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Use of an individual-patient database for analysing caesarean section practices according to the WHO Manual for Robson classification and for developing quality improvement recommendations: a study in Sri Lanka

Short title: Use of a prospective database for the Robson classification in Sri Lanka

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Article summary: strengths and limitations of this study

- Despite being a single-centre study, this is the first study from a setting with limited resources reporting on the use of a prospective individual-patient database for analysing practices on caesarean section.
- This is also the first report on the use of WHO Implementation Manual for Robson Classification in a project aiming at quality improvement. The paper describes how the WHO manual can be used in an action-oriented manner for developing recommendations for improving the quality of maternal health care, and the quality of data collected.
- This pilot experience can be of interests of both researchers and policymakers, providing a model on how different types of variables can inform the Robson classification, and how findings from the Robson classification can be used proactively for decision-making.

Keywords

Quality of care; Health Information system; Robson classification; Caesarean Section

List of abbreviations

APH= Antepartum haemorrhage

BMI= Body mass index

CS= Caesarean section

CPD= Cephalopelvic disproportion

CTG= Cardiotocography

ECV= External cephalic version

Hb= Haemoglobin

IOL= Induction of labour

IUGR= Intrauterine growth restriction

QI= Quality improvement

QoC= Quality of Care

SMART= Specific, Measurable, Achievable, Realistic, Time-bound

SOP= Standards operating procedures

SQUIRE= Standards for Quality Improvement Reporting Excellence

UK= United Kingdom

USA= United States of America

WHO= World Health Organization

WHO MCS= WHO Multi country Survey on Maternal and Newborn Health

ABSTRACT

Objectives. This study aimed at describing the use of a prospective individual patient database on hospital deliveries for analyzing caesarian section (CS) practices according to the WHO Manual for Robson classification, and for developing recommendations for improving the quality of maternal hospital care (QoC).

Design Observational study

Setting De Soysa Teaching Hospital for Women, the largest maternity unit in Sri Lanka.

Data collection and analysis For each case of hospital delivery 150 variables were routinely collected in a standardised form and entered in a database. Data was routinely monitored for ensuring adequate quality. Information on deliveries occurring from July 2015 to June 2017 were analysed according the WHO Robson Classification Manual. Findings were discussed internally to develop quality improvement recommendations.

Results 7504 women delivered in the hospital during the study period and at least one maternal or foetal pathological condition were reported in 2845 (37.9%). Overall CS rate was 30.0%, with 11.9% CS performed pre-labour. According to the Robson classification, Group 3 and Group 1 were the most represented groups (27.0% and 23.1% of population, respectively). The major contributors to the CS rate were Group 5 (29.6%), Group 1 (14.0%), 2a (13.3%) and Group 10 (11.5%). Data on indication to CS suggested potentially inappropriate care, with high frequency of CS performed for abnormal cardiotocography (CTG)/suspected foetal distress, past CS and failed progress of labour or failed induction. Overall 16 recommendations were agreed. Beside updating protocols and hands-on training, activities agreed included monitoring and supervision, criterion-based audits, risk management meetings and appropriate information for patients. Recommendations to further improve the quality of data were also agreed.

Conclusions This study provides an example on how the WHO Manual for Robson classification can be used in an action-oriented manner for developing recommendations for improving the QoC, and the quality of data collected.

INTRODUCTION

Improving the appropriate use of caesarean section (CS) is a major global concern.[1, 2] While globally CS rates at population level are increasing, major disparities exist among countries, with both under-use and over-use of this procedure.[1, 2] Although there is no debate about the need to increase access to safe CS, there is also common agreement that CS should be performed only for medically indicated reasons.[1, 2]

Interventions to reduce unnecessary CSs have shown little success.[2] In the last few years, the World Health Organization (WHO) has endorsed the use of the Robson classification system,[3] and a manual for supporting its implementation was published in 2017.[4] The WHO Robson Classification Manual guide through the implementation of the Robson classification, and provide practical tools for analyzing CS practice in a standardized, reliable, consistent and action-oriented manner.[4] However, still there little published experience on the practical utilization of the WHO Robson Classification Manual,[4] and no concrete experience has been reported so far on how to use the manual in an action-oriented manner.

A rising trend in the national CS rate has been reported in Sri Lanka (33.2% in 2015), with large heterogeneity among different facilities,[5,6] and wide-spread diffusion of inappropriate indications to CS.[7] Nevertheless, few studies have analysed CS practices in a standardised manner [7,8] and no study used findings of such analyses for developing recommendations to improve the quality of maternal health care and the quality of data collected.

Since year 2015 we implemented a prospective individual patient database at the De Soysa Hospital for Women, Colombo, the largest maternity hospital in Sri Lanka. For each case of delivery, about 150 variables were collected and routinely entered in an electronic database.[9] The objective of this study was to describe the use of the information provided by this database to analyse CS practices according to the WHO Robson Classification Manual [4] in an action-oriented manner, with the aim of developing recommendations for improving the quality of maternal hospital care.

METHODS

Study design

The study was designed as an observational study aiming at analysing practices related to CS, and at developing recommendations for improving the quality of hospital care. The results section of this paper reports the findings of the Robson analysis [4] and how such findings were internally discussed and used.

Population and setting

Detailed methods of data collection have been previously reported.[9] Briefly, 150 variables (ie, maternal sociodemographic characteristics, risk factors, process indicators, maternal and neonatal outcomes) were collected for each individual birth using a standardised two-page form, and entered in real time in an electronic database. Data quality assurance procedures included detailed case definitions, standards operating procedures (SOP), regular random checks, and 137 automatic validation rules aiming at minimising data entry errors.[9]

The present paper reports findings relevant to CS practices, on births occurring in the period from July 2015 to June 2017. Missing cases for the variables of interest were overall ≤ 0.7%, except for trial of labour in previous CS, where missing variables were 1.2% (**Supplementary Table 1**).

Data analysis

Data was analysed according the recommendations of the WHO Robson Classification Manual [4] and synthesized according to the standardized reporting tables provided by the Manual (**Supplementary tables 3-5**).[4] According to the WHO methodology,[4] the analysis should follow the following key steps. First, each case of birth was classified into one of the Robson groups (**Box 1**), using six key variables (parity, previous CS, onset of labour, number of foetus, gestational age, foetal lie presentation). Secondly, data were assessed for: 1) quality, 2) type of population, 3) CS rates. As recommended in the WHO Manual,[4] relevant additional information provided by the local data collection system [9] were used as complementary information to allow an in-depth interpretation of CS practices. Specifically, the following types of variables collected by the local individual-patient database were used: maternal age,

gestational age, maternal pathological conditions (such as diabetes, hypertensive disorders and others), foetal pathological conditions, CS indications. For each step, findings were compared to the suggested two sources of interpretation in the WHO manual:[4] 1) the reference ranges and interpretation by Michael Robson;[3,13] 2) the findings of the WHO Multi country Survey on Maternal and Newborn Health (MCS, provided by the WHO Manual as an additional example for possible comparison (this is population characterised by relatively low CS rates and, at the same time, good outcomes of labour and childbirth).

Before starting the data analysis, the information in the database were cleaned. Specifically, the open text category called "other" under "indication for CS" (which already included 18 pre-defined categories [9] were thoroughly checked by two experienced obstetricians and classified, as more appropriate, in one of the predefined categories, or in a new category.

Box 1. The 10 groups of the Robson classification [4]

Group 1: Nulliparous women with a single cephalic pregnancy, ≥37 weeks gestation in spontaneous labour
Group 2: Nulliparous women with a single cephalic pregnancy, ≥37 weeks gestation who had labour induced or were delivered by caesarean section before labour
2a Labour induced
2b Pre-labour caesarean section
Group 3: Multiparous women without a previous caesarean section, with a single cephalic pregnancy, ≥37 weeks gestation in spontaneous labour
Group 4: Multiparous women without a previous caesarean section, with a single cephalic pregnancy, ≥37 weeks gestation who had labour induced or were delivered by caesarean section before labour
4a Labour induced
4b Pre-labour caesarean section
Group 5: All multiparous women with at least one previous caesarean section, with a single cephalic pregnancy, ≥37 weeks gestation
Group 6: All nulliparous women with a single breech pregnancy
Group 7: All multiparous women with a single breech pregnancy including women with previous caesarean section(s)
Group 8: All women with multiple pregnancies including women with previous caesarean section(s)
Group 9: All women with a single pregnancy with a transverse or oblique lie, including women with previous caesarean section(s)

Group 10: All women with a single cephalic pregnancy < 37 weeks gestation, including women with previous caesarean section(s)

Data use for developing recommendation for improving the quality of care

The findings of the analysis were presented during two dedicated workshops, with key hospital staff of different levels (ie, senior obstetricians, neonatologist, registrars, nurses, midwifes and other staff). The meetings were led by local staff (HS, RM), in dialogue with the WHO Collaboration Centre, Trieste, Italy.

The workshops had the following objectives: discussing hospital practices related to CS, identifying possible gaps in quality of care (QoC) provided, identifying possible gaps in data quality and/or in data collection procedures, selecting priorities for action, developing and agreeing recommendations for improving the QoC related to CS and, if needed, the quality of data. Secondary objectives included improving the knowledge of the Robson classification and of the WHO manual,[4] supporting a culture of Quality Improvement (QI), and fostering team work.

During the workshops data were presented and discussed using the standardised reporting tables suggested by the WHO manual (**Supplementary table 2-4**), which included the following subsequent evaluations: 1) Robson classification, 2) data quality, 3) type of population, 4) CS rates. Additionally, the other characteristics of the population identified as informative for the discussion of CS practices (ie, maternal age, gestational age, maternal and foetal pathological conditions, indications to CS were tabulated and discussed. The sources of comparison provided by the WHO manual were also made explicit in the tables. Relevant international literature [1,13-16] were made available to further interpret data.

A pre-defined template for identifying possible QI recommendations was distributed to each participant at the beginning of the workshops (**Supplementary table 5**). It was emphasized that the proposed actions for had to be SMART (Specific, Measurable, Achievable, Realistic, Time-bound).[17] An action-oriented, non-blaming, problem-solving, proactive and participatory attitude was used, for building ownership and commitment to changes among attenders, and for allowing a wide involvement of all type of staff.

Proposed recommendations were discussed and agreed in plenary until consensus was reached. Recommendations are presented in the result section.

Ethical considerations

The study, including data collection and its use for QI purposes, was approved by the Ethics Review Committee of the Faculty of Medicine, University of Colombo. Confidentiality was maintained by de-identifying all files before database entry. Human subjects were not directly involved in the study.

RESULTS

The following paragraphs reports on the result of the Robson analysis as for the WHO manual,[4] and on the related data discussion and development of a list of actions for improving the quality of hospital practices, agreed during the workshops.

Characteristics of the population

A total of 7504 women delivered in the hospital during the study period. Detailed characteristics of the population, with a specific focus on the variables relevant to the analysis of CS practices and the Robson classification are reported in **Supplementary Table 6**. Overall CS rate in the study population was 30.0%, with about a third (11.9%) of the total CS performed pre-labour. Induction of labour (IOL) occurred in 24.6% of cases. Preterm deliveries (before 37 weeks) were observed in 9.4% of cases, with 0.5% of the total newborns being extremely preterm (less than 28 weeks) and 1.3% being very preterm (28 weeks to before 32 weeks completed). At least one maternal or foetal pathological condition, potentially contributing to the decision for CS, was reported in 2845 (37.9%) women. Gestational diabetes was the most frequent condition (13.4%), followed by hypertensive disorders of pregnancy (6.7%) and intrauterine growth restriction (IUGR) (6.7%). Overall, 5.9% of the total sample was obese according to the body mass index (BMI) cut-offs suggested for Asian population (BMI > 27.5).[18,19]

Overall the discussion on these general characteristics of the population focused on the following observations: high rate of CS; relatively high rate of IOL; high prevalence of risk factors (which may be explained by the hospital being a tertiary level centre).

Analysis by Robson Classification

Table 1 presents the Robson classification. Group 3 (multiparous without previous CS, single cephalic at term, in spontaneous labour) and Group 1 (nulliparous, single cephalic at term, in spontaneous labour) were the most represented groups (27.0% and 23.1% respectively). Group 2a (nulliparous, single cephalic at term, with IOL) was the third most represented group (12.8%).

The major contributors to CS were as follows: Group 5 (multiparous with at least one previous CS, single cephalic at term) 29.6%; Group 1 (nulliparous without previous CS, single cephalic at term, in spontaneous labour) 14.0%; Group 2a (nulliparous, single cephalic at term, with IOL) 13.3% and Group 10 (single cephalic, preterm, including previous CS) 11.5%.

Unclassifiable cases accounted for only 42 (0.6%) of total cases. The most prevalent reason was the missing variable previous CS, which was missing in 36 unclassifiable cases (85.7%).

Overall the discussion on **Table 1** focused on the following points: again, data suggested a relatively high rate of IOL (Group 2a and 4a); the rate of missing cases (0.6%) was perceived as reassuring, although it was felt that all efforts had to be made to avoid missing information under the variable “previous CS”.

Table 1. The Robson Classification report table

Setting name: *De Soysa Hospital, Colombo, Sri Lanka*						**period:** July 2015 to June 2017
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**	**Column 6**	**Column 7**
Group	Number of CS in group	Number of women in group	Group size[1] (%)	Group CS rate[2] (%)	Absolute group contribution to overall CS rate[3] (%)	Relative contribution of group to overall CS rate[4] (%)
1	314	1740	23.2	18.0	4.2	14.0
2a	300	958	12.8	31.3	4.0	13.3
2b	158	158	2.1	100	2.1	7.0
3	105	2030	27.1	5.2	1.4	4.7
4a	81	722	9.6	11.2	1.1	3.6
4b	49	49	0.7	100	0.7	2.2
5	666	814	10.9	81.8	8.9	29.6
6	114	139	1.9	82.0	1.5	5.1
7	90	115	1.5	78.3	1.2	4.0
8	63	84	1.1	75.0	0.8	2.8
9	47	65	0.9	72.3	0.6	2.1
10	258	588	7.8	43.9	3.4	11.5
Total	**Total number of CS=2251**	**Total number women delivered= 7504**	**100%**	**Overall CS rate**	**Overall CS rate**	**100%**

Unclassifiable: 42 cases (0.6%) [Number unclassifiable cases / (Total Number women delivered classified + unclassified) X 100]

1. Group size (%) = n of women in the group / total N women delivered in the hospital x 100
2. Group CS rate (%) = n of CS in the group / total N of women in the group x 100
3. Absolute contribution (%) = n of CS in the group / total N of women delivered in the hospital x 100
4. Relative contribution (%) = n of CS in the group / total N of CS in the hospital x 100

Table 2, 3 and 4 summarize findings and their interpretation, related to the data quality, the type of population, and the CS rates. Findings different from the Robson comparison and/or from the MCS reference population are highlighted in grey in the tables.

