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A quality assessment of The Georgian Birth Registry

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Preface

The aim of this report is to assess the quality of selected indicators in the Georgian Birth Registry during the 1st year of implementation. No funding was needed and there were no ethical conflicts.

When contemplating which subject to write my master's thesis on, I decided early on to seek out a global perspective. I thought an epidemiological study would be most interesting, and preferably something that subsequently could have potential real-life value. Health management on a large scale have come to increasingly fascinate me during my medical studies. It seems somehow impossible to make health interventions on a populational and global scale, yet it is done and impact the world every day.

Through the Arctic Research group at the University of Tromsø I encounter Erik Eik Anda, who became my supervisor. He informed me about the birth registry in Georgia which he was working on together with UNICEF and the Georgian Health Department. The registry had been implemented the very same year (2016) and was long sought-after in the Georgian healthcare system. However, it was many possible ways to go about such a big task. Luckily, Finn Egil Skjeldestad joined in as supervisor, with his extended knowledge on statistics, maternal and birth related health and quality control studies. The three of us formed a study model that would both be interesting to write about and hopefully useful for the further development of the registry.

To be one of the first to study and write about such a large-scale project as the Georgian Birth Registry is a true privilege. Through meetings with the supervisors and fellow project participants in Georgia and Norway, I have received a whole new insight into how population statistics are formed and the years of observations that lie behind even the smallest of health interventions. In working with this report, I have become increasingly more assured that I want to pursue a career in global health.

This report would never have been finished without the approval of use of data from the GBR and the invaluable help from my supervisors, Finn Egil Skjeldestad and Erik Eik Anda. Thank you for all your patience, feedback and help!

5th of June 2017, Tromsø. Sandra Kristiansen.

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1 Abstract

1.1 Aim

Assess the quality of the Georgian Birth Registry (GBR) in the 1st year of implementation.

1.2 Method

The GBR was implemented 1st of January 2016 in 285 maternity facilities in Georgia. The mode of reporting is case-report-forms (CRFs) which are filled out electronically by doctors or midwives and entered directly into the birth registry. Reporting to the GBR became mandatory by law on the 1st of May 2016. A formal application for usage of data was sent to the GBR and approved, the register file was retrieved in February 2017 and a study file was made. Number of births from the National Centre of Disease Control (NCDC) were obtained and compared to the GBR to find coverage. Data were analysed in three four-month periods. The Robson variables were assessed with regards to completeness of case reporting, inconsistent case-reporting, and missing Robson information.

1.3 Results

Coverage of births reported to the GBR was 91.9% in 2016. Valid information on all six Robson variables accounted to 4205 (7.4%) of births, while missing information on one or more Robson (R99) variables were found in 92.6% of the birth records.

1.4 Conclusion

The overall data quality in the GBR improved during the 1st year of implementation, but the data are unreliable for antenatal care and obstetric service. However, findings from this report show potential for improvements and further development of the GBR.

2 Abbreviations

CRF – Case-report-form

CS – Caesarean section

GBR – Georgian Birth Registry

MFR – Norwegain Medical Birth Registry

NCDC – National Centre of Disease Control

UNICEF – United Nations Children's Fund

WHO – World Health Organisation

3 Introduction

3.1 Health registries

The cornerstone of public health planning is information on births and deaths. Yet approximately 40 percent of births and 66 percent of deaths go unregistered worldwide, mainly in developing countries(1). The lack of data on population level leads to difficulties aiming goal-oriented and effective health interventions to the population in question, leaving it to estimates and observed trends. A solution for more efficient health management can therefore be to implement and maintain a health registry(2). A health registry is a form of public health surveillance that consists of systematically and continuously obtained health data from a given population. Results are commonly presented from a certain period of time, usually a calendar year. The purpose of a health registry is to monitor the health situation, study quality of treatment, find causes for diseases, and plan and manage health services(3).

3.2 Medical birth registry

A medical birth registry (hereafter birth registry) is a form of health registry which aim specifically at clarifying causes and consequences of health problems related to pregnancy and birth(4). Birth registries were created in several Nordic countries following the thalidomide disaster in Europe; Norway in 1967, Denmark in 1968, Sweden in 1973 and Finland in 1987. The registries have since then proven themselves useful for both surveillance and research purposes(5-9). To measure progress and change, different events and facts are sorted into variables, e.g. perinatal mortality, birth weight and pregnancy duration(10). In time, the variables can pinpoint areas that need special attention and enable estimation of recurrence risks. A properly executed birth registry will allow for investigating trends, such as the rate and changes in rate of medical procedures like caesarean sections (CS).

3.3 The Georgian Birth Registry

On the 1st of January 2016, the country of Georgia launched their own nationwide, fully digitalised medical birth registry – The Georgia Birth Registry (GBR) in association with UNICEF and the University of Tromsø, Norway.

Georgia is a developing, upper-middle-income country, geographically located in Asia but politically oriented towards Europe. The population is an estimated 3.7 million with 57 800 annual births(11, 12). Some information about births have been, and is still, reported to the

National Centre of Disease Control (NCDC), but these are mainly reports on paper and do not have the prerequisite of systematic and thorough medical information. The implementation of the GBR could therefore be a tremendous improvement to the Georgian healthcare system as it for the first time will allow in-depth analysis of the existing health care for birth and pregnancies, which further can have a great impact on future health care routines and interventions. The GBR follow the same principles for birth registries as mentioned above.

3.4 Caesarean section rates and the Robson 10-group system

The World Health Organisation (WHO) suggests that a CS rate greater than 15% is not medically justifiable in any region of the world, and global studies show that when CS rates exceeds 15% the risk factors begin to outweigh the health benefits. Yet, rates are rising and CS is currently the most commonly performed surgical procedure in developed countries (13-15). In Georgia, preliminary investigations suggest that the proportions of CSs are presently 40-50%. CSs require resources and money, prolongs the hospitalization of the mother and increases maternal morbidity and mortality. Controlling caesarean delivery rates is therefore a public health priority(16, 17).

In 2001, Robson proposed a 10-group system that classifies CS based on the *characteristics* of each individual woman and her pregnancy, rather than classifying the *indication* for CS (Table 1). Individual groups are carefully defined, mutually exclusive and totally inclusive. Factors considered are parity, start of labour, previous caesarean delivery, plurality, foetal presentation and gestational age(14, 18)(Table 2). The Robson classification is a widely accepted, risk-based classification system which allows comparison of clinically meaningful maternity population subgroups and the associated CS rates across institutions, countries, development groups and time(19).

