomes.<sup>28–31</sup>

Several studies have reported international variations in CS rates.<sup>8 15 17 32–34</sup> Positive correlations with CS rates have been shown for gross domestic product per capita, proportion of the population living in urban areas, number of doctors and for the presence of a skilled birth. An increased percentage of childbirth interventions in private hospitals compared with public hospitals has also been described.<sup>15 17 32</sup>

Few studies have focused on variations in childbirth interventions other than CS or rates of several childbirth interventions together. In 1990, Notzon described sharp differences in rates of CSs in 21 countries and rates of instrument-assisted births in 14 countries.<sup>9</sup> In 1993, Stephenson *et al* described a 3-fold difference in CSs and a 10-fold difference in instrument-assisted vaginal births in 12 countries.<sup>35</sup> The European Perinatal Health Report confirmed major variation in rates of interventions such as CSs, instrument-assisted births, induction of labour, episiotomy and births without childbirth interventions in 2004 and 2010 in Europe.<sup>8</sup> For example, a secondary analysis of these data showed that national episiotomy rates in all vaginal births ranged from 4.9% in Denmark to 75.0% in Cyprus.<sup>36</sup> Festin *et al*<sup>37</sup> found significant variation in the practice of active management of the third stage of labour in 10 countries.<sup>37</sup> Patterns of associations between childbirth interventions, such as CSs and the use of instruments, and epidurals and intrapartum oxytocin use, have been shown.<sup>5 8 38 39</sup>

In addition to the variation in childbirth interventions, intercountry variations in maternal and perinatal outcomes also exist.<sup>8 40</sup> For example, the proportion of women with obstetric anal sphincter injury (OASI) ranged from 0.1% in Poland and Romania and 0.3% in Slovenia to over 4% in Denmark and Iceland.<sup>36</sup> While the maternal mortality rate in most countries in Europe has not declined significantly over the past decades, in some countries, including the USA, this rate has increased.<sup>8 41</sup> Perinatal mortality rates have declined in many countries worldwide and wide variations persist; however, these figures might be influenced by registration differences and under-reporting in some countries.<sup>8 42 43</sup> Since differences in registration between countries occur, data must be interpreted with this in mind and figures of intervention

rates must not be analysed without describing maternal and perinatal outcomes.

Because of the wide variations in rates of childbirth interventions and maternal and perinatal outcomes that exist between countries, it is important that childbirth interventions are analysed comprehensively, so that rates of several interventions can be compared and patterns can be better understood. This is the first study comparing rates of several interventions with the use of clear definitions of the interventions and outcomes to facilitate meaningful comparisons. This study aims to describe the range of variations in commonly used childbirth interventions in nulliparous and multiparous women in high-income countries around the world, and outcomes, by comparing these rates among multiple countries.

## METHODS AND ANALYSIS

### Research design and setting

This multinational cross-sectional study uses existing data from childbearing women in 2013. The year 2013 was chosen to ensure that required data were available for all participating countries, and were as recent as possible. Data will be analysed in the Netherlands, during the autumn of 2017 and analyses will continue throughout 2018. High-income countries were selected on the basis of their representation in the COST Action IS1405 'BIRTH' (European Cooperation in Science and Technology),<sup>44</sup> and whether the necessary data for this study were available. Low-income countries are not included because of the difficulties in comparing them with high-income countries due to differences in healthcare services and access to care.<sup>45</sup> Countries that were not in the COST Action were also invited to reach more global coverage, and so the use of interventions among countries with diverse maternity care systems could be compared. Participating countries are Belgium, Canada, Chile, Denmark, England, Germany, Iceland, Ireland, Italy, Malta, the Netherlands, Northern Ireland, Norway and the USA. The reporting of this study will adhere to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.

### Participants

Data from all women in participating countries, or from a representative sample of the population, who gave birth to a single child from 37 weeks gestation onwards in 2013 are eligible for inclusion. For countries that cannot provide data from all women who gave birth in 2013, a representative sample of the population will be included. Which proportion of the total population it concerns, will be clearly described. Sample size calculation was not performed, because all available and eligible data from the participating countries for the year 2013 were included. Countries for which no data on parity, gestational age at birth and singleton or multiple gestation were available, were excluded.