Regarding the quality of data (**Table 2**), total number of deliveries and size of Group 9 (single pregnancy, transverse or oblique lie, including previous CS), when compared to the Robson interpretation and the MCS example, suggested no major problems in data quality. The CS rate in Group 9 (72.3%), suggested possible misclassification of a few number of cases (about 15 cases). It was felt that the most likely explanation for this finding could have been that women, presenting initially with an oblique/transverse lie, but having a spontaneous version or a successful external cephalic version after admission, were eventually erroneously classified as abnormal lie.

Table 2. Assessment of the quality of data

Steps for interpretation	Interpretation by Robson	Example: MCS population	Our findings	Additional information from database used to interpret data	Final interpretation
STEP 1. Total number of CS and total number of women delivered	Should be identical to the numbers provided by official register	NA	Total CS= 2251 Total deliveries= 7504	-	There are no missing/incorrect data
STEP 2. Size of Group 9 (should be less than 1%)	<1%	0.4%	0.9%	-	No significant misclassification for this group according to references by Robson
STEP 3. CS in Group 9 (should be 100% by convention)	100%	88.6%	72.3%	-	Misclassification

Abbreviation: CS= Caesarean section; MCS= Multi-country survey; NA= data not available.

Table 3 synthetises the assessment of the type of population. Overall, findings on step 1, 4 and 5 were in line with both the Robson references and the MCS example and did not result in major discussion. Findings on step 2, 3 and 6 to 9 (highlighted in grey in the table), were somehow different from both the Robson and MCS comparisons, and where interpreted based also on the additional information provided by the local database (column five in Table 3). Different possible explanations for these findings were identified, including possible misclassifications, case selection (tertiary referral centre), inappropriate care, or others (Table 3). Specifically, the following were the key findings of the analysis.

On step 2 and 9, the size of Group 3 (multiparous without previous CS, single cephalic at term, in spontaneous labour) plus Group 4 (multiparous without previous CS, single cephalic at term with IOL or CS before labour) was larger than the Robson comparison (37.3% *versus* about 30%) while the ratio of the size of Group 6 (nulliparous, single breech) *versus* Group 7 (multiparous, single breech, including previous CS) was lower (1.2) than the Robson comparison (ratio of 1.2 instead of 2). On both steps, the observed values were similar to the MCS example. It was felt that these findings could be explained by the relatively high prevalence of multiparous women in the study population (55%).

On step 3, the small size of Group 5 (multiparous with at least one previous CS, single cephalic at term) when compared to the overall CS rate (30.0%) suggested relatively low CS rate in the previous years, or a recently increased rate.

On step 6, Group 10 (single cephalic, preterm, including previous CS) was slightly larger than the Robson comparison (7.8% vs 5%), most likely due to the hospital being a tertiary care centre where women in preterm labour and other conditions that warrant preterm delivery are referred to.

On step 7, the ratio of the size of Group 1 (nulliparous, single cephalic at term, in spontaneous labour) *versus* Group 2 (nulliparous single cephalic, at term with IOL or CS before labour) was lower than the Robson comparison (1.5 vs 2), possibly due to the observed relatively high rate of IOL in nulliparous (Group 2a 12.8%, see **Table 1**) when compared to existing literature.[14,20,21]

Table 3. Assessment of the type of population

Steps for interpretation	Interpretation by Robson	Example: MCS population	Our findings	Additional information from database used to interpret data	Final interpretation
STEP 1. Size of Groups 1 + Group 2	35-42%	38.1%	38.1%	-	Rate in line with both references by Robson and MCS reference population
STEP 2. Size of Groups 3+4	30%	46.5%	37.3%	Multiparous in our population 55.0%	Rate higher than Robson references but lower than MCS examples. This may be explained by a high prevalence of multiparous women in our population
STEP 3. Size of Group 5	Half of total CS rate	7.2%	10.9%	-	Lower than half of total CS. This, as suggested by the WHO Manual, may be due to relatively low CS rate in the previous years, or to a recently increased CS rate
STEP 4. Size of Groups 6+7	3-4%	2.7%	3.4%	-	Rate in line with both Robson references and MCS example.
STEP 5. Size of Group 8	1.5-2%	0.9%	1.1%	-	Rate in line with MCS examples.
STEP 6. Size of Group 10	< 5%	4.2%	7.8%	Divisions by gestational age in our preterm population	Higher than both comparisons. This may be explained by the hospital being a tertiary care referral centre
STEP 7. Ratio of the size of Group 1 versus Group 2	Ratio 2 or higher	Ratio 3.3	Ratio 1.5	Indication of IOL	Lower than the comparisons. This associates with a large size of Group 2a, suggesting a high incidence of IOL. This may be explained by: 1) case selection (tertiary care referral centre) 2) inappropriate indication to IOL (deserving further investigation)
STEP 8. Ratio of size of Group 3 versus Group 4	> than 2:1	Ratio 6.3	Ratio 2.6	Indication of IOL	Rate in line with both Robson references, lower than MCS. This may be explained by: 1) misclassification of augmentation as IOL 2) case selection (tertiary care referral centre) 3) inappropriate indication to IOL (deserving further investigation)

STEP 9. Ratio of size of Group 6 versus Group 7	usually 2:1	Ratio 0.8	Ratio 1.2	Multiparous in our population 55.0%	Rate in line with MCS, but lower than Robson references. This may be explained by: 1) high number of multiparous in our population.

Abbreviation: CS= Caesarean section; IOL= Induction of labour; MCS reference population: was the population of the WHO MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth.

The assessment of CS rates (see the following **Table 4**) was complemented by an analysis of the indications to CS using data extracted from the prospective individual patient database (**Supplementary table 7 and 8**). Overall, it was found that main indications to CS were (**Supplementary table 7**): abnormal CTG or suspected foetal distress (27.1%); past CS (23.9%), failure to progress or failed IOL (11.6%); breech/abnormal presentation (8.2%). The following indications, accounting for a total of 147 (6.5%) cases, were identified as potentially inappropriate (in grey in **Supplementary table 7**): prelabour diagnosis of cephalopelvic disproportion (CPD) (2.5%), history of subfertility/bad obstetric history (2.1%), CS for maternal request (1.9%).

When indications to CS were analysed by Robson groups, some indications were observed at a suspected high or low rate compared to the expected, suggesting potentially inappropriate management. Specifically, abnormal CTG/suspected foetal distress were over-represented as an indication to CS, particularly in Robson groups 1 to 4, suggesting possible gaps in the use/interpretation of CTG (in dark grey in **Supplementary table 8**). On the other hand, dystocia was reported as an indication to CS in less than 8% of total cases (in light grey in **Supplementary table 8**), a rate much lower than what observed in United Kingdom (UK) and the United States of America (USA), where dystocia is an indication for about 20% of CS.[22-24] Internal discussion identified the following possible explanations for this specific finding: difficulty by data collectors in classifying dystocia; missing information in the medical file; peculiar characteristics of the Sri Lanka population enrolled -such as lower BMI, maternal age and parity-; better management of labour compared to reported statistics, or other reasons affecting dystocia rate in UK and USA statistics. Misclassifications were identified in 1.9% of the total indications to CS (highlighted with an asterisk in **Supplementary table 8**).

Table 4 reports the interpretation of assessment of CS rate. Overall, findings on step 8 and 9 were in line with both Robson references and MCS examples, and did not resulted in major discussion. Findings from all other steps (in grey in **Table 4**) were somehow different from either the Robson comparison or the MCS example. Details on data interpretation is provided, step by step, in **Table 4**.

Table 4. Assessment of the CS rates

Steps for interpretation	Interpretation by Robson	Example: MCS population	Our findings	Additional information from database used to interpret data	Final interpretation
STEP 1. CS rate in Group 1	Under 10% are achievable	9.8%	18.0%	•Abnormal CTG was the indication in 49.4% of cases •Potentially inappropriate CS indications to CS in 15%.	CS rate higher than Robson and MCS. This may be explained by inappropriate indications (abnormal CTG/suspected foetal distress) and/or inappropriate care.
STEP 2. CS rate in Group 2	Consistently around 20-35%	39.9%	41.0%	•Abnormal CTG was the indication in 58.3% of Group 2a and 30.4% in Group 2b. •Potentially inappropriate CS indications in 25% in 2b.	CS rate higher than Robson and MCS. This may be possibly due to the high rate of IOL, which carry increased risk of CS.
STEP 3. CS rate in Group 3	No higher than 3.0%.	3.0%	5.2%	•Abnormal CTG was the indication in 57.1%.	CS rate higher than Robson and MCS. This may be explained by misclassification (Group 5 misclassified as Group 3) or, most probably, by inappropriate indication to CS (CTG mis-interpretation).
STEP 4. CS rate for Group 4	It rarely should be higher than 15%	23.7%	16.8%	•Abnormal CTG was the indication in 60.5% in 4a and 18.4% in 4b. • failed induction was an indication in 25.9% of 4a.	CS rate higher than Robson. Size of Group 4b suggests low prelabour CS in this group, while the rate of CS in Group 4a was high mainly due to CTG abnormalities and failed IOL. This may be explained by misclassification (Group 5 misclassified as Group 4) or, most probably, by

					inappropriate indication to CS (CTG mis-interpretation).
STEP 5. CS rate in Group 5	Rates of 50-60% are considered appropriate	74.4%	81.8%	•Abnormal CTG was the indication in 70.1%. • Rate of prelabour CS was 62.5%.	CS rate higher than Robson and MCS. Low rate of IOL in this group. The vast majority are CS for past section. This may be explained by the group size by a policy of scheduling pre-labour CS (low offer of trial of labour). Also, women's preference, based on previous information, for repeating CS may have a role.
STEP 6. CS rate for Group 8	Usually around 60%.	57.7%	80.9%	•Multiple pregnancies was the indication in 58.7%. •Elective CS rate in multiple pregnancies was 37.8%	CS rate higher than Robson and MCS. Possible tendency to perform elective CS in multiple pregnancies
STEP 7. CS in Group 10	Usually around 30%	25.1%	41.1%	•Maternal/foetal pathological conditions were the indication in 48.1%.	CS rate higher than Robson and MCS. This may be explained by a high-risk population.
STEP 8. Relative contribution of Groups 1, 2 and 5 to the overall CS rate	Normally contribute to 2/3 (66%) of all CS performed in most hospitals	Contributed to 63.7% of all CS	63.9%	-	In line with both Robson and MCS reference.
STEP 9. Absolute contribution of Group 5 to overall CS rate	NA	Responsible for 28.9% of all CS	Absolute contribution: 8.87% Relative contribution: 29.59%		Absolute contribution lower than MCS (Robson comparison not provided in the WHO manual), Relative contribution in line with MCS (the value provided in the WHO Manual as MCS example refers to the relative contribution).

Abbreviation: CS= Caesarean section; CTG= Cardiotocography; IOL= Induction of labour; TOL= Trial of labour; MCS reference population: was the population of the WHO MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth; NA= data not available.

Developing of quality improvement recommendations

Table 5 reports the key findings of the analysis, the possible explanations, and the agreed recommendations that emerged from the hospital staff discussion. Overall, 16 recommendations were developed, and three were identified as a priority for action (highlighted with an asterisk in **Table 5**). Some recommendations, such as the need to train staff on foetal monitoring, emerged from different key findings, and as such were identified as a priority for action. Most recommendations aimed at improving the implementation of evidenced-based indication for CS and IOL. Beside updating protocols and hands-on training, activities agreed included monitoring and supervision, criterion-based audits, risk management meetings and appropriate information for patients. Recommendations to further improve the quality of data were also agreed (recommendations 15 and 16).

Table 5. Process of development of quality improvement recommendations

Key findings from the analysis	Possible explanations emerged from hospital staff discussion	Agreed recommendations for quality improvement
1. High intrapartum CS rate in Group 1, with potentially inappropriate indications (main current indication is CTG abnormality)	1.Possible inappropriate interpretation of foetal monitoring 2.Possible inappropriate use of oxytocin 3.Possible inappropriate indications to CS	1.Develop a training plan for strengthening capacities of staff in CTG interpretation* 2. Hands-on trainings on instrumental delivery 3. Supportive supervision and monitor over time of staff skills in CTG interpretation and instrumental delivery 3.Criterion-based audits of CS indications 4. Regular risk management meetings with emphasis on diagnosis of foetal distress

2. High rate of IOL and high rate of CS in women undergoing IOL (high contribution of Group 2a to total CS rate and high CS rate in Group 4a)	1.Possible inappropriate indications for IOL 2.Possible inappropriate use of prostaglandin/oxytocin 3.Possible Inappropriate CTG interpretation 4.Possible misdiagnosis of failed IOL	5.Consultant meeting to update IOL protocols (agreeing on criteria for failed IOL according to recent evidence)* 6. Criterion-based audits on IOL 7.Monitor IOL indications, complications and abnormal CTG associated to use of prostaglandins or oxytocin
3. High prevalence of prelabour CS (Group 2b) with more frequent CS indications: abnormal CTG, potentially inappropriate indications 25%, maternal/foetal pathological conditions	1.Inappropriate indications for prelabour CS	8.Update protocols on indications to prelabour CS 9.Criterion-based audits on indications for prelabour CS 10.Review cases of CS for abnormal CTG during staff training
4. High CS rate in Group 3 and 4a (multiparous). More frequent indication is abnormal CTG 5. Very high CS rate in Group 5, majority are elective. Past CS is the main indication	1.Rate of CS in multiparous suggests suboptimal care in this group of women 2.Inappropriate interpretation of CTG 3.Low offer of TOLAC	Recommendations #1a,3,s 11.Criterion-based audits of offers and unsuccessful cases of TOL 12.Use of a patient education leaflets to inform women of TOL benefits and establishment of a nurse-led TOLAC counselling service* 13. Monitoring the prevalence of TOLAC
6. Breech is the fourth most common indication for CS	1.Refusal by mothers to accept ECV due to preconceived prejudices	14.Develop an information leaflet on the value of ECV
7. Low Rate of CS for dystocia with half of CS done in 2nd stage 8. Low CS rate in Group 9	1.Possible problems in data quality 2.Possible misclassification of a few number of cases	15.Training for data collectors and hospital staff on definitions used for the Robson's classification according to WHO manual, stressing also the definition of dystocia 16.Add few internal validation rules on database (previous CS, breech, dystocia) and strengthen monitoring on these variables. Recommendation #2
9. High contribution to CS rate from Group10. Majority of indications for maternal/foetal pathological conditions	1.Iatrogenic indications of IOL/CS in the late preterm period	Recommendation #5 (Update protocols of IOL and elective CS criteria in late preterm and SGA) Recommendation #3 (Criterion-based audits on cases of IOL and elective CS)

Abbreviation: CS = Caesarean section; CTG = Cardiotocography; ECV = External cephalic version; GA = Gestational age; IOL = Induction of labour; SGA = small for gestational age; TOL = Trial of labour; TOLAC = Trial of labour after caesarean.