3.5 Quality of registries and the use of Robson variables as a quality measure

A high-quality birth registry is a useful birth registry. Examining the percentage of "unknown" or "blank" responses to variables is a straightforward and easy measure of data quality. However, a full assessment of the completeness and validity of data requires thorough examination, as quality relies on several factor including high level of case reporting, completeness of registration and accuracy of information (20). Coverage, or completeness, of registration means that the whole population is included. Accuracy refers to the correctness of information of individual pregnant women. High-quality data will also have little discrepancy between reported and “true” data, i.e. data from a certified registry. Continuous and systematic quality control measures are characteristic of a smooth-running birth registry.

The Robson 10-group system is a simple method providing a common starting point for further detailed analysis within which perinatal events and outcomes can be measured and compared. With standardization of audit of events and outcomes, any differences in either sizes of groups, events or outcomes can be explained only by poor data collection, significant epidemiological variability or differences in practice(21). In other words, implying the Robson 10-group system on obstetric data can reveal which variables in the birth registry have poor reporting, and hence the quality of data is assessed.

4 Method

4.1 Preparations before implementation of the GBR

In 2015, the Georgian Birth Registry was outlined in collaboration with UNICEF and the Institute of Community Medicine at the University of Tromsø, using, among others, experiences from the Norwegian Medical Birth Registry (MFR). Variables were selected and the whole software system was created from scratch.

In September 2015, a pilot test of the GBR was run in two hospitals in Tbilisi with continuous feedback from staff. In October 2015, the Georgian Health Department summoned at least one representative from each of the 285 maternity wards and maternity health care clinics for training in how to use the CRFs in the GBR registry system. Training took place in Tbilisi, every session included 50 persons and took half a day to complete. This way, around 600 persons got training in a total of 6 days. After that, representatives from UNICEF and the GBR travelled to hospitals in Kutaisi, Zugdidi and Batumi and trained another 200 people. The few persons who did not meet in Tbilisi or any of the other cities met at the NCDC for training later.

4.2 Reporting to the GBR

Georgia has 105 maternity wards. All births in Georgia are monitored/supervised by a gynaecologist/doctor. In addition, 180 outpatient clinics provide antenatal care with a doctor in charge. The doctor is responsible for plotting the information into the CRFs utilized by the GBR-system, but the task can be delegated to nurses or midwives. Since the GBR is fully digitalised, data are entered directly into the registry. The chief of institution has the main responsibility that data from every birth and pregnancy control is reported to the GBR. The hospitals do not get reimbursed by the government for treating patients unless they report through the GBR.

4.3 Surveillance

On the 1st of May 2016, reporting to the GBR became mandatory by law. This means that the hospitals who did not report did not get reimbursed for treatments by the government. In June 2016, there was a review of the GBR which resulted in quality assessment of reported data, and enforced tasks for improving both case reporting and variable reporting. The improvements included making the interface more user-friendly, from dropdown menus with the most probable outcomes to value ranges, i.e. maximum and minimum birth weight. For gestational age, an automatic routine was implemented to ensure coherence between gestational age from the different antenatal care visits. Some variables were made mandatory in the CRFs, meaning that the computer system could not submit data to the GBR without having certain variable information filled out. This was true for gestational age, which got mandatory at 1st of May 2016 and parity, which got mandatory at the 1st of September 2016(22).

4.4 Making the GBR study file

In February 2017, all available data from 2016 were merged into one file: The Georgian Birth Registry of 2016. The data was pre-sorted into three different platforms within the data file, named Pregnancy, New born and Hospital. For this specific study, we used data from the Pregnancy-platform and New born-platform, which contained information about the mother's health and pregnancy, and child and birth, respectively. Data were merged by ID-number of the mother which corresponded to an identical ID-number of the child. This was done using SPSS (Statistical Package of the Social Sciences) version 24 for PC. Official information on number of births by months in 2016 was obtained from the NCDC and tabulated into the merged data file. In this way, a study file of all official registered births in Georgia for 2016 was made.

4.5 Exclusion criteria

Exclusion criteria were:

- More than one inquire of the identical mother-ID-number. If there were two or more identical inquiries, only one were included.
- More than one inquire of the identical new-born ID-number which *also* had identical birth date, birth weight, sex and Apgar scores for 1,5 and 10 minutes. This was deemed unlikely, even in the occurrence of twins/triplets/quadruplets, and only one inquire were included.
- New born with unlikely birth weight (0-300 grams or 7000+ grams) and/or unlikely gestational age (0-21 weeks).
- New born born in 2015 or 2017.

4.6 Variable definitions

All variables are organised in such way that the denominator is the official number of mothers as reported to the NCDC in 2016. If there is no case reported, the difference in *official* number of mothers and *reported* number of mothers will be a systematic underreporting denoted “No case reported” valid for each variable. Through organisation of the data, it became evident that some “maternal” cases reported missed a “new born” CRF, while none missing CRFs were discovered in the opposite direction. These cases were denoted “Inconsistent case reporting”. Blank, out of range and/or missing information for each variable were denoted “No information”.

The variables used in this thesis are dictated by the Robson 10-group system. The categorisation of the different variables is pre-determined in the GBR-setup. Following is an explanation of the variables and how they are categorised in the GBR;

- “Parity” refers to how many times the mother has delivered, in the GBR this can be any number and there is no pre-determined categorisation of this. I have therefore divided the entries into categories from 1-5+, with entries over 15 defined as out of range and therefore put into the “No information” category.
- “Gestational age” refers to the age of the child at birth, in weeks from the point of conception. In the GBR this can be any number from 0-44. I have therefore categorised this from week 23-27, 28-31, 32-36, 37-39, and 40-44.
- Start of labour refers to how the labour is initialised, in the GBR this is categorised as spontaneous, induced, forceps and caesarean delivery. Since forceps is a means of delivery and not relevant for start of labour, it is counted as invalid information and put into the “No information” category.
- Presenting part refers to which part of the foetus is emerging first, in the GBR this is categorised as occipital normal, occiput posterior, breech, transverse and other.
- Plurality refers to how many foetuses the pregnancy includes, in the GBR this can be any number. I have therefore categorised it as 1, 2 or 3+.
- Previous caesarean delivery is in the GBR categorised as 1, 2 or 3.
- Missing information for all these variables compromises the R99-group in the Robson 10-group system.

