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Complete List of Authors:	Lazzerini, Marzia; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Senanayake, H.; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Mohamed , Rishard ; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Kaluarachchi, Athula; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Fernando , Roshini; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Sakalasuriya , Anshumalie; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Ihsan , Fathima Reshma; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Saravanabhava , Namasivayam; District Hospital Thellippalai, Thellippalai, Sri Lanka Gamaathige , Nalin; De Soysa Hospital for Women, Colombo, Sri Lanka, Neonatology Unit Jayawardena , Madura ; Department of Obstetrics & Gynaecology, Faculty of Medical Sciences, University of Sri Jayawardenapura Gamage, Ruwan Vidana; Base Hospital, Balangoda Covi, Benedetta; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Wanzira, Humphey; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Businelli, Caterina; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Piccoli, Monica ; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo
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Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care

Short title: Individual patient maternal and newborn database to improve quality of care in Sri Lanka

Marzia Lazzerini,[1] Hematha Senanayake,[2,3] Rishard Mohamed,[2,3] Athula Kaluarachchi,[2,3,] Roshini Fernando,[3] Anshumalie Sakalasuriya,[3] Fathima Reshma Ihsan,[3] Namasivayam Saravanabhava,[4] Nalin Gamaathige,[5] Madura Jayawardena,[6] Ruwan Vidana Gamage,[7] Benedetta Covi,[1] Humphrey Wanzira,[1] Caterina Businelli,[1] Monica Piccoli.[1]

[1] WHO Collaborating Centre for Maternal and Child Health, Institute for Maternal and Child Health IRCCS Burlo Garofolo, Trieste, Italy.

[2] University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka

[3] Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo, Colombo, Sri Lanka.

[4] District Hospital Thellippalai, Thellippalai, Sri Lanka.

[5] Neonatology Unit, De Soysa Hospital for Women, Colombo, Sri Lanka

[6] Department of Obstetrics & Gynaecology, Faculty of Medical Sciences, University of Sri Jayawardenapura, Nugegoda 10250, Sri Lanka

[7] Base Hospital, Balangoda, Sri Lanka

Authors' e-mail contacts

ML: marzia.lazzerini@burlo.trieste.it

HS: senanayakeh@gmail.com

RM: mrishard@obg.cmb.ac.lk

AK: akaluarachchi@obg.cmb.ac.lk

RF: ragynobs2009@gmail.com

AS: sakalasuriyasaritha43@gmail.com

FRI: resh.ihsan798@gmail.com

NS: sarabhava@yahoo.com

NG: nalinnicu@gmail.com

MJ: madurammj@yahoo.com

RVG: ruwangamage21@yahoo.com

BC: benedetta.covi@burlo.trieste.it

HW: humphey.wanzira@burlo.trieste.it

CB: caterina.businelli@burlo.trieste.it

MP: monica.piccoli@burlo.trieste.it

Corresponding author
Marzia Lazzerini DTMH, MSc, PhD
WHO Collaborating Centre for Maternal and Child Health
Institute for Maternal and Child Health IRCCS Burlo Garofolo
Via dell'Istria 65/1, 34137, Trieste, ITALY

ABSTRACT

Objectives This study aimed at piloting a prospective individual patient database on hospital deliveries in Colombo, Sri Lanka, and at exploring feasibility, quality of data collected, and uses of data for improving quality of care (QoC).

Design Observational study

Setting De Soysa Teaching Hospital for Women, the largest referral hospital for maternity care in Sri Lanka.

Data collection and analysis From July 2015 to June 2017 for each delivery 150 variables were collected in a standardised form and entered in a database. Data were analysed every eight months and results were made available to local staff. Outcomes of the study included: technical problems; data completeness; data accuracy; key database findings; use of data .

Results 7504 deliveries were recorded. None technical problem was reported. Data completeness exceed that of other existing hospital recording systems. Missing data were less than 1% for maternal variables, and less than 3% for newborn variables. Mistakes in data collection and entry occurred in 0.01% and 0.09% of cases respectively. Key QoC indicators identified in comparison to international standards were: relatively low maternal mortality (0.053%); relatively high maternal near-miss cases (3.4%); high rate of induction of labour (24.6%), caesarean section (30.0%) and episiotomy (56.1%); relatively high rate of preterm babies (9.4%), low-birth-weight babies (16.5%), stillbirth (0.97%), and of total deaths in newborn (1.98%). Recommendations developed focused on the key indicators identified and included the use of checklist to standardise case management, training, clinical audits, and more information for patients. Based on this pilot experience, a list of lessons learned was drawn.