DISCUSSION

This study reports an experience from a lower middle-income country, where information accumulated in an individual patient database was used locally for conducting an in-depth analysis of CS practices according the WHO manual for Robson classification,[4] and for developing recommendations to improve the quality of care.

In respect to previous literature, this study has three main aspects of novelty, which can be of interest of both researchers and policy makers. First, this is the first study conducted in a lower middle-income country, reporting on the use of a prospective individual-patient database to analyse practices on CS. Prospective individual-patient databases are generally lacking in low resources settings. However, the availability of accurate data is relatively limited even in high-income countries, where most often hospital administrative datasets lack key information - such as maternal risk factors - needed for evaluating the case mix and for interpreting the observed CS rates. To our knowledge, even the few studies in high-income countries which utilised individual patient databases for the Robson classification,[25-27] had available much less information that in this study in Sri Lanka, where a large number of variables were prospectively collected.[9] The availability of many variables , including CS indications by Robson groups, was a valuable contribution for an in-depth understanding of CS practices.

Second and most important, the paper provides a model on how findings of the Robson analysis can be used for internal discussion and for QI purposes. The majority of the published studies using the Robson classification focused on the analysis, rather than on the development of recommendations to improve CS practices. A recent systematic review [16,28] cited only six studies that used the Robson classification in a clinical audit cycle to reduce CS rates. We were able to identify only one study, conducted in Canada, where the local Society of Obstetricians and Gynaecologists has formally supported the use of Robson classification,[29] measuring the effectiveness of the Robson analysis, with a before and after design, on the CS rate.[30]

Third, this is the first report on the use of the WHO Implementation Manual for the Robson Classification.[4] In this study, all steps suggested in the WHO manual were followed. The paper documents an example of how the manual can be used in an action-oriented manner.

As additional findings, this study underscored the lack of specific reference standards for the Robson Classification. Interestingly, in several instances the findings of this analysis were within the range of the values provided by the Robson guideline, but not of those provided by the MCS population, or vice-versa. This is not surprising, given the fact that, as stressed in the WHO manual, none of these two comparisons can be taken as an absolute standard.[4] The WHO Manual underlines that either Robson or MCS references “have not been validated against outcomes and should not be taken as a recommendation” and “it is up to the hospital itself to decide what is appropriate care, based on its results and other available evidence”.[4] Being specific for Sri Lanka, this study may help in the future researchers and policymakers in further interpreting data from a similar setting. Meanwhile, more research should be conducted to identify which can be the golden standard for the Robson analysis.

This study did not aim at comparing in detail the findings of the Robson analysis to the international literature, but rather at describing the whole process of how data were internally used to develop recommendations to improve hospital practices. However, few points on key clinical findings can be further discussed here. In most Robson groups, the very high rate of CS performed for abnormal CTG/suspected foetal distress was a reason of concern. Although a similar rate around 25% had been reported in USA [23] the contribution of abnormal CTG In Sri Lanka may highlight a problem unique to countries in economic transition. In these setting, with increasing investment in health infrastructure, CTG machines are becoming increasingly available and, due also to their wide usage in high-income countries, practitioners and policymakers often see them as essential for provision of quality obstetric care. However, the introduction of these technologies not always has been complemented by adequate capacity development. Currently, Sri Lanka does not have mandatory training for staff in CTG interpretation. Further, currently there is a lack of facilities for ancillary tests such as foetal scalp blood sampling and cord blood pH levels, which are important adjuncts in verifying decisions

made based on CTG interpretation. Recently, there have been calls to optimize technical skills of staff on CTG interpretation, by delivering adequate training.[31] Results of this study suggest that improving the quality of CTG interpretation could be an important step in reducing CS rates and increasing appropriateness of care.

The high rate of IOL in our population (24.6%), when compared to existing literature,[14,32,33] is also matter of concern and needs further investigation. IOL should be performed only with a clear medical indication (i.e., when expected benefits outweigh its potential harms).[32] Recent data from high-income settings shows that IOL does not result in increased CS rates,[34,35] while our findings suggest that the high rate of IOL may have contributed to the relatively high rate of CS (group 2a and 4a contributed to 16.9% of the total number of CS, and the two key indications to CS in these groups were abnormal CTG and failed induction, **Table 1** and **Supplementary table 8**). Sri Lanka has the highest rate of IOL in Asia,[32,33] and a better understanding of practices related to IOL may contribute to the current local debate on how to improve quality of maternal care. As recommended by Robson,[36] the Robson classification "provides a common starting point for further analyses for all labour and delivery events and outcomes"; it draws attention to specific groups, where further analysis can be performed to understand the reasons behind the initial observation. We plan to further analyse and report IOL practices in a future paper.

A relevant proportion of CS (6.5%) were performed electively for potentially inappropriate indications (ie, prelabour diagnosis of CPD, history of subfertility, maternal request). However, this is a frequent finding in literature, as documented in studies from USA, Germany, China, Brazil, Argentina, India, Pakistan, and other countries.[37-44] One of the recommendations agreed in this experience was the implementation of the regular auditing of cases of CS without absolute indications, aiming at promoting good practices.

We acknowledge some limitations of this study. The analysis highlighted cases of possible misclassification and missing variable resulting in cases being unclassifiable. However, this

was a rare finding (respectively, 0.5% and 0.6% of total cases, see **Table 1** and **Supplementary table 8**). Data quality was the object of internal discussion, and actions to improve it were within the list of recommendations developed.

Despite not all recommendations developed were SMART,[17] still the process provided the opportunity to discuss clinical practice using objective data, in a constructive, participatory manner, and resulted in a concrete list of actions.

This was a pilot study in one single facility, and will be important to replicate similar experiences in other settings to evaluate generalisability of findings. We believe that the commitment of local staff, a favourable local leadership, and a constructive dialogue with an external partner providing independent technical support, were the three essential favourable elements in succeeding in performing the analysis and most importantly, in using data proactively.

Within the project timelines, it was not possible to follow up the impact of the recommendations developed. Future longer-term studies will be needed to monitor implementation.

CONCLUSIONS

This study provides an example from a setting with limited resources, where information from an individual patient database were used locally for conducting an in-depth analysis of CS practices, following the WHO manual.[4] Further, it was used for developing recommendations to improve the quality of hospital care. Future studies may further explore other aspects of maternal care -such as practices related to IOL- and monitor over time outcomes of the recommendations developed.

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Disclosure of interests

None competing interest

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Author contributions

HS, MP and ML conceived the study and procured funds

HS, MP, CB and ML developed the data collections tools

RF, AS and FRI collected data

BC, HW, EPV and ML analysed the data

All authors interpreted data and contributed to the manuscript

ML wrote the first draft of the paper, all authors contributed to the final version of the paper

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Use of an individual-patient database for analysing caesarean section practices according to the WHO Manual for Robson classification and for developing quality improvement recommendations: a study in Sri Lanka

Supplementary file

Table of Contents

Supplementary Table 1. Missing cases for the variables of interest

Variables	Total	Missing	% Missing
Maternal age	7504	34	0.4
Parity	7504	34	0.4
Gestational age at delivery	7504	47	0.6
Previous caesarean section	7504	38	0.5
If previous caesarean section, trial of labour	7504	91	1.2
Multiple pregnancies	7504	35	0.4
Presentation	7504	43	0.6
Labour onset	7504	36	0.4
Delivery	7504	32	0.4
Delivery mode	7504	37	0.4
If operative delivery, indication	7504	38	0.5
If caesarean section, type	7504	37	0.4
Indication of labour	7504	36	0.4
Mode of induction	7504	42	0.5
Pre-gestational diabetes	7504	35	0.4
Gestational diabetes mellitus in diet	7504	35	0.4
Gestational diabetes mellitus in drug therapy	7504	36	0.4
Pre-gestational hypertension	7504	33	0.4
Gestational hypertension (no proteinuria)	7504	35	0.4
Pre-eclampsia not severe	7504	35	0.4
Pre-eclampsia severe	7504	35	0.4
Eclampsia	7504	34	0.4
BMI	7504	53	0.7
Maternal cardiac disease	7504	34	0.4
Polyhydramnios	7504	36	0.4
Oligohydramnios	7504	38	0.4
IUGR	7504	36	0.4
APH/major placentia previa	7504	37	0.4
Severe anaemia	7504	38	0.5
Chorioamnionitis	7504	36	0.4

Abbreviation: APH= Antepartum haemorrhage; BMI= Body mass index; IUGR= Intrauterine growth restriction.

Supplementary Table 2. Steps to assess quality of data using the Robson Classification Report Table according to WHO implementation manual[1]

Step	Interpretation by Robson	Example: MCS population*	Further Interpretation
1. Look at the total numbers of CS and of women delivered in your hospital	These numbers should be identical to the total number of CS and of women delivered in your hospital.	NA	If these numbers do not match, then data is missing or incorrect. Some women may not have been classified in the Robson groups because of missing variables or were incorrectly classified as to type of delivery. Sometimes multiple pregnancies are counted as babies rather than mothers.
2. Look at the size of Group 9. Singletons in transverse or oblique lie	It should be less than 1%.	0.4%	If this is > 1%, it is probable that women with breech (or other) presentations have been misclassified as transverse /oblique lie and allocated to this group. As the classification includes all women who have delivered, if any one group is smaller or bigger, look to the other groups which sometimes will show where the misclassification is.
3. Look at the CS rate of Group 9	It should be 100% by convention.	88.6%	By convention, if the woman gives birth vaginally by internal version, it should be classified as either cephalic or breech. The CS rate in Group 9 should be 100%

Notes: *MCS reference population was the population of the MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth.

Abbreviations: CS= caesarean section; NA= not available.

[1] World Health Organization. Robson Classification: Implementation Manual. Geneva, 2017.http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/robson-classification/en/ (accessed 28 June 2018)

Supplementary Table 3. Steps to assess type of population using the Robson Classification Report Table according to WHO implementation manual[1]

Step	Interpretation by Robson	Example: MCS population*	Further Interpretation
1. Look at the size of Groups 1 + Group 2. Nulliparous women ≥37 weeks gestation singleton cephalic	This usually represents 35-42% of obstetric population of most hospitals.	38.1%	In settings with high proportion of women who have only one child rather than more than one child, the group of nulliparous women i.e. Groups 1 and 2 tends to be larger. In settings where the opposite is true, the size of Groups 1 + Group 2 will be smaller since most of the population will be represented by multiparous women.
2. Look at the size of Groups 3 + 4 -Multiparous women ≥37 weeks gestation singleton cephalic, without previous CS	This usually represents about 30% of women.	46.5%	In settings with high proportion of women with more than one child rather than only one child, the size of Groups 3 + Group 4 will be higher than 30% (provided they have delivered vaginally). Another reason for a low size of Groups 3 and 4 could be that the size of Group 5 is very high which would be accompanied by a very high overall CS rate.
3. Look at the size of Group 5 - Multiparous women ≥37	It is related to the overall CS rate. The size of Group 5 is	7.2%	The size of Group 5 is usually related to the overall CS rate. If the size of this group is larger, it means that there has

[1] World Health Organization. Robson Classification: Implementation Manual. Geneva, 2017.http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/robson-classification/en/ (accessed 28 June 2018)

weeks gestation singleton cephalic with previous CS	roughly usually about half of the total CS rate. In settings with low overall CS rates, it is usually under 10%.		been a high CS rate in the past years in that hospital and mainly in Groups 1 and 2. In places with high CS rates, the size of this group could be > 15%.
4. Look at the size of Groups 6 + 7 Breeches in nulliparous & multiparous women	It should be 3-4%	2.7%	If the total is much over 4%, the most common reason is usually a high rate of preterm deliveries or a higher proportion of nulliparous women. Therefore, look at size of Group 10. If that is over 4-5%, this hypothesis could be true.
5. Look at the size of Groups 8 - Multiples	It should be 1.5-2%	0.9%	If it is higher, the hospital is probably tertiary (high risk, referral) or runs a fertilization program. If lower, probably a lot of the twins are referred out especially if the remaining twins have a low caesarean section rate
6. Look at the size of Groups 10 - Preterm cephalic singletons	It should be less than 5% in most normal risk settings.	4.2%	If it is higher, the hospital is probably tertiary (high risk, referral) or there is a high risk of preterm births in the population that the hospital serves. If, in addition, the CS rate is low in this group, it could represent a preponderance of spontaneous preterm labour. If the CS rate in this group is high, it could suggest more provider-initiated pre-labour CS for foetal growth restriction or pre-eclampsia and other pregnancy or medical complications.
7. Look at the Ratio of the size of Group 1 versus Group 2 (Divide the size of Group 1 by the size of Group 2) - Nullipara term cephalic singletons	It is usually 2:1 or higher	Ratio 3.3	If it is lower, suspect poor data quality: nulliparous women who received oxytocin for augmentation (acceleration) of labour (and should be in Group 1) may have been

spontaneous labour / Nullipara term cephalic singletons induced or pre-labour CS			misclassified as "induction" (and incorrectly classified as Group 2). If data collection is correct, a lower ratio may indicate that you have a high induction/prelabour CS issue which may indicate a high-risk population in nulliparous women and are likely therefore to have a high CS rate. Additional information on pre-labour stillbirths would be the next question to ask. On the contrary, if the ratio is very high, you may want to look at your pre-labour stillbirth rate in this population which may indicate that you are not inducing enough. Or alternatively you may have a very low risk population
8. Look at the Ratio of the size of Group 3 versus Group 4. (Divide the size of Group 3 by the size of Group 4): Multipara without previous CS, term cephalic singletons spontaneous labour / Multipara without previous CS, term cephalic singletons induced or pre-labour CS	It is always higher than the ratio of Group 1/Group 2 in the same institution, i.e, larger than 2:1. This is very reliable finding in confirming data quality and culture of the organization.	Ratio 6.3	If it is lower, suspect poor data quality: multiparous women who received oxytocin for "augmentation" of labour (and should be in Group 3) may have been misclassified as "induction" (and incorrectly classified as Group 4). A low ratio (due to large Group 4b) may suggest a poor previous maternal experience in vaginal delivery and a request for pre-labour CS in multiparous women. Another explanation may be pre-labour CS done to perform tubal ligation (common in settings where family planning is not easily available).
9. Look at the Ratio of the size of Group 6 versus Group 7. (Divide the size of Group 6 by the size of Group 7) Nullipara breech / Multipara breech	It is usually a 2:1 because breeches are more frequent in nulliparous women than in multiparous women.	Ratio 0.8	If the ratio is different, suspect either unusual nullipara/multipara ratio or inaccurate data collection.