## Patient involvement

Informed consent was not sought and women were not involved in the design of this study, because only anonymised national data or data from a representative sample of the population from 2013 will be used, which in most countries was routinely collected or collected after informed consent.

## Outcome measures

### Primary outcomes

The following variables are defined as primary outcomes: induction of labour (none; cervical ripening; artificial rupture of membranes; oxytocin; other method; unspecified), augmentation of labour, intrapartum use of oxytocin, artificial rupture of membranes, intrapartum antibiotics, epidural/spinal anaesthesia for labour (CS excluded), other pharmacological pain relief (none; systemic (non-)opioid analgesia; inhaled nitrous oxide; other; unspecified), episiotomy in vaginal births (none; mediolateral; midline; unspecified), spontaneous vaginal birth, instrument-assisted birth (International Classification of Diseases (ICD) code 081) (none; vacuum extraction; forceps delivery; unspecified), CS (ICD code 082) (none; planned; emergency; unspecified), active management of third stage of labour and use of oxytocin within 2 hours postpartum.

### Secondary outcomes

Secondary outcomes are perinatal mortality, Apgar score below 7 at 5 min, maternal mortality, postpartum haemorrhages  $\geq 1000$  mL (ICD code 072) and OASI (ICD code 070.2 and 070.3).

### Definitions

Clear operational definitions of the interventions and childbirth outcome measures will be used in order to allow valid international comparisons. Definitions of variables will vary among the countries. To ensure optimal uniformity, detailed instructions for the definitions of the variables will be given to the investigators.

### *Spontaneous onset of labour*

Spontaneous onset of labour means spontaneous onset of regular uterine contractions that was not preceded by cervical ripening or the use of any other method of inducing uterine contractions.

### *Induction of labour*

For induction of labour, more than one method can be used. Induction is defined as a technique to stimulate uterine contractions artificially prior to spontaneous contractions and includes administration of oxytocin to stimulate uterus contractions after spontaneous ruptured membranes in the absence of uterine contractions, or administration of oxytocin after cervical ripening and/or artificial rupture of membranes.<sup>46</sup> Cervical ripening is defined as an application of cervical ripening agents (such as prostaglandins) or mechanical interventions

(such as insertion of catheters) and is also included in the definition of induction of labour.

### *Augmentation of labour*

Augmentation of labour is the administration of oxytocin to stimulate uterus contractions after spontaneous onset of labour.<sup>47</sup>

### *Artificial rupture of membranes*

Artificial rupture of membranes means breaking the amniotic fluid sac artificially, regardless of the moment (before or during labour) or indication (eg, for induction of labour).

### *Epidural anaesthesia*

Epidural/spinal/neuroaxial anaesthesia refers to its use for pain management during labour contractions (spontaneous or induced). In case of a planned CS, epidural anaesthesia is considered not applicable and will be defined as no epidural anaesthesia.

### *Episiotomy in vaginal births*

An episiotomy is the use of a deliberate incision of the perineum to accelerate vaginal birth.<sup>48</sup> Episiotomy will be described for women with vaginal births only.

### *Caesarean section*

Planned CS is defined as a CS that was planned before onset of labour and was performed electively before or after spontaneous onset of labour. Emergency CS is defined as a CS that was not planned prior to the onset of labour.

### *Active management of the third stage of labour and oxytocin in the postpartum period*

Active management of the third stage of labour is defined as a combination of administration of an uterotonic agent after birth, early cord clamping and controlled cord traction. For use of oxytocin in the postpartum period, oxytocin can be administered intravenously or intramuscularly within 2 hours postpartum, including oxytocin use for induction or augmentation of labour which is continued after birth.

### *Mortality*

Perinatal and maternal mortality are defined as mortality within 7 days postpartum.

### *Obstetric anal sphincter injury*

OASI is a tear that extends to the external anal sphincter or when the rectal mucosa is torn.

## Countries and data source characteristics in 2013

The following data will be collected to provide an overview of the characteristics of the countries represented in this study: total number of inhabitants, number of births in the country in 2013, proportion of births in the provided dataset, Gross National Income per capita in 2013 (as specified by the World Bank<sup>45</sup>), source of the data (civil registration; medical birth register or child health system;

hospital discharge system; perinatal survey; confidential enquiry; other routine surveys; linked data source) and the organisation responsible for providing the data.