4.7 Coverage, completeness and time periods

Coverage was defined as how reporting to the GBR corresponded with reporting to the NCDC. Completeness of variable reporting included within-range values/categories for each variable, while incomplete (invalid) variable reporting were denoted to the categories “No case reporting”, “Inconsistent case reporting” and “No information”.

Furthermore, the year 2016 was divided into three four-month periods because of the law that occurred on the 1st of May. Time periods were therefore set from January-April, May-August and September-December.

4.8 Statistical analysis

The variables I wanted to examine were cross tabled against time to investigate fluctuation of the variables within different time periods. This was done using the analyse function in SPSS and look for frequency of variables vs. time period.

4.9 Formal approvals and ethical concerns

Data was obtained by official application to the NCDC and to the GBR for use of data. All data received were anonymised and the key that generated random numbers from the personal identification numbers has been deleted. No further permissions from the Regional Ethics Committee or the Norwegian Centre for Research data are needed. No ethical conflicts were discovered.

5 Results

The official numbers of births reported to the NCDC in 2016 was 56695, whereas the number of births reported to the GBR were 52122. This translates to 4573 births missing. The total coverage of data in the GBR was therefore 91.9% in 2016.

The discrepancy between reported data to the NCDC and reported data to the GBR is highest for the months January to April, with a total of 12.8 % of births missing from the GBR, and lowest for the months May to August, with a total of 4.2 % births missing from the GBR (Table 3).

In Table 4, “no case reporting” and “inconsistent case reporting” represents systematic missing information. “No case reporting” was highest in the initial months January to April, with a total of 10.4%, and lowest in May to August with a total of 2.4%. “Inconsistent case reporting” was highest in September to December with 4.3% and lowest in May to August with 1.9%. “No information”, defined as absent/invalid/out of range information, was unique for each variable.

Parity had valid information ranging from 8.1-12.8% during the first two time periods. When parity became a mandatory variable in the CRFs, valid information leaped to 91.6% in September through December.

Gestational age had only the systematic missing information for the last two months, as gestational age had become mandatory information in the GBR from May.

Start of labour had valid information ranging from 36.8%-42.9% throughout the year.

Presenting part had in general the highest valid information of all the variables, ranging from 85.2-95.6% throughout the year. The systematic missing information, mainly “no case reporting”, dominates the missing information for presenting part.

Plurality had valid information ranging from 1.1-3.5% during the first two time periods, with an increase to 45.7% in September through December. However, 18.2% were reported to carry twins and 8.1% reported to carry triplets.

Previous CS had valid information ranging from 30.1-41.7% throughout the year, translating to the same percentage of women registered with one or more previous caesarean deliveries (Table 4).

Valid information among all variables compromising the Robson concept were present in a total of 7.4% of registered births throughout the year. This means that out of 52122 births only 4205 had enough information to perform a Robson classification. Reported Robson information were 0.6-1.2% January through August, with an increase to 20.4% September to December. Missing Robson (R99) group was in total 92.6% throughout the year (Table 5).

6 Discussion

6.1 General overlook

The general tendency is that completeness of reporting in the GBR increases towards the end of the year. This is true for five out of six variables, as the second or third time period have enhanced completeness of data compared to the first period (Table 4). The most probable explanation for this development is the law from 1st of May which made reporting to the GBR mandatory. The implementation of selected mandatory variables would also have improved reporting, and it also shows that the registry is continuously reviewing its advancement and need for modification.

6.2 Change of practice

The GBR was purposely implemented on a "swift notice" in Georgia due to budgeting reasons and the wish for rapid initialisation by the government. This meant limited time to consider feedback from pilot testing and make modifications before launching, as well as preparations within institutions and for health workers that would report to the registry. The health care system in Georgia have no prior experience with systematically reporting to a medical registry, and health workers were prior to the GBR not accustomed with being personally responsible for accurately filling out CRFs(22). Hence, a change of practice and culture are taking place within the Georgian healthcare system. Studies regarding culture changes in health care practices show competing claims whether organisational cultures are capable of being shaped by external manipulation to beneficial effects, but key factors to promote change appear to include adequate leadership and perceived ownership(23).

6.3 Coverage of data

A key observation is that the reported number of births (56695 in the NCDC and 52122 births in the GBR) is high compared to the inhabitant number of 3.7 million and a reported fertility rate of 1.82(24). In comparison, Norway has 5.1 million inhabitants, 58890 annual births and a fertility rate of 1.71(24, 25).

The coverage of data in the GBR were 91.9% compared to the NCDC. A possible explanation of the discrepancy could be due to a phenomenon where people who do not actually live in Georgia "immigrate" to register children in order to obtain health care benefits. This is common in Georgia and would mean that a birth will be reported to the NCDC but not to the

GBR(22). However, the extent of this practice is difficult to quantify and literature supporting this claim have not been found in English.

6.4 Variable feedback and review

It can be discussed whether the 267 variables in the GBR are too many. It also appears that some of them are too specific, wrongly categorised and/or not clearly defined.

The variable “Start of labour” have several interesting findings. Firstly, CS as a means of start of labour would translate to elective CS, but this is only reported for a maximum of 0.8% of births. In comparison, the results from the variable “previous CS” suggests that up to 41.7% of women have undergone CS earlier. If we were only to look at these two variables the rate of CS would seem somehow ambiguous, even when spontaneous CS before start of labour is not taken into account. Still, the low invalid reporting could be explained by yet another variable in the GBR called “Delivery type”, which also offers CS as an option. Since “Delivery type” is not a Robson variable, the data is not used in this report. This portrays that double registration can be problematic when data is not registered with clear definitions and common understanding by the data providers. In executing studies that only looks at certain variables, such as this study, double registration increase the risk of crucial information gone missing to the variable unlooked at. Secondly, “Start of labour” had categorisation which wrongly included forceps. This was not the only variable with wrong categorisation, making room for confusion within the data set. Thirdly, “Start of labour” was not made mandatory in the GBR. A recent study which looks upon Robson classification and the hierarchy of the variables suggests that “Start of labour” is the most vital information to acquire, meaning without this information one could not perform a Robson classification(26). This becomes apparent in Table 5 where valid Robson information could only be made for 7.4% of all births. Bearing in mind the high CS-rates in Georgia and the benefits of Robson classification, “Start of labour” should improve its categorisation and then be considered mandatory in the GBR.