Notes: *MCS reference population was the population of the MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth.

Abbreviation: CS= caesarean section.

Supplementary Table 4. Steps to assess caesarean section rates using the Robson Classification Report Table according to WHO implementation manual[1]

Step	Interpretation by Robson	Example: MCS population*	Further Interpretation
1. Look at the CS rate for Group 1	Rates under 10% are achievable	9.8%	This rate can only be interpreted accurately when you have considered the ratio of the sizes of Groups 1 and 2. In principle, the higher the ratio of size of Groups 1:2, the higher the likelihood of both the CS rate in Group 1 and 2 being individually higher. However, the overall CS rate in Groups 1 and 2 combined may still be low or the same.
2. Look at the CS rate for Group 2	Consistently around 20-35%	39.9%	CS rates in Group 2 reflect the size and rates in 2a and 2b. If size of Group 2b is large, the overall CS rates in Group 2 is also going to be large. If Group 2b is relatively small, then high rates of CS in Group 2 may

[1] World Health Organization. Robson Classification: Implementation Manual. Geneva, 2017.http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/robson-classification/en/ (accessed 28 June 2018)

			indicate poor success rates for induction or poor choice of women to induce and consequently a high rate of CS in Group 2a. Remember the general principle of not interpreting one single subgroup on its own without knowing what is left out. The interpretation of group 2a requires knowing the relative sizes of Groups 1 and 2b.
3. Look at the CS rate for Group 3	Normally, no higher than 3.0%.	3.0%	In units with higher CS rates in this group, this may be due to poor data collection. It is possible that women with previous scars (Group 5) were incorrectly classified as Group 3. Other possible reasons for high rates could be for example to do tubal ligation in settings with poor access to contraception, or maternal request.
4. Look at the CS rate for Group 4	It rarely should be higher than 15%	23.7%	CS rates in Group 4 reflect the size and rates in 4a and 4b. If size of Group 4b is large, the overall CS rates in Group 4 is also going to be high. If Group 4b is relatively small, then high rates of CS in Group 4 may indicate poor success rates for induction or poor choice of women to induce and consequently a high rate of CS in Group 4a. Poor data collection could also be a reason for high CS rates in Group 4; for example, due to inclusion of women with previous scars in this group (when they should be in Group 5). Lastly, a high CS rate in Group 4 may reflect a high maternal request for CS even if these women have delivered their first pregnancy vaginally. This may be because of a previously traumatic or prolonged labour or to do tubal ligation in settings with poor access to contraception.
5.Look at the CS rate for Group 5	Rates of 50-60% are considered appropriate provided you have good maternal and perinatal outcome.	74.4%	If rates are higher, this is possibly due to a large Group 5.2 (women with 2 or more previous CS). This could also be due to a policy of scheduling pre-labour CS for all women with 1 previous scar without attempting a trial of labour.

6. Look at the CS rate for Group 8	It is usually around 60%.	57.7%	Variations will depend on the type of twin pregnancy and the ratio of nulliparous/multiparous with or without a previous scar.
7. Look at the CS rate in Group 10	In most populations it is usually around 30%	25.1%	If higher than 30%, it is usually due to many cases of high risk pregnancies (e.g. foetal growth restriction, preeclampsia) that will need preterm pre-labour CS. If lower than 30%, it suggests a relatively higher rate of preterm spontaneous labour and hence a lower overall CS rate.
8. Look at the relative contribution of Groups 1, 2 and 5 to the overall CS rate (add the contribution of each of these groups)	These three groups combined normally contribute to 2/3 (66%) of all CS performed in most hospitals.	These three groups combined contributed to 63.7% of all CS	These three groups should be the focus of attention if the hospital is trying to lower the overall CS rate. The higher the overall CS rate, the greater the focus should be in Group 1.
9. Look at the absolute contribution of Group 5 to the overall CS rate		This group was responsible for 28.9% of all CS	If it is very high, this may indicate that in previous years, CS rates in Groups 1 and 2 have been high and it is worth exploring further.

Notes: *MCS reference population was the population of the MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth.

Abbreviation: CS= caesarean section.

Supplementary Table 5. Template for agreeing actions at hospital level to improve the quality of care

Date: **Group Participants:**

Key findings from the analysis	Possible explanations	Agreed recommendations for quality improvement

Instructions:

1. Identify a moderator whose duty is to make sure that the pre-defined template is filled in pre-established time (90 minutes total), that everyone has the right to speak and actively participate, and that the final version of the table corresponds to group opinions
2. Identify a secretary whose job is to take notes, summarize the opinions of the group in the template, act as a presenter in plenary (15 min maximum), save the template in an electronic file (the results will be attached to final report that will be distributed)

3. Participants are requested to make concise and specific interventions lasting up to 1-2 minutes, leaving the possibility to express their opinions to others. It is required to make proposals with a problem-solving attitude
4. We recommend to fill the first column first (key findings) and then the other lines in horizonal
5. Is not necessary to identify many priorities, 5-10 are enough. For the same priority it's possible to specify 1 or more actions
6. Some examples of different possible actions:
   - *development of policies and operational plans (for training, quality, work conditions, improve data collection and other aspects of database)*
   - *development of protocols and procedures*
   - *theoretical and practical training (related to EBM clinical practices or quality of care)*
   - *periodical audit (clinical, on indicators) or team meetings*
   - *adopt quality standards and targets and implement a monitoring system with periodic analyzes and discussions of data*

Actions should be **SMART: Specific, Measurable, Achievable, Realistic, Time-bound** in the real context of the hospital.

Supplementary Table 6. Characteristics of the population

Population	n (N=7504)	%
Maternal age		
<18 years	95	1.2
18-24 years	1862	24.8
25-34 years	4253	56.6
35-39 years	1036	13.8
>40 years	224	2.9
Parity		
0	3342	44.5
≥1	4128	55.0
Gestational age		
<28 weeks	41	0.5
28-31 weeks	96	1.3
32-36 weeks	571	7.6
>37 weeks	6749	89.9
Previous caesarean section	956	12.7
Cephalic	7122	94.9
Breech	273	3.6
Other	66	0.9
Multiple pregnancies	84	1.1
Labour onset		
Spontaneous	4726	62.9
Induction	1849	24.6
Pre-labour caesarean section	893	11.9
Mode of delivery		
Vaginal spontaneous	4906	65.3
Vaginal operative	310	4.1
Caesarean section	2251	30.0
At least one maternal or foetal pathological conditions	2845	37.9
Pre-gestational diabetes	266	3.5
Gestational diabetes, total	1002	13.4
On diet	417	5.6
On drug therapy	585	7.8
Hypertensive disorders of pregnancy, any	506	6.7

Pre-gestational hypertension	168	2.2
Gestational hypertension	179	2.4
Pre-eclampsia not severe	78	1.0
Pre-eclampsia severe	69	0.9
Eclampsia	12	0.2
Obesity (BMI > 27.5)*	440	5.9
Maternal age > 40 years	224	2.9
Maternal cardiac disease	234	3.1
Oligohydramnios	131	1.8
Polyhydramnios	96	1.3
IUGR**	504	6.7
APH/major placentia previa	112	1.5
Severe anaemia (Hb <7)	40	0.5
Chorioamnionitis	11	0.2

Notes: *as defined on data collection form; **defined as weight < 10 centile of estimated weight for gestational age or < 10 centile for abdominal circumference (Bangladesh growth chart), based on ultrasound.

Abbreviation: APH= Antepartum haemorrhage; BMI= Body mass index; Hb= Haemoglobin; IUGR= Intrauterine growth restriction.

Supplementary Table 7. Main indications to CS

Main indication	n (N=2251)	%
CTG abnormal/suspected foetal distress	610	27.1
Past caesarean section	538	23.9
Failure to progress or failed IOL	261	11.6
Failed IOL	109	4.8
Dystocia 1st stage	77	3.4
Dystocia 2nd stage	75	3.3
Breech/abnormal lie	184	8.2
Hypertension/preeclampsia/eclampsia	100	4.4
IUGR	82	3.6
APH/major placenta previa	68	3.0
Prelabour diagnosis of CPD	57	2.5
History of subfertility/bad obstetric history	47	2.1
Cardiac disease	45	2.0
Maternal request	43	1.9
Multiple pregnancies	40	1.8
Diabetes	25	1.1
Thick meconium	16	0.7
Pre-term	10	0.4
Other	118	5.2
Missing	7	0.3

Abbreviation: APH= Antepartum haemorrhage; CPD= Cephalopelvic disproportion; CTG= Cardiotocography; IOL= induction of labour; IUGR= Intrauterine growth restriction.

Supplementary Table 8. Main indications to CS by Robson group

Robson group Main indication	1	2a	2b	3	4a	4b	5	6	7	8	9	10	Missing	Total
CTG abnormal/suspected foetal distress	155	175	48	60	49	9	49	5	6	3	2*	48	1	610
Past caesarean section	0	0	0	3*	0	1*	467	6	18	2	7*	34	0	538
Failure to progress or failed induction														
Failed induction	0	63	0	0	21	0	15	0	1	1	0	8	0	109
Dystocia 1st stage	27	27	2	8	3	3*	3	0	1	0	0	3	0	77
Dystocia 2nd stage	13	16	3*	1	3	0	33	0	0	0	2*	3	1	75
Breech/abnormal lie	1*	0	1*	1*	0	0	1*	91	55	7	26	1*	0	184
Hypertension/preeclampsia/eclampsia	6	4	9	2	0	4	18	1	0	3	0	52	1	100
IUGR	11	3	9	6	0	3	9	2	4	2	0	32	1	82
APH/major placenta previa	8	2	6	6	0	1	9	2	2	1	3*	27	1	68
Prelabour diagnosis of CPD	25	3	14	0	0	3	7	0	0	2	1*	2	0	57
History of subfertility/bad obstetric history	14	0	16	0	0	2	0	5	0	0	1*	9	0	47
Cardiac disease	7	0	9	2	0	7	10	1	1	1	0	7	0	45
Maternal request	8	0	10	1	0	3	21	0	0	0	0	0	0	43
Multiple pregnancies	0	0	1	0	0	0	1*	0	0	37	0	1*	0	40
Diabetes	5	0	2	2	1	1	7	0	1	0	0	6	0	25
Thick meconium	10	4	1	1	0	0	0	0	0	0	0	0	0	16
Pre-term	0	0	3*	0	0	1*	4*	0	0	1	0	1	0	10
Other	22	3	23	11	4	10	10	1	1	3	5	24	1	118
Missing	2	0	1	1	0	1	2	0	0	0	0	0	0	7
Total	314	300	158	105	81	49	666	114	90	63	47	258	6	2251

Note: * Possible groups misclassifications;

Abbreviation: APH= Antepartum haemorrhage; CPD= Cephalopelvic disproportion; CTG= Cardiotocography; IUGR= Intrauterine growth restriction.

Key findings and comments:

Indications for CS in Group 1:

• Abnormal CTG = 49.4%

• Potentially inappropriate indications (antepartum diagnosis of CPD, bad obstetric history, subfertility, maternal request) = 15%

• Dystocia = 12.7%

Indications for CS in Group 2a:

• Abnormal CTG = 58.3%

• Failed induction = 21%

• Dystocia = 14.3%

Indications for CS in Group 2b:

• Abnormal CTG = 30.4%

• Potentially inappropriate indications (antepartum diagnosis of CPD, bad obstetric history, subfertility, maternal request) = 25%

Indications for CS in Group 3:

• Abnormal CTG = 57.1%

• Dystocia = 8.5%

Indications for CS in Group 4a:

• Abnormal CTG = 60.5%

• Failed induction = 25.9%

• Dystocia = 7.4%

Indications for CS in Group 4b:

• Abnormal CTG = 18.4%

• Maternal/foetal issues = 32.6%

• Other = 20.4%

Indications for CS in Group 5:

• Previous CS = 70.1%

• Abnormal CTG = 7.4%

• Dystocia = 5.4%

• Maternal request = 3.2%

Indications for CS in Group 8:

• Multiple pregnancy = 58.7%

• Breech/abnormal lie = 11.1%

Indications for CS in Group 10:

• Maternal/fetal issues (preeclampsia/diabetes/maternal cardiac diseases/IUGR/APH) 48.1%

• Abnormal CTG 18.6%

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Implementation of the WHO Manual for Robson classification: an example from Sri Lanka using a local database for developing quality improvement recommendations

Short title: Use of a prospective database for the Robson classification in Sri Lanka

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List of abbreviations

APH= Antepartum haemorrhage
BMI= Body mass index
CS= Caesarean section
CPD= Cephalopelvic disproportion
CTG= Cardiotocography
ECV= External cephalic version
Hb= Haemoglobin
IOL= Induction of labour
IUGR= Intrauterine growth restriction
QI= Quality improvement
QoC= Quality of Care
SMART= Specific, Measurable, Achievable, Realistic, Time-bound
SOP= Standards operating procedures
SQUIRE= Standards for Quality Improvement Reporting Excellence
UK= United Kingdom
USA= United States of America
WHO= World Health Organization
WHO MCS= WHO Multi country Survey on Maternal and Newborn Health

ABSTRACT

Objectives. This study aimed at describing the use of a prospective database on hospital deliveries for analyzing caesarian section (CS) practices according to the WHO Manual for Robson classification, and for developing recommendations for improving the quality of care (QoC).