### Independent variables

Independent variables are parity (nulliparous; multiparous), maternal age at the time of giving birth (<20; 20–24; 25–29; 30–34; 35–39; ≥40 years), maternal body mass index (BMI) (<18.5; 18.5–24.9; 25.0–29.9; 30.0–34.9; 35.0–39.9; ≥40.0 kg/m<sup>2</sup>), gestational weight gain (mean and IQR, in grams), ethnic background, socioeconomic status (high; medium; low), gestational age at birth (37; 38; 39; 40; 41; ≥42 weeks), birth weight (<2500; 2500–3499; 3500–4499; ≥4500 g), place of birth (hospital; birth centre; home; other) and care provider responsible at onset of labour and at birth (midwife; obstetrician/gynaecologist; nurse midwife; general practitioner; other). Categories for ethnic background will depend on national classifications and will therefore vary between countries. The definition of ethnicity that is used in each country will be used to describe ethnicity in the descriptive analyses. When data from all countries are collected, an attempt will be made to provide a uniform definition (if possible) to enable adjustment for ethnicity. It may not be possible for most of the countries to collect data on whether a woman is a refugee or a migrant (as definitions of ‘migrant’ vary across the countries). The variable socioeconomic status will be categorised as high (75th percentile), medium (25th–75th percentile) and low (25th percentile) and the definition will also depend on national classifications. Some countries are not able to provide information on socioeconomic status and will therefore provide another variable that relates to socioeconomic status, such as education. How socioeconomic status is defined, will be clearly described for each country. An attempt will be made to provide a uniform definition (if possible) to enable adjustment for socioeconomic status. Place of birth will be categorised as in a hospital (a hospital where a CS can be performed), birth centre (a centre or hospital where a CS cannot be performed), home and other.

### Analysis

The results will be analysed and presented by country and will be stratified by parity. The results will be reported in absolute numbers and percentages. Univariable analyses will be performed to report on variations in rates of interventions and multivariable logistic regression analyses will be conducted to investigate variations among countries adjusted for maternal age, maternal BMI, gestational weight gain, ethnic background, socioeconomic status and infant birth weight. Because stratification by parity will not be used for outcomes with only a few cases, for these outcomes adjustments for parity will be added. ORs and 99% CIs will be used to compare the probability of interventions and the risk for maternal and perinatal outcomes compared with the weighted mean rate of the complete dataset, to ensure that all countries

contribute equally to the analyses. For the multivariable logistic regression analyses, outcome variables will be dichotomised and dummy variables will be created for potential confounders. To give a better understanding of the relationships between interventions, the results of interventions will be linked (such as emergency CS and instrument-assisted births) and illustrated in box plots with adjusted ORs and 99% CIs. Statistical analyses will be performed using STATA V.14 (StataCorp, College Station, Texas, USA).

### Missing data

The amount and type of missing data will be reported for each variable by country. If a country’s dataset has no information about a specific variable or has data regarding a dependent variable with >10% missing, the country’s data will be excluded from the analysis for that specific variable. If an independent variable included in the multivariable analyses is available, but there is >5% missing, data will be imputed using multiple imputation.

### Ethical and data protection issues

Investigators will be asked to describe their national ethical standards and data protection laws. They will also be asked to report the proportion of cases for which data are missing in the dataset. Countries for which no anonymised crude data at the level of individual women can be provided, will participate with aggregated data and these data will be used in the descriptive analyses. Finally, investigators will be asked to provide information on the standard quality procedures of the data source and the provided dataset, how missing data are dealt with and contradictions, and how checks are done to ensure that all eligible births are recorded. If the conditions for participation of the country are met, a data access agreement will be signed between the investigator’s institution and the VU University Medical Center.

### ETHICS AND DISSEMINATION

The Medical Ethics Review Committee of VU University Medical Center Amsterdam confirmed that official approval of this study was not required, because it concerns a secondary analysis of existing data (reference 2016.317). This multinational cross-sectional study with data from high-income countries will describe variations in childbirth interventions and maternal and perinatal outcomes. A comparison of intervention rates and rates of childbirth outcomes between countries will identify opportunities to improve maternal and perinatal outcomes. Results will be disseminated at national and international conferences and published in peer-reviewed journals.