A variable with questionable validity of data, is “Plurality”. In the last four months, “Plurality” displays 26.3% occurrence of twins and triplets. In comparison, there was 1.69% multiple births in Norway in 2016 and the number is of similar proportions in other countries(27, 28). The reason for this wrong-reporting is not certain, but it depicts the importance of being critical to the data found and look for possible sources for mistakes, even when the numbers are not as apparent as in this case.

The GBR also portrays a wide variety of screening tests. An example is "New born phenylketonuria", where the lab results do not come back until weeks after testing and will therefore not be registered in the GBR. Perhaps too many interests played a part when deciding on the variables.

The 267 variables were, as mentioned earlier, spread across three different platforms within the data file. The number of variables not only makes the GBR a massive data file, but the division into platforms make it somehow difficult to navigate through and assess.

6.5 Factors that can influence rate of caesarean sections in Georgia

In Georgia, doctors are paid more to perform a CS compared with assisting in vaginal birth. In addition, the hospitals are paid more by the government for CS compared to vaginal birth. Any system that rewards certain practices could influence the treatment of patients, even when indication is low. Hospitals in Georgia often have an overcapacity of beds and staff, making it easy to facilitate the increased capacity derived from excess CS(22). These factors must be considered when assessing the assumed CS rate of 40-50%.

6.6 Practical strengths and weaknesses

The many reporting facilities in Georgia represent a potential source of complication, for example can it be expected that more health care staff in time will require training, making it challenging with logistics. Also, the practices in using the registry can vary among institutions. Another potential weakness is that reported data, typed by the healthcare workers, goes straight to the registry without further quality assessment other than retrospective quality controls. A strength with this model is however that it eliminates the need for a middle-part or double-entry. Also, computer knowledge among healthcare workers, computer technology and internet coverage is reportedly good in Georgia, further adding to the strengths of using a fully digitalised registry. Lastly, the rate at which the GBR was developed and implemented in Georgia, as well as the capability to train a large number of health care staff in a short period of time, shows a force of action that is promising to the future of this registry.

6.7 Lessons from other registries

Medical registries exist in several countries, however the quality controls performed are more often described in internal reports rather than published data. In a quality assessment of the Swedish Medical Birth registry from 1990, birth certificates were compared to digital registry information. Another study that investigated quality of an antibiotics and infection's registry used the registry's denominator data and evaluated completeness, representativeness and accuracy compared to administrative data. In 2006, the Murmansk County Birth Registry (MCBR) was implemented in a region in Russia and quality controls were performed during the first year and the year after, using a similar variable-assessment approach as this report. (9, 29, 30). These examples show that there are many ways to perform quality assessments of large-scale registries, based on the resources at hand.

The Swedish study found that mistakes in the basic medical records were quite common, were information was missing in the registry but found in other medical journals. These mistakes can be due to inappropriate timing of data collection. For example, maternal height, weight, and weight gain during pregnancy are information that should be noted when the woman is admitted for delivery. As most women are in active labour during time of admittance, there may not be time for making these measurements and their clinical value at that moment can be questioned. On the other hand, when the woman comes to antenatal care she will spend around 20 minutes with a doctor and/or midwife, making it more logical to measure height and weight, ask for smoking habits, family situation, medical diagnosis and so on(30). Although the Swedish study are quite old at the time speaking, the results found can still be useful to the GBR. For example, it can become mandatory to ask certain questions at the antenatal care rather than "whenever" in the pregnancy, minimising the risk of information going missing along the way.

6.8 Conclusion

The data quality in the Georgian Birth Registry becomes progressively better during the 1st year of implementation. Nevertheless, short planning time and many variables contribute to make the reporting uncertain, as depicted in fairly low coverage and high percentage of missing information. It is central to mention that the data found in the GBR have not yet been used as a basis for real-life health interventions. However, it has shown very useful in letting the health care system and hospital staff getting to know the system. For health workers to perceive ownership in the registry and implement reporting as a way of their normal routine, is vital for the future success of the GBR. The understanding of confounding factors are also important for further knowledge about the data. Even if the data reviewed in this report are uncertain, the experiences of the 1st year of implementation and the findings from this report portrays a useful starting point for further development of the GBR. In time, the GBR will undoubtedly become a valuable source of data for the Georgian health care system.

6.9 Recommendations

Following is a summary of recommendations to further improve the GBR:

- Fewer, more well-defined variables with correct categories that are merged into one platform. This can be particularly relevant during the initial years. Additional variables could then be added in time when the first variable set have been thoroughly reviewed and managed.
- The Robson variables should be made mandatory to ensure that classifying of caesarean sections is initialised.
- Actions should be taken to make the performing of CS less economically beneficial.
- CRFs can be reviewed to be made even more user-friendly and understandable. More variables could have dropdown menus with well-defined categories, and no entries allowed outside the dropdown menu. For variables that are not suited to have dropdown menus, minimum and maximum values of allowed data could be an option.
- Review the need for double registration.
- Regular quality controls and reviews.
- Make a five-year plan, set goals and improve year-by-year.
- Annual or half-year meetings with regional institutions where quality assessments are benchmarked.

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8 Tables

8.1 Table 1 - The Robson 10-group system + R99

R99	Missing Robson information
R1	Nulliparous, single cephalic pregnancy, greater than or equal to 37 weeks gestation, spontaneous labour
R2	Nulliparous, single cephalic pregnancy, greater than or equal to 37 weeks gestation, induced labour or were delivery by caesarean section before labour
R3	Multiparous, without previous uterine scar, single cephalic pregnancy, greater than or equal to 37 weeks, spontaneous labour
R4	Multiparous, without a previous uterine scar, single cephalic pregnancy, greater than or equal to 37 weeks gestation, induced labour or delivery by caesarean section
R5	Multiparous, at least one previous uterine scar, single cephalic pregnancy, greater than or equal to 37 weeks gestation
R6	Nulliparous, single breech pregnancy
R7	Multiparous, single breech pregnancy, including women with previous uterine scars
R8	Multiple pregnancies, including women with previous uterine scars
R9	Single pregnancy, transverse or oblique lie, including women with previous uterine scars
R10	Single cephalic pregnancy, at less than or equal to 36 weeks gestation, including women with previous scars

Reference (18)