Design Observational study

Setting University Obstetric Unit De Soysa Hospital for Women, the largest maternity unit in Sri Lanka.

Data collection and analysis For each childbirth, 150 variables were routinely collected in a standardised form and entered into a database. Data was routinely monitored for ensuring quality. Information on deliveries occurring from July 2015 to June 2017 were analysed according the WHO Robson Classification Manual. Findings were discussed internally to develop quality improvement recommendations.

Results 7504 women delivered in the hospital during the study period and at least one maternal or foetal pathological condition were reported in 2845 (37.9%). The CS rate was 30.0%, with 11.9% CS being performed pre-labour. According to the Robson classification, Group 3 and Group 1 were the most represented groups (27.0% and 23.1% of population, respectively). The major contributors to the CS rate were Group 5 (29.6%), Group 1 (14.0%), 2a (13.3%) and Group 10 (11.5%). The most commonly reported indications for CS included abnormal cardiotocography (CTG)/suspected foetal distress, past CS and failed progress of labour or failed induction. These suggested the need for further discussion on CS practices. Overall, 18 recommendations were agreed on. Beside updating protocols and hands-on training, activities agreed included monitoring and supervision, criterion-based audits, risk management meetings and appropriate information for patients and recommendations to further improve the quality of data. .

Conclusions This study provides an example on how the WHO Manual for Robson classification can be used in an action-oriented manner for developing recommendations for improving the QoC, and the quality of data collected.

Article summary: strengths and limitations of this study

- Despite being a single-centre study, this is the first study from a setting with limited resources reporting on the use of a prospective individual-patient database for analysing practices on caesarean section.
- This is also the first report on the use of WHO Implementation Manual for Robson Classification in a project aiming at quality improvement. The paper describes how the WHO manual can be used in an action-oriented manner for developing recommendations for improving the quality of maternal health care, and the quality of data collected.
- This pilot experience can be of interests of both researchers and policymakers, providing a model on how different types of variables can inform the Robson classification, and how findings from the Robson classification can be used proactively for decision-making.

INTRODUCTION

Improving the appropriate use of caesarean section (CS) is a major global concern. [1, 2] While global CS rates at population level are rising, major disparities exist among countries, with both under and over-use of this procedure.[1, 2] Although there is no debate about the need to increase access to safe CS, there is also common agreement that CS should be performed only for medically indicated reasons.[1, 2]

Interventions to reduce unnecessary CSs have shown little success.[2] In the last few years, the World Health Organization (WHO) has endorsed the use of the Robson classification system,[3] and a manual for supporting its implementation was published in 2017.[4] The WHO Robson Classification Manual guides the implementation of the Robson classification and provides practical tools for analyzing CS practice in a standardized, reliable, consistent and action-oriented manner.[4] However, there is still little published experience on the practical utilization of the WHO Robson Classification Manual,[4] and no concrete experience has been reported so far on how to use the manual in an action-oriented manner.

A rising trend in the national CS rate has been reported in Sri Lanka (33.2% in 2015), with large heterogeneity among different facilities [5,6] and widespread diffusion of inappropriate indications for CS [7] Nevertheless, few studies have analysed CS practices in a standardised manner [7,8] and no study used findings of such analyses for developing recommendations to improve the quality of maternal healthcare and the quality of data collected.

Since year 2015 we implemented a prospective individual patient database at the De Soysa Hospital for Women, Colombo, the largest maternity hospital in Sri Lanka. For each case of delivery, about 150 variables were collected and routinely entered in an electronic database [9] The objective of this study was to describe the use of the information provided by this database to analyse CS practices according to the WHO Robson Classification Manual [4] in an action-oriented manner, with the aim of developing recommendations for improving the quality of maternal hospital care.

METHODS

Study design

The study was designed as an observational study aimed at analysing practices related to CS, and at developing recommendations for improving the quality of hospital care. The results section of this paper reports the findings of the Robson analysis [4] and how such findings were internally discussed and used.

Population and setting

The study was conducted at University Obstetric Unit De Soysa Hospital for Women, the largest maternity unit in Sri Lanka. Detailed methods of data collection have been previously reported. [9] Briefly, 150 variables (ie, maternal sociodemographic characteristics, risk factors, process indicators, maternal and neonatal outcomes) were collected for each individual birth using a standardised two-page form, and entered in real time in an electronic database. Data quality assurance procedures included detailed case definitions, standards operating procedures (SOP), regular random checks, and 137 automatic validation rules aiming at minimising data entry errors.[9]

The present paper reports findings relevant to CS practices on births occurring from July 2015 to June 2017. Missing cases for the variables of interest were overall ≤ 0.7%, except for trial of labour in previous CS, where missing variables were 1.2% (**Supplementary Table 1**).

Data analysis

Data was analysed according the recommendations of the WHO Robson Classification Manual [4] and synthesized according to the standardized reporting tables provided by the Manual (**Supplementary tables 2-4**).[4] According to the WHO methodology,[4] the analysis should follow the following key steps. First, each case of birth was classified into one of the Robson groups (**Box 1**), using six key variables (parity, previous CS, onset of labour, number of foetus, gestational age, foetal lie presentation). Secondly, data was assessed for: 1) quality, 2) type of population, 3) CS rates. As recommended in the WHO Manual, [4] relevant additional information provided by the local data collection system [9] was used as complementary information to allow an in-depth interpretation of CS practices. Specifically, the following types of variables collected by the local individual-patient database were used: maternal age, gestational age, maternal pathological conditions (e.g. diabetes, hypertensive disorders and others), foetal pathological conditions, CS indications. For each step, findings

were compared to the suggested two sources of interpretation in the WHO manual [4]: 1) the reference ranges and interpretation by Michael Robson; [3,10] 2) the findings of the WHO Multicountry Survey on Maternal and Newborn Health (MCS, provided by the WHO Manual as an additional example for comparison (this is a population characterised by a combination of relatively low CS rates and good outcomes of labour and childbirth).

Before starting the data analysis, the information in the database was cleaned. Specifically, the open text category called "other" under "indication for CS" (which already included 18 pre-defined categories [9] were thoroughly checked by two experienced obstetricians and classified, as more appropriate, in one of the predefined categories, or in a new category.

Box 1. The 10 groups of the Robson classification [4]

Group 1: Nulliparous women with a single cephalic pregnancy, ≥37 weeks gestation in spontaneous labour
Group 2: Nulliparous women with a single cephalic pregnancy, ≥37 weeks gestation who had labour induced or were delivered by caesarean section before labour
2a Labour induced
2b Pre-labour caesarean section
Group 3: Multiparous women without a previous caesarean section, with a single cephalic pregnancy, ≥37 weeks gestation in spontaneous labour
Group 4: Multiparous women without a previous caesarean section, with a single cephalic pregnancy, ≥37 weeks gestation who had labour induced or were delivered by caesarean section before labour
4a Labour induced
4b Pre-labour caesarean section
Group 5: All multiparous women with at least one previous caesarean section, with a single cephalic pregnancy, ≥37 weeks gestation
Group 6: All nulliparous women with a single breech pregnancy
Group 7: All multiparous women with a single breech pregnancy including women with previous caesarean section(s)
Group 8: All women with multiple pregnancies including women with previous caesarean section(s)
Group 9: All women with a single pregnancy with a transverse or oblique lie, including women with previous caesarean section(s)
Group 10: All women with a single cephalic pregnancy < 37 weeks gestation, including women with previous caesarean section(s)

Data use for developing recommendation for improving the quality of care

The findings of the analysis were presented during two dedicated workshops with key hospital staff of different levels (ie, senior obstetricians, neonatologist, registrars, nurses, midwifes and other staff). The meetings were led by local staff (HS, MR), in dialogue with the WHO Collaboration Centre, Trieste, Italy.

The workshops had the following objectives: discussing hospital practices related to CS, identifying possible gaps in quality of care (QoC) provided, identifying possible gaps in data quality and/or in data collection procedures, selecting priorities for action, developing and agreeing recommendations for improving the QoC related to CS and, if needed, the quality of data. Secondary objectives included improving the knowledge of the Robson classification and of the WHO manual [4], supporting a culture of Quality Improvement (QI), and fostering team work.

During the workshops data were presented and discussed using the standardised reporting tables suggested by the WHO manual (**Supplementary table 2-4**), which included the following subsequent evaluations: 1) Robson classification, 2) data quality, 3) type of population, 4) CS rates. Additionally, the other characteristics of the population identified as informative for the discussion of CS practices (i.e., maternal age, gestational age, maternal and foetal pathological conditions, indications for CS were tabulated and discussed. The sources of comparison provided by the WHO manual were also made explicit in the tables. Relevant international literature [1,10-13] were made available to further interpret data.

A pre-defined template for identifying possible QI recommendations was distributed to each participant at the beginning of the workshops (**Supplementary table 5**). It was emphasized that the proposed actions had to be SMART (Specific, Measurable, Achievable, Realistic, Time-bound) 14]. An action-oriented, non-blaming, problem-solving, proactive and participatory attitude was used for building ownership and commitment to changes among participants, and for allowing a wide involvement of all type of staff.

Proposed recommendations were discussed and agreed in plenary until consensus was reached. Recommendations are presented in the results section.

Patient and Public Involvement

Patient or public were not directly involved in the study. However, the selection of the variables to be included in the database was informed by patient experience, as reported in literature (1,9). The development of recommendations for improving the quality of care took into account the importance of promoting patient-centered care.

Ethical considerations

The study, including data collection and its use for QI purposes, was approved by the Ethics Review Committee of the Faculty of Medicine, University of Colombo. Confidentiality was maintained by de-identifying all files before database entry. Human subjects were not directly involved in the study.

RESULTS

The following paragraphs reports on the result of the Robson analysis as for the WHO manual [4], and on the related data discussion and development of a list of actions for improving the quality of hospital practices, agreed during the workshops.

Characteristics of the population

A total of 7504 women delivered in the hospital during the study period. Detailed characteristics of the population, with a specific focus on the variables relevant to the analysis of CS practices and the Robson classification are reported in **Supplementary Table 6**. Overall CS rate in the study population was 30.0%, with about a third (11.9%) of the total CS performed pre-labour. Induction of labour (IOL) occurred in 24.6% of cases. Preterm deliveries (before 37 weeks) were observed in 9.4% of cases, with 0.5% of the total newborns being extremely preterm (less than 28 weeks) and 1.3% being very preterm (28 weeks to before 32 weeks completed). At least one maternal or foetal pathological condition, potentially contributing to the decision for CS or IOL, was reported in 2845 (37.9%) women. Gestational diabetes was the most frequent condition (13.4%), followed by hypertensive disorders of pregnancy (6.7%) and intrauterine growth restriction (IUGR) (6.7%). Overall, 5.9% of the total sample was obese according to the body mass index (BMI) cut-offs suggested for Asian population (BMI > 27.5) [15,16].

Overall the discussion on these general characteristics of the population focused on the following observations: high rate of CS; relatively high rate of IOL; high prevalence of risk factors (which may be explained by the hospital being a tertiary level centre).

Analysis by Robson Classification

Table 1 presents the Robson classification (adapted by adding also information on group 2a and 2b, 4a and 4b). Group 3 (multiparous without previous CS, single cephalic at term, in spontaneous labour) and Group 1 (nulliparous, single cephalic at term, in spontaneous labour) were the most represented groups (27.0% and 23.1% respectively). Group 2a (nulliparous, single cephalic at term, with IOL) was the third most represented group (12.8%).

The major contributors to CS were as follows: Group 5 (multiparous with at least one previous CS, single cephalic at term) 29.6%; Group 1 (nulliparous without previous CS, single cephalic at term, in spontaneous labour) 14.0%; Group 2a (nulliparous, single cephalic at term, with IOL) 13.3% and Group 10 (single cephalic, preterm, including previous CS) 11.5%.

Unclassifiable cases accounted for only 42 (0.6%) of total cases. The most prevalent reason was the missing variable previous CS, which was missing in 36 unclassifiable cases (85.7%).

Overall the discussion on **Table 1** focused on the following points: data showed a relatively high rate of IOL (Group 2a and 4a); the rate of missing cases (0.6%) was perceived as reassuring, although it was felt that all efforts had to be made to avoid missing information under the variable “previous CS”.

Table 1. The Robson Classification report table

Setting name: *De Soysa Hospital, Colombo, Sri Lanka*					**period:** July 2015 to June 2017	
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**	**Column 6**	**Column 7**
Group	Number of CS in group	Number of women in group	Group size[1] (%)	Group CS rate[2] (%)	Absolute group contribution to overall CS rate[3] (%)	Relative contribution of group to overall CS rate[4] (%)
1	314	1740	23.2	18.0	4.2	14.0
2	458	1116	14.9	41.0	6.1	20.3
2a	300	958	12.8	31.3	4.0	13.3
2b	158	158	2.1	100	2.1	7.0
3	105	2030	27.1	5.2	1.4	4.7
4	130	771	10.3	16.9	1.7	5.8
4a	81	722	9.6	11.2	1.1	3.6
4b	49	49	0.7	100	0.7	2.2
5	666	814	10.9	81.8	8.9	29.6
6	114	139	1.9	82.0	1.5	5.1
7	90	115	1.5	78.3	1.2	4.0
8	63	84	1.1	75.0	0.8	2.8
9	47	65	0.9	72.3	0.6	2.1
10	258	588	7.8	43.9	3.4	11.5
Total	**Total number of CS=2251**	**Total number women delivered= 7504**	**100%**	**Overall CS rate**	**Overall CS rate**	**100%**

Unclassifiable: 42 cases (0.6%) [Number unclassifiable cases / (Total Number women delivered classified + unclassified) X 100]	1. Group size (%) = n of women in the group / total N women delivered in the hospital x 100 2. Group CS rate (%) = n of CS in the group / total N of women in the group x 100 3. Absolute contribution (%) = n of CS in the group / total N of women delivered in the hospital x 100 4. Relative contribution (%) = n of CS in the group / total N of CS in the hospital x 100

Tables 2, 3 and 4 summarize findings and their interpretation, related to the data quality, the type of population, and the CS rates. Findings different from the Robson comparison and/or from the MCS reference population are highlighted in grey in the tables.