Conclusions The study shows that the implemented system of data collection is feasible and can accumulate reliable data. Most importantly, this experience provides an example on how database findings can be used for discussing hospital practices, identifying gaps, and agree recommendations for improving the QoC.

Article summary: strengths and limitations of this study

- The study reports on the first individual patient database for comprehensive prospective data collection on births in Sri Lanka. Very few individual patient databases exist in general in low and middle-income countries (LMIC).
- The study showed that implementing the database is feasible and can produce a large number of reliable information that can be used for quality improvement purposes, thus providing a model that can be adopted by policy makers in other similar settings.
- Although the study was single-centre, it has the merit of reporting both technical feasibility related to the database implementation, quality of data (ie, data completeness and accuracy), lessons learned, and, actual use of data – the latter three being often neglected issues -.

Keywords

Quality of care; Health Information system; mothers and newborns.

Disclosure of interests

None competing interest

List of abbreviations

LMIC = low and middle-income countries

MM= maternal mortality ratio

QoC= Quality of Care

WHO = World Health Organization

BACKGROUND

The availability of an actionable health information system is one of the key components of the World Health Organisation (WHO) framework for improving the quality of maternal and newborn health care (1,2) and one the recommended cross-cutting actions in the WHO Strategy for Ending Preventable Maternal Mortality (EPMM) (3). According to WHO standards (2), "the health information systems should enable using data to ensure timely actions to improve the care of every woman and newborn". More specifically, a health facility should have mechanisms for data collection, analysis and feedback as part of the activities for monitoring and improving performance around the time of childbirth (2).

However, estimates have highlighted major gaps in data collection even on key indicators: only one third of countries have the capacity to count or register maternal deaths (3,4) and less than two fifths of all countries have a complete civil registration system with accurate attribution of the cause of death (3,5). Quality of data is also a reason of significant concern: according to a WHO review, although most countries are using some core indicators to monitor performance in maternal and newborn care, virtually no low- or lower-middle-income country has a full system of data sharing and transparent quality control in place (6). The availability of accurate data is relatively limited even in high-income countries, were most often hospital administrative datasets lack key information - such as maternal risk factors- needed for evaluating the case mix and for interpreting the observed outcomes (7).

Sri Lanka is a lower middle-income country (8). Since the civil war ended in 2009, the economy has grown on average at 6.2% per year (8), in transition from being predominantly rural-based to one that is urban-oriented around manufacturing and services. Major progresses have been made in maternal healthcare in past decades: according to the last estimates the reported maternal mortality ratio (MMR) is relatively low (33.7/100.000) (9). However, no significant improvement in the MMR have been observed in the last 10 years (8-11). The latest national Maternal Mortality Review have shown that 50% of maternal deaths are from direct causes, with preventable causes, such as post-partum haemorrhage and sepsis, being among the top five causes of death (9). Almost 80% all women died in hospitals (9), where specialized facilities are available, thus suggesting possible gaps in quality of the care provided (9). Inappropriate practices are suggested also by other indicators, such as the rising rate of caesarean section (CS) (12), peaking above 50% in selected facilities (12). The estimated rate of induction of labour in Sri Lanka is currently among the highest in Asia (35.5%) and the rate of inductions without medical indication is reported to be 27.8% (13).

Presently in Sri Lanka the health information system collects data only on selected maternal and newborn indicators, in an aggregate form. The objective of this study was to pilot, in the largest maternity unit in Sri Lanka, a system for collecting prospectively, for each case of delivery, a wide number of variables reflecting maternal and newborn characteristics, hospital practices and outcomes. The study aimed at exploring the feasibility of such system, the quality of data collected, and the concrete uses of data to improve quality of health care.

METHODS

Population and setting

The study was conducted at De Soysa Teaching Hospital for Women in Colombo, the largest referral hospital for maternity care in Sri Lanka. In June 2015, a database for routinely collecting individual patient data was implemented in wards 3 and 15, the two wards of the University Obstetrics Unit in the hospital, where about half of the total deliveries of the hospital take place.
All deliveries occurring in these two wards, with no exclusions, were to be entered in the database. This paper reports finding of the first 24 months of data collection, from July 2015 to June 2017.

Data collection tools

For each case of delivery, data were collected in a standardised form ("Yellow Form") and entered in a database. The "Yellow Form" was two pages long (**Appendix 1**), and recorded 150 variables for each case of delivery: demographic and socio-economic data of the woman (8 variables); characteristics of pregnancy and risk factors (28 variables); process of care during birth (60 variables); maternal health outcomes (31 variables); newborn health at birth and during hospitalisation, process of care and health outcomes (23 variables). The database was developed using Epidata (14), a free software that allows for inclusion of internal checks. Data were collected and entered in the database by dedicated trained data collectors.