8.2 Table 2 - Variables in the Robson 10-group system

The category of the pregnancy	Single cephalic pregnancy (1) Single breech pregnancy (1) Single oblique or transverse lie (1) Multiple pregnancy (2+) /missing (R99)
Previous obstetric record	Nulliparous (P0) Multiparous (without a uterine scar) (P1+) Multiparous (with a uterine scar)(P1+) /missing (R99)
The course of labour and delivery	Spontaneous labour Induced labour Caesarean section before labour (emergency or elective) /missing (R99)
The gestation of the pregnancy	The gestational age in complete weeks at the time of delivery (preterm - less than or equal to 36 weeks, full term - greater than or equal to 37 weeks) /missing (R99)

Reference (18)

8.3 Table 3 – Number of births reported to the GBR vs. official number of births reported to the NCDC, 2016.

	Jan-Apr		May-Aug		Sept-Dec		Total	
	N	%	N	%	N	%	N	%
NCDC	18256	100	19538	100	18892	100	56695	100
GBR	15927	87.2	18708	95.8	17487	92.6	52122	91.9
Difference	2338	12.8	830	4.2	1405	7.4	4573	8.1

8.4 Table 4 – Completeness of variables

Variables	Jan.-April N=18265	May-August N=19538	Sept.-Dec. N=18892
Parity	%	%	%
No case reporting	10.4	2.4	3.1
Inconsistent case reporting	2.4	1.9	4.3
No information	79.2	82.8	0.9
1	3.7	5.6	36.4
2	2.5	3.9	28.8
3	1.2	1.9	14.1
4	0.4	0.7	6.2
5+	0.3	0.7	6.1
Gestational age	%	%	%
No case reporting	10.4	2.4	3.1
Inconsistent case reporting	2.4	1.9	4.3
No information	34.5	0.0	0.0
23-27	0.4	0.6	0.5
28-31	0.5	0.8	0.9
32-36	2.9	5.6	5.4
37-39	32.7	61.1	59.0
40-44	16.2	27.5	26.8
Start of labour	%	%	%
No case reporting	10.4	2.4	3.1
Inconsistent case reporting	2.4	1.9	4.3
No information	50.4	52.9	51.5
Spontaneous	36.0	42.5	40.6
Induced	0.0	0.1	0.0
Caesarean delivery	0.8	0.3	0.4
Presenting part	%	%	%
No case report	10.4	2.4	3.1
Inconsistent case report	2.4	1.9	4.3
No information	2.1	0.1	0.2
Occipital, normal	65.0	71.4	68.7
Occiput posterior	0.0	0.0	0.1
Breech	4.6	4.5	4.7
Transverse	1.9	2.3	2.1
Others	13.7	17.4	16.8
Plurality	%	%	%
No case report	10.4	2.4	3.1
Inconsistent case report	2.4	1.9	4.3
No information	83.7	94.7	46.6
1	1.4	0.5	19.7
2	1.4	0.4	18.2
3	0.7	0.2	8.1
Previous CS	%	%	%
No case report	10.4	2.4	3.1
Inconsistent case report	2.4	1.9	4.3
No information	57.1	54.1	51.9
1	16.3	24.3	23.1
2	10.6	14.0	13.8
3	3.2	3.4	3.7

8.5 Table 5 – Robson table

	Jan-Apr		May-Aug		Sept-Dec		Total	
Valid Robson	N	%	N	%	N	%	N	%
No case reporting	1894	10.4	466	2.4	590	3.1	2950	5.2
Inconsistent case reporting	444	2.4	364	1.9	815	4.3	1623	2.9
Missing variable information	15700	86.0	18588	95.1	13629	72.1	47917	84.5
Reported information	227	1.2	120	0.6	3858	20.4	4205	7.4

GRADE-evaluation of key articles

Reference: Robson M, Murphy M, Byrne F. Quality assurance: The 10-Group Classification System (Robson classification), induction of labor, and cesarean delivery. Int J Gynaecol Obstet. 2015;131 Suppl 1:S23-7.			**Design:** Cohort study analysed as "patient series" Documentation level: IIb GRADE-reccomendation: B
Aim	**Materials og method**	**Results**	**Discussion/Comments**
Describe the 10-group classification system (TGCS) methodology using 2013 data from the National Maternity Hospital, Dublin, Ireland. Demonstrate how the TGCS can be used as a common starting point to routinely audit induction of labor and cesarean deliveries. **Conclusion** With standardisation of perinatal audit of events and outcomes, any differences in either events or outcomes can be explained only by poor data collection, significant epidemiological variables or differences in practice. Other information than TGCS is required to ensure overall quality of care. The full benefit of the TGCS will not be realised until it is used routinely by all labour and delivery units. **Country** Ireland **Year data collected** Data for 2013 analysed in 2015	**Data source:** Data for 2013 from the National Maternity Hospital (NMH), Dublin, Ireland. **Inclusion:** All women delivering neonates weighing more than or equal to 500 grams in the NMH in 2013. **Exclusion:** Women delivering neonates weighing under 500 grams in the NMH in 2013 **Abbreviations:** Dyst = dystocia, IUA = inefficient uterine action, IIT = inability to treat, FI = fetal intolerance, OC = over contracting, PR = poor response, EUA = efficient uterine action, CPD = cephalopelvic disproportion, POP = persistent occipito posterior position, VE= vaginal examination, PET = pre-eclamptic toxaemia, SROM = spontaneous rupture for membranes	**Table 1 – The TGCS for caesarean deliveries:** 2024/8755 (23.1%) had a caesarean delivery. Robson group: size of group, % - caesarean delivery rate in group, % - contriution of each group, % (23.1%). Robson 1: 23.3 – 7.1 – 1.7. Robson 2: 14.9 – 35.9 – 5.3. Robson 3: 29.3 – 1.2 – 0.4. Robson 4: 10.8 – 13.8 – 1.5. Robson 5: 11.5 – 68.1 – 7.8. Robson 6: 2.0 – 93.8 – 1.9. Robson 7: 1.6 – 89.9 – 1.4. Robson 8: 2.3 – 65.7 – 1.5. Robson 9: 0.5 – 100 – 0.5 Robson 10: 3.9 – 30.4 – 1.2. **Table 2 – Total single cephalic nulliparous preg at greater than or equal to 37 weeks of gestation (groups 1 and 2, n = 3345):** Spontaneous labor 61.0% (2040/3345), Induced labour 35.7% (1195/3345), Pre-labour caesarean 3.3%(110/3345) **Table 3 – Indications for caes deliv in group 1 (7.1%)** Fetal reasons (no oxytocin) 1.2%, Dyst/IUA/IIT/FI 3.5%, Dyst/IUA/ITT/OC 1.5%, Dyst/IUA/PR 0.4%, Dyst (no oxytocin) 0.05% Dyst/EUA/CPD/POP 0.4%. **Table 4 – Events and outcomes in group 1** Oxytocin 53.9%. Epidural 70.0%. Electronic monitoring 87.7%. Apgar <7 at 5 min 0.7%. Caesarean deliv at VE=10 0.9%. Neonatal weight over/equal 4.0 kg 14.5%. Maternal age over/equal 35 y 18.3%. BMI over/equal 30 7.2%. **Table 5 – Indications for induction of labour in group 2a** Fetal reasons 9.3%, PET/hypertension 3.4%, Post-date pregnancy 7.6%, SROM 9.5%, Maternal reasons 4.1%, Nonmedical reasons or dates 1.9% + many more **Table 6 – Indicatins for pre-labour ceas deliv in group 2b** Fetal reasons 1.3%, PET/hypertension 0.3%, APH/placentia previa/abruption 0.5%, Maternal medical reason 0.9%, No medical indication 0.4%.	**Was the study based on a random selection of suited patient group? Were the inclusion criteria for the selection defined clearly?** Yes, the study included all women who gave birth to children over or equal to 500 gram at the same hospital in 2013. **Was it assured that the selection was not too selected?** No. Since only one hospital was included in the study, it can occur that the women giving birth there would have the same or similar demographic/social/etnic background. **Were all the patient in the same stadium?** Yes and no. Yes -everyone was pregnant. No – births occured at different weeks of gestation. Strengths: - Distribution and size of groups were fairly standard - No missing data - Size and CS rate of group 9 shows good data quality Weaknesses: - Less than 2:1 ratio between sizes of groups 1 and 2 points to a high incidence of induction and CS in this cohort. **Do the authors show to other litteraturet hat strengthens/weakens the resutlts?Yes.**