Regarding the quality of data (**Table 2**), total number of deliveries and size of Group 9 (single pregnancy, transverse or oblique lie, including previous CS), when compared to the Robson interpretation and the MCS example, suggested no major problems in data quality. The CS rate in Group 9 (72.3%), suggested possible misclassification of a few number of cases (about 15 cases). It was felt that the most likely explanation for this finding could have been that women, presenting initially with an oblique/transverse lie, but having a spontaneous version or a successful external cephalic version after admission, were eventually erroneously classified as abnormal lie.

Table 2. Assessment of the quality of data

Steps for interpretation	Interpretation by Robson	Example: MCS population	Our findings	Additional information from database used to interpret data	Final interpretation
STEP 1. Total number of CS and total number of women delivered	Should be identical to the numbers provided by official register	NA	Total CS= 2251 Total deliveries= 7504	-	There are no missing/incorrect data
STEP 2. Size of Group 9 (should be less than 1%)	<1%	0.4%	0.9%	-	No significant misclassification for this group according to references by Robson
STEP 3. CS in Group 9 (should be 100% by convention)	100%	88.6%	72.3%	-	Misclassification

Abbreviation: CS= Caesarean section; MCS= Multi-country survey; NA= data not available.

Table 3 synthetises the assessment of the type of population. Overall, findings on step 1, 4 and 5 were in line with both the Robson references and the MCS example and did not result in major discussion. Findings on step 2, 3 and 6 to 9 (highlighted in grey in the table), were somehow different from both the Robson and MCS comparisons, and where interpreted based also on the additional information provided by the local database (column five in Table 3). Different possible explanations for these findings were identified, including possible misclassifications, case selection (tertiary referral centre), inappropriate care, or others (Table 3). Specifically, the following were the key findings of the analysis.

On step 2 and 9, the size of Group 3 (multiparous without previous CS, single cephalic at term, in spontaneous labour) plus Group 4 (multiparous without previous CS, single cephalic at term with IOL or CS before labour) was larger than the Robson comparison (37.3% *versus* about 30%) while the ratio of the size of Group 6 (nulliparous, single breech) *versus* Group 7 (multiparous, single breech, including previous CS) was lower (1.2) than the Robson comparison (ratio of 1.2 instead of 2). On both steps, the observed values were similar to the MCS example. It was felt that these findings could be explained by the relatively high prevalence of multiparous women in the study population (55%).

On step 3, the small size of Group 5 (multiparous with at least one previous CS, single cephalic at term) when compared to the overall CS rate (30.0%) suggested relatively low CS rate in the previous years, or a recently increased rate, or misclassification (wrong classification especially in group 3 where the CS rate is unusually high at 5.2%).

On step 6, Group 10 (single cephalic, preterm, including previous CS) was slightly larger than the Robson comparison (7.8% vs 5%), most likely due to the hospital being a tertiary care, or to possible misclassification (eg, breech presentation misclassified as cephalic)

On step 7, the ratio of the size of Group 1 (nulliparous, single cephalic at term, in spontaneous labour) *versus* Group 2 (nulliparous single cephalic, at term with IOL or CS before labour) was lower than the Robson comparison (1.5 vs 2), possibly due to the observed relatively high rate of IOL in nulliparous (Group 2a 12.8%, see **Table 1**) when compared to existing literature [11,17,18].

Table 3. Assessment of the type of population

Steps for interpretation	Interpretation by Robson	Example: MCS population	Our findings	Additional information from database used to interpret data	Final interpretation
STEP 1. Size of Groups 1 + Group 2	35-42%	38.1%	38.1%	-	Rate in line with both references by Robson and MCS reference population
STEP 2. Size of Groups 3+4	30%	46.5%	37.3%	Multiparous in our population 55.0%	Rate higher than Robson references but lower than MCS examples. This may be explained by a high prevalence of multiparous women in our population
STEP 3. Size of Group 5	Half of total CS rate	7.2%	10.9%	-	Lower than half of total CS. This, as suggested by the WHO Manual, may be due to relatively low CS rate in the previous years, or to a recently increased CS rate or to misclassification.
STEP 4. Size of Groups 6+7	3-4%	2.7%	3.4%	-	Rate in line with both Robson references and MCS examples
STEP 5. Size of Group 8	1.5-2%	0.9%	1.1%	-	Rate in line with MCS examples.
STEP 6. Size of Group 10	< 5%	4.2%	7.8%	Divisions by gestational age in our preterm population	Higher than both comparisons. This may be explained by the hospital being a tertiary care referral centre, or by misclassification.
STEP 7. Ratio of the size of Group 1 versus Group 2	Ratio 2 or higher	Ratio 3.3	Ratio 1.5	Indication of IOL	Lower than the comparisons. This associates with a large size of Group 2a, suggesting a high incidence of IOL. This may be explained by: 1) case selection (tertiary care referral centre) 2) inappropriate indication to IOL (deserving further investigation)
STEP 8. Ratio of size of Group 3 versus Group 4	> than 2:1	Ratio 6.3	Ratio 2.6	Indication of IOL	Rate in line with both Robson references, lower than MCS. This may be explained by: 1) misclassification of augmentation as IOL 2) case selection (tertiary care referral centre) 3) inappropriate indication to IOL (deserving further investigation)

STEP 9. Ratio of size of Group 6 versus Group 7	usually 2:1	Ratio 0.8	Ratio 1.2	Multiparous in our population 55.0%	Rate in line with MCS, but lower than Robson references. This may be explained by: 1) high number of multiparous in our population.

Abbreviation: CS= Caesarean section; IOL= Induction of labour; MCS reference population: was the population of the WHO MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth.

The assessment of CS rates (see the following **Table 4**) was complemented by an analysis of the indications for CS using data extracted from the patient database (**Supplementary table 7 and 8**). Overall, it was found that the main indications for CS were (**Supplementary table 7**): abnormal CTG or suspected foetal distress (27.1%); past CS (23.9%), failure to progress or failed IOL (11.6%); breech/abnormal presentation (8.2%). The following indications, accounting for a total of 147 (6.5%) cases, were identified as potentially inappropriate (in grey in **Supplementary table 7**): prelabour diagnosis of cephalopelvic disproportion (CPD) (2.5%), history of subfertility/bad obstetric history (2.1%), CS for maternal request (1.9%).

When indications to CS were analysed by Robson groups, some indications were observed at a suspected high or low rate compared to the expected, suggesting potentially inappropriate management. Specifically, abnormal CTG/suspected foetal distress were over-represented as an indication to CS, particularly in Robson groups 1 to 4, suggesting possible gaps in the use/interpretation of CTG (in dark grey in **Supplementary table 8**). On the other hand, dystocia was reported as an indication for CS in less than 8% of total cases (in light grey in **Supplementary table 8**), a rate much lower than what observed in United Kingdom (UK) and the United States of America (USA), where dystocia is an indication for about 20% of CS.[19-21] Internal discussion identified the following possible explanations for this specific finding: difficulty by data collectors in classifying dystocia; missing information in the medical file; peculiar characteristics of the Sri Lanka population enrolled - such as lower BMI, maternal age and parity; better management of labour compared to reported statistics, or other reasons affecting dystocia rate in UK and USA statistics. Misclassifications were identified in 1.9% of the total indications to CS (highlighted with an asterisk in **Supplementary table 8**).

Table 4 reports the interpretation of assessment of CS rate. Overall, findings on step 8 and 9 were in line with both Robson references and MCS examples, and did not resulted in major discussion. Findings from all other steps (in grey in **Table 4**) were somehow different from either the Robson comparison or the MCS example. Details on data interpretation are provided, step by step, in **Table 4**.

Table 4. Assessment of the CS rates

Steps for interpretation	Interpretation by Robson	Example: MCS population	Our findings	Additional information from database used to interpret data	Final interpretation
STEP 1. CS rate in Group 1	Under 10% are achievable	9.8%	18.0%	•Abnormal CTG was the indication in 49.4% of cases •Potentially inappropriate CS indications to CS in 15%.	CS rate higher than Robson and MCS. This may be explained by inappropriate indications (abnormal CTG/suspected foetal distress) and/or inappropriate care.
STEP 2. CS rate in Group 2	Consistently around 20-35%	39.9%	41.0%	•Abnormal CTG was the indication in 58.3% of Group 2a and 30.4% in Group 2b. •Potentially inappropriate CS indications in 25% in 2b.	CS rate higher than Robson and MCS. This may be possibly due to the high rate of IOL, which carry increased risk of CS.
STEP 3. CS rate in Group 3	No higher than 3.0%.	3.0%	5.2%	•Abnormal CTG was the indication in 57.1%.	CS rate higher than Robson and MCS. This may be explained by misclassification (Group 5 misclassified as Group 3) or, most probably, by inappropriate indication to CS (CTG mis-interpretation).
STEP 4. CS rate for Group 4	It rarely should be higher than 15%	23.7%	16.8%	•Abnormal CTG was the indication in 60.5% in 4a and 18.4% in 4b. • failed induction was an indication in 25.9% of 4a.	CS rate higher than Robson. Size of Group 4b suggests low prelabour CS in this group, while the rate of CS in Group 4a was high mainly due to CTG abnormalities and failed IOL. This may be explained by misclassification (Group 5 misclassified as Group 4) or, most probably, by inappropriate indication to CS (CTG mis-interpretation).

STEP 5. CS rate in Group 5	Rates of 50-60% are considered appropriate	74.4%	81.8%	•Abnormal CTG was the indication in 70.1%. • Rate of prelabour CS was 62.5%.	CS rate higher than Robson and MCS. Low rate of IOL in this group. The vast majority are CS for past section. This may be explained by the group size or a policy of scheduling pre-labour CS (low offer of trial of labour). Also, women's preference, based on previous information, for repeating CS may have a role.
STEP 6. CS rate for Group 8	Usually around 60%.	57.7%	80.9%	•Multiple pregnancy was the indication in 58.7%. •Elective CS rate in multiple pregnancies was 37.8%	CS rate higher than Robson and MCS. Possible tendency to perform elective CS in multiple pregnancies
STEP 7. CS in Group 10	Usually around 30%	25.1%	41.1%	•Maternal/foetal pathological conditions were the indication in 48.1%.	CS rate higher than Robson and MCS. This may be explained by a high-risk population.
STEP 8. Relative contribution of Groups 1, 2 and 5 to the overall CS rate	Normally contribute to 2/3 (66%) of all CS performed in most hospitals	Contributed to 63.7% of all CS	63.9%	-	In line with both Robson and MCS reference.
STEP 9. Absolute contribution of Group 5 to overall CS rate	NA	Responsible for 28.9% of all CS	Absolute contribution: 8.87% Relative contribution: 29.59%		Absolute contribution lower than MCS (Robson comparison not provided in the WHO manual), Relative contribution in line with MCS (the value provided in the WHO Manual as MCS example refers to the relative contribution).

Abbreviation: CS= Caesarean section; CTG= Cardiotocography; IOL= Induction of labour; TOL= Trial of labour; MCS reference population: was the population of the WHO MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth; NA= data not available.

Developing of quality improvement recommendations

Table 5 reports the key findings of the analysis, the possible explanations, and the agreed recommendations that emerged from the hospital staff discussion. Overall, 18 recommendations were developed, and three were identified as priorities for action (highlighted with an asterisk in **Table 5**). Some recommendations, such as the need to train staff on foetal monitoring, emerged from different key findings and as such were identified as a priority for action. Most recommendations aimed at improving the implementation of evidenced-based indications for CS and IOL. Beside updating protocols and hands-on training, activities agreed included monitoring and supervision, criterion-based audits, risk management meetings and appropriate information for patients. Recommendations to further improve the quality of data were also agreed upon (recommendations 17 and 18).

Table 5. Process of development of quality improvement recommendations

Key findings from the analysis	Possible explanations emerged from hospital staff discussion	Agreed recommendations for quality improvement
1. High intrapartum CS rate in Group 1, with potentially inappropriate indications (main current indication was CTG abnormality)	1.Possible inappropriate interpretation of foetal monitoring 2.Possible inappropriate use of oxytocin 3.Possible inappropriate indications to CS	1.Develop a training plan for strengthening capacities of staff in CTG interpretation* 2. Hands-on trainings on instrumental delivery 3. Supportive supervision and monitor over time staff skills in CTG interpretation and instrumental delivery 4. Adoption of Robson classification of CS indications (22) 5.Criterion-based audits of CS indications 6. Regular risk management meetings with emphasis on diagnosis of foetal distress
2. High rate of IOL and high rates of CS in women undergoing IOL (high contribution of Group 2a to total CS rate and high CS rate in Group 4a)	1.Possible inappropriate indications for IOL 2.Possible inappropriate use of prostaglandin/oxytocin 3.Possible Inappropriate CTG interpretation 4.Possible misdiagnosis of failed IOL	7.Consultant meeting to update IOL protocols (agreeing on criteria for failed IOL according to recent evidence)* 8. Criterion-based audits on IOL

		9.Monitor IOL indications, complications and abnormal CTG associated with use of prostaglandins or oxytocin
3. High prevalence of prelabour CS (Group 2b) with more frequent CS indications: abnormal CTG, potentially inappropriate indications 25%, presence of maternal/foetal pathological conditions	1.Inappropriate indications for prelabour CS	10.Update protocols on indications for prelabour CS 11.Criterion-based audits on indications for prelabour CS 12.Review cases of CS for abnormal CTG during staff training
4. High CS rate in Group 3 and 4a (multiparous). More frequent indication is abnormal CTG 5. Very high CS rate in Group 5, majority are elective. Past CS is the main indication	1.Rate of CS in multiparous suggests suboptimal care in this group of women 2.Inappropriate interpretation of CTG 3.Low offer of TOLAC	Recommendations #1,2,3,s 13.Criterion-based audits of offers and unsuccessful cases of TOL 14.Use of a patient education leaflets to inform women of TOL benefits and establishment of a nurse-led TOLAC counselling service* 15. Monitoring the prevalence of TOLAC
6. Breech is the fourth most common indication for CS	1.Refusal by mothers to accept ECV due to preconceived prejudices	16.Develop an information leaflet on the value of ECV
7. Low Rate of CS for dystocia with half of CS done in 2nd stage 8. Low CS rate in Group 9	1.Possible problems in data quality 2.Possible misclassification of a few number of cases	17.Training for data collectors and hospital staff on definitions used for the Robson's classification according to WHO manual, stressing also the definition of dystocia 18.Add few internal validation rules on database (previous CS, breech, dystocia) and strengthen monitoring on these variables. Recommendation #2
9. High contribution to CS rate from Group10. Majority of indications for maternal/foetal pathological conditions	1.Iatrogenic indications of IOL/CS in the late preterm period	Recommendation #7 (Update protocols of IOL and elective CS criteria in late preterm and SGA) Recommendation #5 (Criterion-based audits on cases of IOL and elective CS)

Abbreviation: CS = Caesarean section; CTG = Cardiotocography; ECV = External cephalic version; GA = Gestational age; IOL = Induction of labour; SGA = small for gestational age; TOL = Trial of labour; TOLAC = Trial of labour after caesarean.