### DISCUSSION

For some interventions, there is lack of consensus and ongoing debate about indications for their use and



whether an intervention is necessary, for example, planned CS for breech presentations, or after a previous CS,<sup>8</sup> or the use of episiotomy for prevention of major perineal tears in nulliparous and multiparous women.<sup>49</sup> It is important to avoid unnecessary interventions in child-bearing women and at the same time ensure that those interventions that are necessary take place.

This study only aims to describe variation in intervention rates, related to a number of maternal and birth characteristics. The design of this study is inappropriate for making causal associations. Therefore, the results need to be interpreted with caution. Indications for the use of childbirth interventions are rarely reported clearly in national data. Although multivariable analyses are conducted to adjust for characteristics, the indications for the use of interventions cannot be included in this study. Also other potential maternal confounders such as pre-existing medical condition and previous history cannot be included. This limits interpretation of the results, and reveals at the same time that auditing indications of childbirth interventions is important to ensure better comparisons between countries in future studies.

A major strength of this study is the use of crude data at the level of individual women and the use of strict definitions. This will allow us to conduct multivariable analyses and make valid comparisons between countries. As described before, the literature shows patterns of associations between commonly used childbirth interventions. Our data will permit exploration of these associations between interventions, which will give a better understanding of the patterns of intervention use and the impact of variations on mother and child.

Studying variations in a large number of interventions across countries will inform the debate about optimal rates and the results will contribute to the improvement of the quality of care. In subsequent studies, factors influencing major variations in intervention rates can be examined and addressed.

#### Author affiliations

<sup>1</sup>Department of Midwifery Science, AVAG, Amsterdam Public Health Research Institute, VU University Medical Center, Amsterdam, The Netherlands

<sup>2</sup>Department of Midwifery Science, VU University Medical Center, Amsterdam, The Netherlands

<sup>3</sup>Department of Obstetrics, Leiden University Medical Center, Leiden, The Netherlands

<sup>4</sup>Nursing and Midwifery Research Unit, Faculty of Medicine and Pharmacy, Vrije Universiteit Brussel, Brussel, Belgium

<sup>5</sup>Department of Development and Regeneration KU Leuven, University of Leuven, Leuven, Belgium

<sup>6</sup>Faculty of Medicine and Health Sciences, Centre for Research and Innovation in Care (CRIC), University of Antwerp, Antwerp, Belgium

<sup>7</sup>Faculty of Health and Social Work, Research Unit Healthy Living, Uc Leuven-Limburg, Leuven, Belgium

<sup>8</sup>Universidade Estadual do Sudoeste da Bahia, Vitória da Conquista, Brazil

<sup>9</sup>University of British Columbia, Vancouver, Canada

<sup>10</sup>Department of Women's and New Born Health Promotion-School of Midwifery Faculty of Medicine, University of Chile, Santiago, Chile

<sup>11</sup>Department of Midwifery, Metropolitan University College, Copenhagen, Denmark

<sup>12</sup>Department of Health Services Research, The University of Liverpool, Liverpool, UK

<sup>13</sup>Midwifery Research and Education Unit, Department of Obstetrics, Gynaecology and Reproductive Medicine, Hannover Medical School, Hannover, Germany

<sup>14</sup>Midwifery Programme, Faculty of Nursing, School of Health Sciences, University of Iceland, Reykjavik, Iceland

<sup>15</sup>School of Nursing and Midwifery, Trinity College Dublin, Dublin, Ireland

<sup>16</sup>Department of Anatomy, Faculty of Medicine and Surgery, University of Malta, Tal-Qroqq, Malta

<sup>17</sup>Institute of Nursing and Health Research, Ulster University, Jordanstown, UK

<sup>18</sup>Western Norway University of Applied Sciences (HVL), Bergen, Norway

<sup>19</sup>Boston University School of Public Health, Boston, Massachusetts, USA

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**Competing interests** None declared.

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**Data sharing statement** Patient-level data and full dataset are available, but restrictions apply to the availability of these data which were used under license for the current study, and so are not publicly available. Consent was not obtained but the presented data are anonymised and risk of identification is low.

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