Reference:
Vogel JP, Betran AP, Vindevoghel N, Souza JP, Torloni MR, Zhang J, et al.
Use of the Robson classification to assess caesarean section trends in 21 countries: a secondary analysis of two WHO multicountry surveys
Lancet Glob Health. 2015;3(5):e260-70.

Design: Metaanalysis	
Documentation level	Ia
GRADE-reccomendation	A

Aim	Materials og method	Results	Discussion/comments:
Analyse the contribution of specific obstetric populations to changes in caesarean section (CS) rates, by using the Robson classification in two WHO multicountry surveys of deliveries in health-care facilities. **Conclusion** CS increased across all HDI groups.Nulliparous population was largest contributor to overall CS rate, especially in veriy high/high HDI countries. Incidence of labour induction increased across all HDI groups. High and growing rates of CS in Latin-American countries. **Country** Global **Year of data collection** Data from 2005-05, 2007-08 and 2010-11 analysed in 2017	**Data:** Deliveries in 287 facilities that were included in both the WHO Global Survey of Maternal and Perinatal Health (WHOGS) (2004-05 and 2007-08) and the WHO Multi-Country Survey of Maternal and Newborn Health (WHOMCS) (2010-11). **Study design:** Technical content of the two cross-sectional, facility-based, multi country surveys (WHOGS and WHOMCS) was reviewed by a specialist panel. WHOGS and WHOMCS had collected data prospectively from time of presentation at the facility until discharge or the seventh day postpartum. **Exclusions:** Facilities that participated in only one survey. Women delivering at less than 22 weeks or with unknown gestational age. Angola were excluded due to poor data. **Method:** Data from the two surveys were used to establish the average annual percentage change (AAPC) in caesarean section rates per country. Countries were stratified according to Human Development Index (HDI) group (very high/high, medium, low). Robson criteria were applied to both datasets. **Material:** 227811 + 239144 women, most 20-35 y of age, multiparous, spontaneous onset of labour	Of the 287 facilities, 70% were urban areas with a mix of tertiary, secondary and primary health-care facilities and 30% other referral level or missing. **Table 1 – Individual characteristics of women delivering** Compared with WHOGS, the WHOMCS had significantly more women with multiple pregnancy (p=0.002) and term deliveries (p=0.003). **Table 2 – Changes in CS rate between the two surveys** Overall rate of of CS was significantly higher in WHOMCS (31.2%) than WHOGS (26.4%, p=0.003). CS rate ranged from 5.3% in Niger to 46.2% in China in WHOGS and from 9.8% in Niger to 47.6 in WHOMCS. Most countries had positive AAPC in CS rate ranging from +1.0% per year (China) to +16.8% per year (Cambodia). Japan had -2.5% per year. **Figure 2 – Robson groups in WHOGS and WHOMCS stratified by HDI group** In all 3 HDI groups, nulliparous women (Robson 1 and 2) were the largest relative contributor to overall CS rate accounting for 1/3 of CS. Secondly were Robson 5 with ¼ of CS. 1.4% of women in WHOGS and 2.5% in WHOMCS could not be classified due to missing or contradictory data. Very high/high HDI countries: overall CS rate increased from 34.4% in WHOGS to 40.0% in WHOMCS. Moderate HDI countries: overall CS rate increased from 28.4% to 32.4%. Low HDI countries: overall CS rate increased from 14.4% to 20.3%.	**Strengths:** - Biggest application of Robson classification on a multi-nation dataset with the purpose of investigate CS-trends. - Large study population - Consistency in study methods - Similar definitions of variables collected across facilities. Weaknesses: - Not possible to assess changes in obstetric care (gain/loss of infrastructure, availability of essensial interventions, staff etc.) over time and how this could have affected the use of CS. - Suboptimal medical reporting in facilities can occur and subsequently affect dataquality. - A small group of women in both datasets could not be classified.