DISCUSSION

This study reports experience from a lower middle-income country, where information accumulated in an individual patient database was used locally for conducting an in-depth analysis of CS practices according the WHO manual for Robson classification,[4] and for developing recommendations to improve the quality of care.

In respect to previous literature, this study has three main aspects of novelty, which can be of interest of both researchers and policy makers. First, this is the first study conducted in a lower middle-income country, reporting on the use of a prospective individual patient database to analyse practices on CS. Such databases are generally lacking in low resources settings. Furthermore, the availability of accurate data is relatively limited even in high-income countries, where most hospital administrative datasets lack key information such as maternal risk factors. These are needed for evaluating the case mix and for interpreting the observed CS rates. To our knowledge, even the few studies in high-income countries which utilised individual patient databases for the Robson classification,[22-24] had access to much less information that in this study in Sri Lanka, where a large number of variables were collected prospectively[9]. The availability of many variables , including CS indications by Robson groups, was invaluable for an in-depth understanding of CS practices.

Second and most important, the paper provides a model on how findings of the Robson analysis can be used for internal discussion and for QI purposes. Existing literature has reported heterogeneity of practices related to CS and substandard practices have been identified even in “developed countries, such as Australia, France, Italy, and others (25-27). However, the majority of the published studies using the Robson classification focused on the analysis, rather than on the development of recommendations to improve CS practices. A recent systematic review [16,28] cited only six studies that used the Robson classification in a clinical audit cycle to reduce CS rates. We were able to identify only one study, conducted in Canada, where the local Society of Obstetricians and Gynaecologists has formally supported the use of Robson classification and [29], measuring the effect of the Robson analysis on the CS rate, with a before and after design.[30]

Third, this is the first report on the use of the WHO Implementation Manual for the Robson Classification [4], where, all steps suggested therein were followed. The paper documents an example of how the manual can be used in an action-oriented manner.

As additional findings, this study underscored the lack of specific reference standards for the Robson Classification. Interestingly, in several instances the findings of this analysis were within the range of the values provided by the Robson guideline, but not of those provided by the MCS population, or vice-versa. This is not surprising, given the fact that as stressed in the WHO manual, none of these two comparisons could be taken as an absolute standard.[4] The WHO Manual underlines that neither Robson nor MCS references "have been validated against outcomes and should not be taken as a recommendation" and "it is up to the hospital itself to decide what is appropriate care, based on its results and other available evidence".[4] Being specific for Sri Lanka, this study may help in the future researchers and policymakers in further interpreting data from a similar setting. Meanwhile, more research should be conducted to identify which can be the golden standard for the Robson analysis.

This study did not aim at comparing in detail the findings of the Robson analysis to the international literature, but rather at describing the whole process of how data were internally used to develop recommendations to improve hospital practices. However, few points on key clinical findings can be further discussed here. In most Robson groups, the very high rate of CS performed for abnormal CTG/suspected foetal distress was a reason of concern. Although a similar rate around 25% had been reported in USA [23] the contribution of abnormal CTG In Sri Lanka may highlight a problem unique to countries in economic transition. In these settings, with increasing investment in health infrastructure, CTG machines are becoming increasingly available and, due also to their wide usage in high-income countries, practitioners and policymakers often see them as essential for provision of quality obstetric care. However, the introduction of these technologies not always has been complemented by adequate capacity development. Currently, Sri Lanka does not have mandatory training for staff in CTG interpretation. Further, currently there is a lack of facilities for ancillary tests such as foetal scalp blood sampling and cord blood pH levels, which are important adjuncts in verifying decisions made based on CTG interpretation. Recently, there

have been calls to optimize technical skills of staff on CTG interpretation, by delivering adequate training [31]. Results of this study suggest that improving the quality of CTG interpretation could be an important step towards reducing CS rates and increasing appropriateness of care.

The high rate of IOL in our population (24.6%), when compared to existing literature [14,32,33] is also matter of concern that needs further investigation. IOL should be performed only with a clear medical indication (i.e., when expected benefits outweigh its potential harms).[32] Recent data from high-income settings shows that IOL does not result in increased CS rates,[34,35] while our findings suggest that the high rate of IOL may have contributed to the relatively high rate of CS (group 2a and 4a contributed to 16.9% of the total number of CS, and the two key indications to CS in these groups were abnormal CTG and failed induction, **Table 1** and **Supplementary table 8**). Sri Lanka has the highest rate of IOL in Asia [32,33] and a better understanding of practices related to IOL may contribute to the current local debate on how to improve quality of maternal care. As recommended by Robson [36] the Robson classification "provides a common starting point for further analyses for all labour and delivery events and outcomes"; it draws attention to specific groups, where further analysis can be performed to understand the reasons behind the initial observation. We plan to further analyse and report IOL practices in a future paper.

A relevant proportion of CS (6.5%) was performed electively for potentially inappropriate indications (i.e., prelabour diagnosis of CPD, history of subfertility, maternal request). However, this is a frequent finding in the literature, as documented in studies from USA, Germany, China, Brazil, Argentina, India, Pakistan, and other countries.[37-44] One of the recommendations agreed in this experience was the implementation of the regular auditing of cases of CS without absolute indications, aiming at promoting good practices.

We acknowledge some limitations of this study. The analysis highlighted cases of possible misclassification and missing variable resulting in cases being unclassifiable. However, this was a rare finding (respectively, 0.5% and 0.6% of total cases, see **Table 1** and **Supplementary table 8**). Data quality was the object of internal discussion, and actions to improve it were within the list of recommendations developed.

Despite not all recommendations developed fitting into the remit of SMART,[17] still the process provided the opportunity to discuss clinical practice using objective data in a constructive, participatory manner, and resulted in a concrete list of actions. Activities agreed aligned both with evidenced-based recommendations on effective interventions for improve health worker performance [45], taking into account also previous experience of the team [46-50].

This was a pilot study in one single facility and it will be important to replicate similar experiences in other settings to evaluate generalisability of findings. We believe that the commitment of local staff, a favourable local leadership and a constructive dialogue with an external partner providing independent technical support, were the three essential favourable elements in succeeding in performing the analysis and most importantly, in using data proactively.

The study does not report perinatal outcomes such as perinatal mortality rates. We have planned two wait some more time to collect a larger sample to be able to have adequate power to analyze and discuss hard (bur relatively rare) outcomes such as perinatal mortality.

Within the project timelines, it was not possible to follow up the impact of the recommendations developed. Future longer-term studies will be needed to monitor implementation.

CONCLUSIONS

This study provides an example from a setting with limited resources where information from an individual patient database were used locally for conducting an in-depth analysis of CS practices, following the WHO manual [4]. Further, it was used for developing recommendations to improve the quality of hospital care. Future studies may further explore other aspects of maternal care, such as practices related to IOL- and monitor over time outcomes of the recommendations developed.

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None competing interest

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Author contributions

HS, MP and ML conceived the study and procured funds; HS, MP, CB, RM and ML developed the data collections tools; RF, AS and FRI collected data; BC, HW, EPV and ML analysed the data; all authors interpreted data and contributed to the manuscript; ML wrote the first draft of the paper, all authors contributed to the final version of the paper

Data availability statement

The dataset is available from Benedetta Covi

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Use of an individual-patient database for analysing caesarean section practices according to the WHO Manual for Robson classification and for developing quality improvement recommendations: a study in Sri Lanka

Supplementary file

Table of Contents

Supplementary Table 1. Missing cases for the variables of interest

Variables	Total	Missing	% Missing
Maternal age	7504	34	0.4
Parity	7504	34	0.4
Gestational age at delivery	7504	47	0.6
Previous caesarean section	7504	38	0.5
If previous caesarean section, trial of labour	7504	91	1.2
Multiple pregnancies	7504	35	0.4
Presentation	7504	43	0.6
Labour onset	7504	36	0.4
Delivery	7504	32	0.4
Delivery mode	7504	37	0.4
If operative delivery, indication	7504	38	0.5
If caesarean section, type	7504	37	0.4
Indication of labour	7504	36	0.4
Mode of induction	7504	42	0.5
Pre-gestational diabetes	7504	35	0.4
Gestational diabetes mellitus in diet	7504	35	0.4
Gestational diabetes mellitus in drug therapy	7504	36	0.4
Pre-gestational hypertension	7504	33	0.4
Gestational hypertension (no proteinuria)	7504	35	0.4
Pre-eclampsia not severe	7504	35	0.4
Pre-eclampsia severe	7504	35	0.4
Eclampsia	7504	34	0.4
BMI	7504	53	0.7
Maternal cardiac disease	7504	34	0.4
Polyhydramnios	7504	36	0.4
Oligohydramnios	7504	38	0.4
IUGR	7504	36	0.4
APH/major placentia previa	7504	37	0.4
Severe anaemia	7504	38	0.5
Chorioamnionitis	7504	36	0.4

Abbreviation: APH= Antepartum haemorrhage; BMI= Body mass index; IUGR= Intrauterine growth restriction.

Supplementary Table 2. Steps to assess quality of data [1]

Step	Interpretation by Robson	Example: MCS population*	Further Interpretation
1. Look at the total numbers of CS and of women delivered in your hospital	These numbers should be identical to the total number of CS and of women delivered in your hospital.	NA	If these numbers do not match, then data is missing or incorrect. Some women may not have been classified in the Robson groups because of missing variables or were incorrectly classified as to type of delivery. Sometimes multiple pregnancies are counted as babies rather than mothers.
2. Look at the size of Group 9. Singletons in transverse or oblique lie	It should be less than 1%.	0.4%	If this is > 1%, it is probable that women with breech (or other) presentations have been misclassified as transverse /oblique lie and allocated to this group. As the classification includes all women who have delivered, if any one group is smaller or bigger, look to the other groups which sometimes will show where the misclassification is.
3. Look at the CS rate of Group 9	It should be 100% by convention.	88.6%	By convention, if the woman gives birth vaginally by internal version, it should be classified as either cephalic or breech. The CS rate in Group 9 should be 100%

Notes: *MCS reference population was the population of the MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth.

Abbreviations: CS= caesarean section; NA= not available.

[1] World Health Organization. Robson Classification: Implementation Manual. Geneva, 2017.http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/robson-classification/en/ (accessed 28 June 2018)

Supplementary Table 3. Steps to assess type of population [1]

Step	Interpretation by Robson	Example: MCS population*	Further Interpretation
1. Look at the size of Groups 1 + Group 2. Nulliparous women ≥37 weeks gestation singleton cephalic	This usually represents 35-42% of obstetric population of most hospitals.	38.1%	In settings with high proportion of women who have only one child rather than more than one child, the group of nulliparous women i.e. Groups 1 and 2 tends to be larger. In settings where the opposite is true, the size of Groups 1 + Group 2 will be smaller since most of the population will be represented by multiparous women.
2. Look at the size of Groups 3 + 4 -Multiparous women ≥37 weeks gestation singleton cephalic, without previous CS	This usually represents about 30% of women.	46.5%	In settings with high proportion of women with more than one child rather than only one child, the size of Groups 3 + Group 4 will be higher than 30% (provided they have delivered vaginally). Another reason for a low size of Groups 3 and 4 could be that the size of Group 5 is very high which would be accompanied by a very high overall CS rate.
3. Look at the size of Group 5 - Multiparous women ≥37 weeks gestation singleton cephalic with previous CS	It is related to the overall CS rate. The size of Group 5 is roughly usually about half of the total CS rate. In settings with low overall CS rates, it is usually under 10%.	7.2%	The size of Group 5 is usually related to the overall CS rate. If the size of this group is larger, it means that there has been a high CS rate in the past years in that hospital and mainly in Groups 1 and 2. In places with high CS rates, the size of this group could be > 15%.
4. Look at the size of Groups 6 + 7 Breeches in nulliparous & multiparous women	It should be 3-4%	2.7%	If the total is much over 4%, the most common reason is usually a high rate of preterm deliveries or a higher proportion of nulliparous women. Therefore, look at size of Group 10. If that is over 4-5%, this hypothesis

[1] World Health Organization. Robson Classification: Implementation Manual. Geneva, 2017.http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/robson-classification/en/ (accessed 28 June 2018)

			could be true.
5. Look at the size of Groups 8 - Multiples	It should be 1.5-2%	0.9%	If it is higher, the hospital is probably tertiary (high risk, referral) or runs a fertilization program. If lower, probably a lot of the twins are referred out especially if the remaining twins have a low caesarean section rate
6. Look at the size of Groups 10 - Preterm cephalic singletons	It should be less than 5% in most normal risk settings.	4.2%	If it is higher, the hospital is probably tertiary (high risk, referral) or there is a high risk of preterm births in the population that the hospital serves. If, in addition, the CS rate is low in this group, it could represent a preponderance of spontaneous preterm labour. If the CS rate in this group is high, it could suggest more provider-initiated pre-labour CS for foetal growth restriction or pre-eclampsia and other pregnancy or medical complications.
7. Look at the Ratio of the size of Group 1 versus Group 2 (Divide the size of Group 1 by the size of Group 2) - Nullipara term cephalic singletons spontaneous labour / Nullipara term cephalic singletons induced or pre-labour CS	It is usually 2:1 or higher	Ratio 3.3	If it is lower, suspect poor data quality: nulliparous women who received oxytocin for augmentation (acceleration) of labour (and should be in Group 1) may have been misclassified as “induction” (and incorrectly classified as Group 2). If data collection is correct, a lower ratio may indicate that you have a high induction/prelabour CS issue which may indicate a high-risk population in nulliparous women and are likely therefore to have a high CS rate. Additional information on pre-labour stillbirths would be the next question to ask. On the contrary, if the ratio is very high, you may want to look at your pre-labour stillbirth rate in this population which may indicate that

			you are not inducing enough. Or alternatively you may have a very low risk population
8. Look at the Ratio of the size of Group 3 versus Group 4. (Divide the size of Group 3 by the size of Group 4): Multipara without previous CS, term cephalic singletons spontaneous labour / Multipara without previous CS, term cephalic singletons induced or pre-labour CS	It is always higher than the ratio of Group 1/Group 2 in the same institution, i.e, larger than 2:1. This is very reliable finding in confirming data quality and culture of the organization.	Ratio 6.3	If it is lower, suspect poor data quality: multiparous women who received oxytocin for "augmentation" of labour (and should be in Group 3) may have been misclassified as "induction" (and incorrectly classified as Group 4). A low ratio (due to large Group 4b) may suggest a poor previous maternal experience in vaginal delivery and a request for pre-labour CS in multiparous women. Another explanation may be pre-labour CS done to perform tubal ligation (common in settings where family planning is not easily available).
9. Look at the Ratio of the size of Group 6 versus Group 7. (Divide the size of Group 6 by the size of Group 7) Nullipara breech / Multipara breech	It is usually a 2:1 because breeches are more frequent in nulliparous women than in multiparous women.	Ratio 0.8	If the ratio is different, suspect either unusual nullipara/multipara ratio or inaccurate data collection.