Data quality assurance procedures

The Yellow Form was developed through a participatory approach with local staff. The team involved included: six senior obstetricians from De Soysa Hospital and other hospitals in Sri Lanka, eight midwifery-qualified nurses, two registrars in obstetrics and gynaecology, one neonatologist, one registrar in neonatology, two data collectors. Two external researchers (one obstetrician and one epidemiologist) participated as facilitators. Instructions on how to fill the form, and specific case definitions were developed in parallel with the development of form and embedded in it (**Appendix 1**).

Both the form of data collection and the instructions on how to fill it and how to transfer information in the database were field tested. Procedures of data collection were field tested to evaluate the following domains: if the sequence of data in the form was appropriate; if case definitions were clear; if data collectors were able to fill the form and enter data in the database; if time needed to fill the form and enter data in the database was acceptable to allow routine data collection; if there were sources of systematic error or bias; if there was any technical problem. Data collectors were young medical doctors who were trained on the standard operating procedures (SOP) of data collection and data entry and supervised over time.

The database was designed in a way that the interface for data entry was almost identical to the "Yellow Form". To further minimise data-entry errors, the database contained 137 internal automatic validation rules, aiming at minimising errors in biological plausibility of data (i.e. normal ranges), data completeness and internal consistency.

For the initial period of data collection for each case of delivery two data collectors independently filled a Yellow Form and data were cross-checked to evaluate consistency. This procedure was kept until when errors in data collection were consistently low (ie. below 0.02%; this was achieved in the time period of about 1 month). Subsequently, data completeness and accuracy in data collection and data entry was monitored by an external independent data monitor who randomly reviewed 5% of forms and 5% entered cases. Missing cases or errors in data collection/entry were to be corrected in real time. Data were also externally monitored for completeness and internal consistency at about four months intervals.

Data analysis and use

Data were analysed at intervals of eight months by a standardized plan for analysis, agree among partners. This included: a descriptive analysis of all the key variables in the database; an analysis of CS appropriateness according to Robson Classification (15,16) and other minor secondary analyses as suggested by the finding of the primary analysis and as requested by partners. Data were analysed by the external team (WHO Collaborating Centre) and made available as tables and graphs to the local staff (De Soysa hospital) in the format of a power point presentation.

Outcomes

This study aimed at evaluating feasibility of implementing the database, the quality of data collected, and the use of data. Outcomes of the study are reported in Box 1 and further described below.

Technical problems in data collection were defined as any technical problem occurring with the use of the database (either with the software or with the computer). These had to be notified by data collectors in real time to the local coordinator and to the external team.

Database completeness was checked by an independent assessor by comparing the number of cases entered in the database with data in the official hospital registers, and specifically with the following eight data sources: i) birth register; ii) intensive care unit (ICU) admissions register; iii) operating theatre (OT) register; iv) neonatal intensive care unit (NICU) admissions register; v) Special Care Baby Unit (SCBU) admissions register; vi) maternal deaths reviews; vii) perinatal mortality and morbidity statistics; viii)) monthly reports.

The number of missing cases for each variable was calculated as the number of missing cases in the database out of the total expected entries for that variable.

Accuracy in data collection was measured by the number of variables correctly recorded in the yellow form when compared to the original medical files. Accuracy in data enter was measured by the number of variables correctly recorded in the database compared to the yellow forms. Both accuracy in data collection and data entry were assessed by an external independent data collector who randomly checked 5% of forms and 5% of entered cases, respectively.

Database findings included a descriptive analysis of the key variables as agreed among partners. Data on multiple pregnancies where not included in this primary descriptive analysis of newborn outcomes.

Use of data for quality improvement purposes included any action-oriented type of use, such as use for internal discussion.

Box 1. Outcomes of the study

i) Technical problems:

- any type of technical problem in implementing and using the database.

ii) Data completeness:

- number of cases entered in the database versus data in the official registers;
- number of missing cases for each variable in the database.

iii) Data accuracy:

- number of correct variables in the yellow form versus the original medical files;
- number of correct variables in the database compared to the yellow forms.

iv) Database findings:

- descriptive analysis of the key variables as agreed among partners.

v) **Use of data for quality improvement purposes:**

- any action-oriented type of use.

Ethical considerations

The study 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. Informed consent was not requested by the Ethics Review Committee.

RESULTS

Technical problems

No technical problems occurred. The data collectors reported that there were no technical difficulties in managing the database.

Data completeness

Table 1 reports the number of total cases in the database when compared to other official hospital data sources. Numbers were matching, except for the cases of hysterectomies, for which the database appear to contain one additional case (verified as actually being a real case).