Reference: Cnattingius S, Ericson A, Gunnarskog J, Kallen B. A Quality Study of a Medical Birth Registry. Scand J Soc Med. 1990;18(2):143-8.			**Design** Retrospective quality assessing study analysed as "patient series". Dokumentation-level: IIb GRADE-reccomendation: A
Aim	**Materials og method**	**Results**	**Discussion/comments:**
Present general principles in quality analysing of registries which may be of value for the planning of similar registries in other countries or other fields. **Conclusion** The Swedish MBR is suitable for evaluation of «hard» data, but care must be applied for other types of information. Possible sources of error: - Validity of diagnoses: difference between hospitals and geographic areas, changing habits - Hospital of birth, significant confounder between diagn. - Mistakes in the individual record in the register **Country** Sweden **Year of data collection** Data for 1974 and 1986 collected in 1990	**Data:** Data from the Swedish medical birth registry (MBR) of 1974 and 1986. **Method:** For each y approx 0.5% random sample was selected and copies of the original hospital records obtained, these were read in detail and compared with data in the register. Quality of each item was independently assessed, score 1 = poor, 2 = acceptable, can be used with some care, 3 = good with low rate of errors. Variability in use of diagnosis between hospitals were studied. Different types of errors were identified and quantified, and the efficiency of the two methods of data collection (one mode used 1973-1981 and another from 1982 onwards) evaluated.	**Fig 1 – Flow chart for the two periods of the MBR** 1982-copies and 1973-1981-copies into the MBR **Table 1 – Content of the MBR 1973-1981** Type of representation (number, date, weeks, digit, grams, etc) and quality scores (1-3) for 40 variables like civil status, no. of previous pregnancies, date of birth etc. **Table 2 – Content of the MBR 1982 onwards** Type of representation (number, date, weeks, digit, grams, etc) and quality scores (1-3) for 67 variables like civil status, no. of previous pregnancies, date of birth etc. **Table 3 – Variability in freq of diagnoses among hospitals** 1974 (93 hospitals) compared to 1986 (73 hospitals) for 11 diagnoses like diabetes, abruptio placentae, fetal distress etc. Number of hospitals with deviating rates. Extreme rates recorded (highest/lowest). Mean rates. **Types of errors in the register** - Non-transferral of information from medical record to register - Mistakes in data entry into the computer medium - Digits versus check boxes - Mistakes in the basic medical records - Variability in the use of diagnoses between hospitals	**Was the study based on a random selection of suited patient group?** Yes. **Were the inclusion criteria for the selection defined clearly?** Not relevant. **Was it assured that the selection was not too selected?** Yes. Random selection of 0.5% of data from each of the year that were to be studied in the registry. **Were all the patient in the same stadium?** Not relevant. **Strengths:** The Swedish MBR is suitable for evaluating "hard data" **Weaknesses:** - Many possible sources of error in the register **Do the authors show to other litteraturet hat strengthens/weakens the resutlts?**Yes

Reference: Anda EE, Nieboer E, Voitov AV, Kovalenko AA, Lapina YM, Voitova EA, et al. Implementation, quality control and selected pregnancy outcomes of the Murmansk County Birth Registry in Russia. Int J Circumpolar Health. 2008;67(4):318-34			**Design:** Registry-based cohort study Documentation level: IIa GRADE-reccomendation: B
Aim:	**Materials and method**	**Results**	**Discussion/comments**
Describe the essential features of the newly established Murmansk County Birth Registry (MCBR), make preliminary comparisons for selected variables related to pregnancy and delivery in Nordic countries and in Murmansk County (MO) and explore research possibilities. **Conclusion:** A medical birth registry of satisfactory quality have been established for the world's largest arctic population. **Country:** **Russia, Norway, Finland, Sweden** **Year of data collection** Data for (2005), 2006 and 2007 analysed in 2008	**Data source:** Data from implementation of the MCBR and quality controls in 2006 and 2007 from 14(2006) and 15(2007) delivery departments. **Materials & method:** Information in the registry came from 4 sources; mother's medical history files, mother's obstetric journal, newborn's delivery record and mothers themselves during interviews by physician/midwife who also gathered information from the respective delivery department. The registry forms were sent to the Registry office in Murmansk and information entered into access database by "double-entry". Network quality assurance measures were built in the registry. Quality controls were performed 2006 and 2007, picking random files for each hospital. Goal was to check a minimum of 30 files or 10% from each hospital. 6 fields from registry forms evaluated: mothers date of birth, use of an upgraded maternity ward (yes/no), delivery type (3 tick-off boxes), complications during delivery (21 tick-off boxes and several ICD-10 codes), weight of newborn, sex of newborn. 2006: 410 files investigated, 2007: 547 files investigated. 2006 and 2007: 1500 data entries checked for transfer error to the database.	Coverage of data in MCBR = 98.6%. Proportion of errors below 1% both years. **Table 2 – Distribution of deliveries among the delivery departments in the MO in 2006.** 14 hospitals whereas 3 have 52.4% of all deliveries. **Table 3 – Results of quality control activities in 2006 and 2007:** Variables: Birth date of mother, Upgrade of maternity ward, Type of delivery, Complic during delivery, Sex of baby, Weight of baby. Missing (%) and mistakes (%) 2006 – 2007: 1.1% and 0.89% - 0.15% and 0.84%. **Table 4a – Selected variables from the birth registries of the study area (concerning the mother) for 2006** Average age of delivering women in MO were 3.6, 3.7 and 3.3 y lower than Norway, Sweden and Finland respectively. Compared to Nordic countries, MO had fewer women with parity of 3, lower BMI, similar smoking habits. **Table 4b – Selected variables from the birth registries of the study area (concerning the child) for 2006** Average birthweight 179-235 g lower in MO compared to Nordic countries. Perinatal mortality at 28 weeks was different between MO and the Nordic countries (p<0.02). Shorter gestational age in MO, 39.0 weeks compared to 39.2, 39.3 and 39.4 in Norway, Sweden, Finland. In tables 4a and 4b, values are arithmetic averages which should not be influenced by reported error rate.	**Were the groups comparabale for important background factors?** Yes, Stardardised variables in the registries. **Were the exposed individuals representative for a defined population?** Yes – data from 4 different registries. **Strengths:** - Large study population - Mainly equal definitions of variables across registries **Weaknesses:** - Paper registration transferred to computer format vs. Registries that are fully digitalised - Use of "double entry" will give an error source (minimum 7-10/10000). - Some differences in variable definitions and what is classified as end-point, can give observed differences even when there are none or larger observed differences