Notes: *MCS reference population was the population of the MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth.

Abbreviation: CS= caesarean section.

Supplementary Table 4. Steps to assess caesarean section rates [1]

Step	Interpretation by Robson	Example: MCS population*	Further Interpretation
1. Look at the CS rate for Group 1	Rates under 10% are achievable	9.8%	This rate can only be interpreted accurately when you have considered the ratio of the sizes of Groups 1 and 2. In principle, the higher the ratio of size of Groups 1:2, the higher the likelihood of both the CS rate in Group 1 and 2 being individually higher. However, the overall CS rate in Groups 1 and 2 combined may still be low or the same.
2. Look at the CS rate for Group 2	Consistently around 20-35%	39.9%	CS rates in Group 2 reflect the size and rates in 2a and 2b. If size of Group 2b is large, the overall CS rates in Group 2 is also going to be large. If Group 2b is relatively small, then high rates of CS in Group 2 may indicate poor success rates for induction or poor choice of women to induce and consequently a high rate of CS in Group 2a. Remember the general principle of not interpreting one single subgroup on its own without knowing what is left out. The interpretation of group 2a requires knowing the relative sizes of Groups 1 and 2b.
3. Look at the CS rate for Group 3	Normally, no higher than 3.0%.	3.0%	In units with higher CS rates in this group, this may be due to poor data collection. It is possible that women with previous scars (Group 5) were incorrectly classified as Group 3. Other possible reasons for high rates could be for example to do tubal ligation in settings with poor access to contraception, or maternal request.
4. Look at the CS rate for Group 4	It rarely should be higher than 15%	23.7%	CS rates in Group 4 reflect the size and rates in 4a and 4b. If size of Group 4b is large, the overall CS rates in Group 4 is also going to be high. If Group 4b is relatively small, then high rates of CS in Group 4 may indicate poor success rates for induction or poor choice of women to induce and consequently a high rate of CS in Group 4a. Poor data collection could also be a reason for high

[1] World Health Organization. Robson Classification: Implementation Manual. Geneva, 2017.http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/robson-classification/en/ (accessed 28 June 2018)

			CS rates in Group 4; for example, due to inclusion of women with previous scars in this group (when they should be in Group 5). Lastly, a high CS rate in Group 4 may reflect a high maternal request for CS even if these women have delivered their first pregnancy vaginally. This may be because of a previously traumatic or prolonged labour or to do tubal ligation in settings with poor access to contraception.
5.Look at the CS rate for Group 5	Rates of 50-60% are considered appropriate provided you have good maternal and perinatal outcome.	74.4%	If rates are higher, this is possibly due to a large Group 5.2 (women with 2 or more previous CS). This could also be due to a policy of scheduling pre-labour CS for all women with 1 previous scar without attempting a trial of labour.
6. Look at the CS rate for Group 8	It is usually around 60%.	57.7%	Variations will depend on the type of twin pregnancy and the ratio of nulliparous/multiparous with or without a previous scar.
7. Look at the CS rate in Group 10	In most populations it is usually around 30%	25.1%	If higher than 30%, it is usually due to many cases of high risk pregnancies (e.g. foetal growth restriction, preeclampsia) that will need preterm pre-labour CS. If lower than 30%, it suggests a relatively higher rate of preterm spontaneous labour and hence a lower overall CS rate.
8. Look at the relative contribution of Groups 1, 2 and 5 to the overall CS rate (add the contribution of each of these groups)	These three groups combined normally contribute to 2/3 (66%) of all CS performed in most hospitals.	These three groups combined contributed to 63.7% of all CS	These three groups should be the focus of attention if the hospital is trying to lower the overall CS rate. The higher the overall CS rate, the greater the focus should be in Group 1.
9. Look at the absolute contribution of Group 5 to the overall		This group was responsible for 28.9% of all CS	If it is very high, this may indicate that in previous years, CS rates in Groups 1 and 2 have been high and it is worth exploring further.

CS rate			

Notes: *MCS reference population was the population of the MCS with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth.

Abbreviation: CS= caesarean section.

Supplementary Table 5. Template for agreeing actions at hospital level to improve the quality of care

Date: **Group Participants:**

Key findings from the analysis	Possible explanations	Agreed recommendations for quality improvement

Instructions:

1. Identify a moderator whose duty is to make sure that the pre-defined template is filled in pre-established time (90 minutes total), that everyone has the right to speak and actively participate, and that the final version of the table corresponds to group opinions
2. Identify a secretary whose job is to take notes, summarize the opinions of the group in the template, act as a presenter in plenary (15 min maximum), save the template in an electronic file (the results will be attached to final report that will be distributed)
3. Participants are requested to make concise and specific interventions lasting up to 1-2 minutes, leaving the possibility to express their opinions to others. It is required to make proposals with a problem-solving attitude
4. We recommend to fill the first column first (key findings) and then the other lines in horizonal
5. Is not necessary to identify many priorities, 5-10 are enough. For the same priority it's possible to specify 1 or more actions
6. Some examples of different possible actions:
   - *development of policies and operational plans (for training, quality, work conditions, improve data collection and other aspects of database)*
   - *development of protocols and procedures*
   - *theoretical and practical training (related to EBM clinical practices or quality of care)*
   - *periodical audit (clinical, on indicators) or team meetings*
   - *adopt quality standards and targets and implement a monitoring system with periodic analyzes and discussions of data*

Actions should be **SMART: Specific, Measurable, Achievable, Realistic, Time-bound** in the real context of the hospital.

Supplementary Table 6. Characteristics of the population

Population	n (N=7504)	%
Maternal age		
<18 years	95	1.2
18-24 years	1862	24.8
25-34 years	4253	56.6
35-39 years	1036	13.8
>40 years	224	2.9
Parity		
0	3342	44.5
≥1	4128	55.0
Gestational age		
<28 weeks	41	0.5
28-31 weeks	96	1.3
32-36 weeks	571	7.6
>37 weeks	6749	89.9
Previous caesarean section	956	12.7
Cephalic	7122	94.9
Breech	273	3.6
Other	66	0.9
Multiple pregnancies	84	1.1
Labour onset		
Spontaneous	4726	62.9
Induction	1849	24.6
Pre-labour caesarean section	893	11.9
Mode of delivery		
Vaginal spontaneous	4906	65.3
Vaginal operative	310	4.1
Caesarean section	2251	30.0
At least one maternal or foetal pathological conditions	2845	37.9
Pre-gestational diabetes	266	3.5
Gestational diabetes, total	1002	13.4
On diet	417	5.6
On drug therapy	585	7.8
Hypertensive disorders of pregnancy, any	506	6.7
Pre-gestational hypertension	168	2.2
Gestational hypertension	179	2.4
Pre-eclampsia not severe	78	1.0
Pre-eclampsia severe	69	0.9

Eclampsia	12	0.2
Obesity (BMI > 27.5)*	440	5.9
Maternal age > 40 years	224	2.9
Maternal cardiac disease	234	3.1
Oligohydramnios	131	1.8
Polyhydramnios	96	1.3
IUGR**	504	6.7
APH/major placentia previa	112	1.5
Severe anaemia (Hb <7)	40	0.5
Chorioamnionitis	11	0.2

Notes: *as defined on data collection form; **defined as weight < 10 centile of estimated weight for gestational age or < 10 centile for abdominal circumference (Bangladesh growth chart), based on ultrasound.

Abbreviation: APH= Antepartum haemorrhage; BMI= Body mass index; Hb= Haemoglobin; IUGR= Intrauterine growth restriction.

Supplementary Table 7. Main indications to CS

Main indication	n (N=2251)	%
CTG abnormal/suspected foetal distress	610	27.1
Past caesarean section	538	23.9
Failure to progress or failed IOL	261	11.6
Failed IOL	109	4.8
Dystocia 1st stage	77	3.4
Dystocia 2nd stage	75	3.3
Breech/abnormal lie	184	8.2
Hypertension/preeclampsia/eclampsia	100	4.4
IUGR	82	3.6
APH/major placenta previa	68	3.0
Prelabour diagnosis of CPD	57	2.5
History of subfertility/bad obstetric history	47	2.1
Cardiac disease	45	2.0
Maternal request	43	1.9
Multiple pregnancies	40	1.8
Diabetes	25	1.1
Thick meconium	16	0.7
Pre-term	10	0.4
Other	118	5.2
Missing	7	0.3

Abbreviation: APH= Antepartum haemorrhage; CPD= Cephalopelvic disproportion; CTG= Cardiotocography; IOL= induction of labour; IUGR= Intrauterine growth restriction.

Supplementary Table 8. Main indications to CS by Robson group

Robson group / Main indication	1	2a	2b	3	4a	4b	5	6	7	8	9	10	Missing	Total
CTG abnormal/suspected foetal distress	155	175	48	60	49	9	49	5	6	3	2*	48	1	610
Past caesarean section	0	0	0	3*	0	1*	467	6	18	2	7*	34	0	538
Failure to progress or failed induction														
Failed induction	0	63	0	0	21	0	15	0	1	1	0	8	0	109
Dystocia 1st stage	27	27	2	8	3	3*	3	0	1	0	0	3	0	77
Dystocia 2nd stage	13	16	3*	1	3	0	33	0	0	0	2*	3	1	75
Breech/abnormal lie	1*	0	1*	1*	0	0	1*	91	55	7	26	1*	0	184
Hypertension/preeclampsia/eclampsia	6	4	9	2	0	4	18	1	0	3	0	52	1	100
IUGR	11	3	9	6	0	3	9	2	4	2	0	32	1	82
APH/major placenta previa	8	2	6	6	0	1	9	2	2	1	3*	27	1	68
Prelabour diagnosis of CPD	25	3	14	0	0	3	7	0	0	2	1*	2	0	57
History of subfertility/bad obstetric history	14	0	16	0	0	2	0	5	0	0	1*	9	0	47
Cardiac disease	7	0	9	2	0	7	10	1	1	1	0	7	0	45
Maternal request	8	0	10	1	0	3	21	0	0	0	0	0	0	43
Multiple pregnancies	0	0	1	0	0	0	1*	0	0	37	0	1*	0	40
Diabetes	5	0	2	2	1	1	7	0	1	0	0	6	0	25
Thick meconium	10	4	1	1	0	0	0	0	0	0	0	0	0	16
Pre-term	0	0	3*	0	0	1*	4*	0	0	1	0	1	0	10
Other	22	3	23	11	4	10	10	1	1	3	5	24	1	118
Missing	2	0	1	1	0	1	2	0	0	0	0	0	0	7
Total	314	300	158	105	81	49	666	114	90	63	47	258	6	2251

Note: * Possible groups misclassifications;

Abbreviation: APH= Antepartum haemorrhage; CPD= Cephalopelvic disproportion; CTG= Cardiotocography; IUGR= Intrauterine growth restriction.

Key findings and comments:

Indications for CS in Group 1:

• Abnormal CTG = 49.4%

• Potentially inappropriate indications (antepartum diagnosis of CPD, bad obstetric history, subfertility, maternal request) = 15%

• Dystocia = 12.7%

Indications for CS in Group 2a:

• Abnormal CTG = 58.3%

• Failed induction = 21%

• Dystocia = 14.3%

Indications for CS in Group 2b:

• Abnormal CTG = 30.4%

• Potentially inappropriate indications (antepartum diagnosis of CPD, bad obstetric history, subfertility, maternal request) = 25%

Indications for CS in Group 3:

• Abnormal CTG = 57.1%

• Dystocia = 8.5%

Indications for CS in Group 4a:

• Abnormal CTG = 60.5%

• Failed induction = 25.9%

• Dystocia = 7.4%

Indications for CS in Group 4b:

• Abnormal CTG = 18.4%

• Maternal/foetal issues = 32.6%

• Other = 20.4%

Indications for CS in Group 5:

- Previous CS = 70.1%
- Abnormal CTG = 7.4%
- Dystocia = 5.4%
- Maternal request = 3.2%

Indications for CS in Group 8:

- Multiple pregnancy = 58.7%
- Breech/abnormal lie = 11.1%

Indications for CS in Group 10:

- Maternal/fetal issues (preeclampsia/diabetes/maternal cardiac diseases/IUGR/APH) 48.1%
- Abnormal CTG 18.6%

Supplementary File. STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Item No		Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 4
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 5
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5
Methods			
Study design	4	Present key elements of study design early in the paper	Page 6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Page 6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 7
Bias	9	Describe any efforts to address potential sources of bias	Page 6
Study size	10	Explain how the study size was arrived at	Page 6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 6-7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 6
		(*b*) Describe any methods used to examine subgroups and interactions	Page 6
		(*c*) Explain how missing data were addressed	Page 6 Supplementary Table 1
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 9

		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Supplementary Table 6
		(b) Indicate number of participants with missing data for each variable of interest	Supplementary Table 1
Outcome data	15*	Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 9-19 Table 1-5
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 21
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 23-24
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 22-23
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 24
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 25

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.