Reference: Betran AP, Merialdi M, Lauer JA, Bing-Shun W, Thomas J, Van Look P, et al. Rates of caesarean section: analysis of global, regional and national estimates. Paediatr Perinat Epidemiol. 2007;21(2):98-113.			**Design:** Ecological study/metaanalysis Documentational level: Ib GRADE-reccomendation: A
Aim	**Materials and method**	**Results**	**Discussions/comments**
Estimate the proportion of births by CS at national, regional and global levels, describe regional and subregional patterns and correlate rates with other reproductive health indicators. **Conclusion** Global CS rate is 15%. When CS rates rise substantially above 15%, risks begin to outweigh benefits. CS rates respond primarily to economic determinants in an S-curve fashion. Inverse association between CS rates and maternal, infant and neonatal mortality in countries with high mortality levels. The global and regional overview of CS rates establishes a comparative basis for the investigation of country-specific determinants. **Country** Global **Year of data collection** Data from most recent years analysed in 2007	**Data:** 126 countries. For developing countries: 53 identified surveys undertaken by the Demographic and Health Surveys (DHS) programme. For developed countries: 34 European countries where data were obtained from the European Health of All Database, for 39 other developed countries data were obtained by electronic publication databased, web search pages and government web sites. **Method:** Countries were grouped accordin to the UN classification for regional and subregional averages. Estimates were calculated as weighted means, with weight for the country's share of live births in the region. Regional and subregional coverage was calculated of total livebirths for which national data on CS were available. CS rates were correlated with maternal mortality ratio (maternal deaths per 100 000 livebirths), infant mortality rates (infant death per 1000 livebirths) neonatal mortality rates (neonat deaths per 1000 livebirth) and rates of skilled birth attendant (%) by transforming variables to log scale and applying non-parametric regression technicues to identify patterns of data. **Inclusion:** For countries with more than one available DHS survey, the most recent was used.	**Table 1 – CS rates by region and subregion and coverage of the estimates** Data from 126 countries represented nearly 89% of global livebirths in 2002. Coverage ranged from 83% in Africa to 100% in Northern America. The global rate of CS is estimated as 15%, although unevenly distributed. Rates are higher in developed countries, Latin America and Carribean and lower in other developing countries. Average rate of CS is 4.3% in Africa, 15.9% in Asia, 19% in Europe, 29.2% in Latin Am and Carrib. In developed countries, the proportion of CS births is 21.1% whereas the least developed countries only 2% of deliveries are CS. **Figure 2 – CS rates vs. maternal mortality ratio (MMR); log-log plots** Inverse association between maternal mort and CS rates, although the strength of the association weakens with decreasing MMR. Strong regional clustering suggests common regional factors determine both CS and mortality rates. **Table 2 – CS rates in China** CS rates ranges from 22.5% to 63.2%, unweighed mean 40.5%. **Figure 3 – CS rate vs. MMR in countries with CS rates above 15%, log-log plot** CS rates below 15% are correlated with lower maternal mortality, above 15% are predominantly correlated with higher maternal mortality. Similar pattern is found for neonatal mort and infant mort. **Fig 4 – CS rate vs. skilled birth attendant rate, log-log** CS rates are highly correlated with proportion of births attended by health personnel. Except Latin America, countries with skilled birth att rates below 80% consistently show CS rates below 10-15%.	**Strengths:** - Large study population - Fairly equal consensus of variables across countries and registries - Used data from the DHS. (The DHS is a large worldwide database of demographic and health data from nationally representative household surveys, it uses standardised method of data collection and -processing, and are often considered "the best available gold standard" for developing countries.) **Weaknesses:** - Confunding factors regarding association btw CS rates and reprod health outcomes can not be eliminated. - A large number of countries remain without national data on CS, especially Western Asia and Middle Africa, and could therefore not be included in this study.

Reference:
Robson MS.
Can we reduce the caesarean section rate?
Best Pract Res Clin Obstet Gynaecol. 2001;15(1):179-94.

Design: Comment

Documentation level	
GRADE-recommendation	

Aim

To introduce a standard classification system of CS.

Conclusion

A CS rate can only be considered appropriate if the information is available to explain and justify it.

- Information needs to be: clinically relevant, carefully defined, accurately collected, timely, available
- Auditing of CS: audit CS using the obst concept and their parameters, use standardised indications for induction and CS, monthly critical analysis of the 10 groups incl comparison with prev months and other units, subdivide the 10 groups for more detailed analysis as appropriate
- Implementing change: good info systems required, daily multidisciplinary meetings, senior midwifery and medical leadership, commitment from staff, changes to management, continue critical and continuous assessment

Country

England

Year data collected

2001

Materials og method

Data: Information from other articles cited in the paper.

Method: Use characteristics of the mother and pregnancy, rather than indication for CS, to assess the CS rates.

Results

Table 1 – The 10-group classification

1. Nulliparous, single cephalic ≥ 37 w, spontaneous labour
2. Nulliparous, single cephalic ≥ 37 w, induced or CS before labour
3. Multiparous (ex. prev. CS), single cephalic, ≥ 37 w, spontaneous labour
4. Multiparous (ex. prev. CS), single cephalic, ≥ 37 w, induced or CS before labour
5. Previous CS, single cephalic, ≥ 37 w
6. All nulliparous breeches
7. All multiparous breeches (incl. prev. CS)
8. All multiple preg (incl. prev. CS)
9. All abnormal lies (incl. prev. CS)
10. All single cephalic, ≤ 36 w (incl. prev. CS)

Table 2 – The obstetric concepts and their parameters

1. Category of pregnancy – Single cephalic, single breech, single oblique or transverse lie, multiple
2. Previous obstetric record – Nulliparous, multiparous (without uterine scar), multiparous (with uterine scar)
3. Course of labour and delivery – Spontaneous, induced, caesarean section before labour (elective or emergency)
4. Gestation – Gestational age in completed weeks at time of delivery

Fig 1 – the labour ward audit style

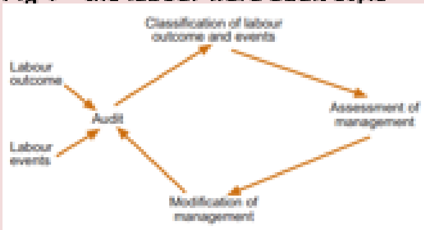

Figure 1. The labour ward audit cycle.

Diskusjon/kommentarer

This paper is more a comment and suggestion for improvement, rather than a study. However, it had a great impact in the obstetric world and founded the basis of a whole new approach to CS. It is therefore important to thoroughly assess this paper.