Table 1. Number of cases in the database compared to hospital registers and other official sources of data

	Database	Hospital registers	Source of data for comparison
Maternal indicators			
Total deliveries	7504	7504	Birth register
Maternal deaths	4	4	maternal deaths reviews
Admission to ICU	239	239	ICU register
PPH	147	147	Birth register
OT after delivery	11	11	OT register
Hysterectomy	22	21	OT register
Newborn indicators [1]			
Stillbirth	82	82	Birth register, monthly reports
Admission to NICU	105	105	NICU register
Admission to SCBU	1121	1121	SCBU register
Neonatal deaths after birth	81	81	Birth register + NICU and SCBU registers + perinatal mortality and

			morbidity statistics

Notes: [1] Including also the second twin in multiple pregnancies.

Abbreviation: ICU= Intensive care unit; NICU= Neonatal intensive care unit; OT= operating theatre; PPH= post-partum haemorrhage; SCBU= semi-intensive baby unit

Number of missing variables is reported in **Appendix 2**. Missing data were less than 1% for all maternal variables, and less than 2% in all but two newborn variables.

Data accuracy

Random checks by an independent data monitor on 5% of Yellow Forms and 5% of entered cases revealed that mistakes in data collection in the forms occurred in 0.01% of cases, while mistakes in data entry in the database occurred in 0.09% of cases.

Database findings

Tables 2,3 and 4 report the descriptive analysis of key indicators in the database. Overall, during the two years of the study period, 7504 deliveries were entered (Table 2). In terms of socio-demographic characteristics, most of women belonged to the following categories: 4253 (56.7%) were 25 to 34 years old; 6028 (80.3%) had secondary education; 6253 (83.3%) were housewives; 5231 (69.7%) had a normal nutritional status. Overall, in 4182 (55.7%) of deliveries there was at least one risk factor, the most prevalent being gestational diabetes (13.4%), pre-term or post-term delivery (12.9%), and previous CS (12.7%). Overall 2870 (38.2%) were primigravidae.

Table 2. Maternal characteristics

	n (N=7504)	%
Age categories		
< 18 years	236	3.14
19-24 ears	1721	22.93
25-34 years	4253	56.68
35-39 years	1036	13.81
>40 years	224	2.99
Missing	34	0.44
Number of pregnancies		
1	2870	38.24
2	2313	30.82
≥3	2285	30.47
Missing	34	0.45
Education		

None	23	0.31
Primary	235	3.13
Secondary	6028	80.33
Higher	1181	15.74
Missing	37	0.49
Work		
Not reported by the mother	77	1.03
Working	1136	15.14
Housewife	6253	83.33
Missing	38	0.51
Marital status		
Married	7350	97.95
Unmarried	96	1.28
Living together	20	0.27
Missing	38	0.51
Nutritional status [1]		
Underweight	670	8.93
Normal	5231	69.71
Overweight	1110	14.79
Obese	440	5.86
Missing	53	0.71
Women with risk factors (any) [2]	4182	55.73
Risk factors		
Gestational diabetes, total	1002	13.36
On diet	417	5.56
On drug therapy	585	7.80
Gestational age <37 >= 41	966	12.87
Previous CS	956	12.74
Hypertensive disorders of pregnancy, any	506	6.74
Pre-gestational hypertension	168	2.24
Gestational hypertension	179	2.39
Pre-eclampsia not severe	78	1.04
Pre-eclampsia severe	69	0.92
Eclampsia	12	0.16
IUGR at ultrasound	504	6.72
Obesity	440	5.86
Breech/transverse lie	339	4.52
Pre-gestational diabetes	266	3.54
Maternal cardiac disease	234	3.12
Fetal conditions, other	223	3.10

Maternal hypothyroidism	219	2.92
Maternal age >40	224	2.9
Oligohydramnios	131	1.75
APH	112	1.49
Polyhydramnios	96	1.28
Multiple pregnancies	84	1.12
Severe anaemia	40	0.53
Chorioamnionitis	11	0.15

Notes: [1] As defined by National Guidelines in Sri Lanka. [2] Any of the risk factor.

Abbreviations: APH= ante-partum haemorrhage; CS= caesarian section; IUGR= intra-uterine growth retardation.

In terms of process indicators and maternal outcomes (**Table 3**), 1849 (24.6%) of women had their labour induced, and 2251 (30.0%) had a CS. When analysed according to the Robson recommendations (15), the CS rate by Robson group appeared to be particularly high in group 1 (nulliparous, single cephalic, at term, in spontaneous labour), 3 (multiparous, single cephalic, at term in spontaneous labour), and 5 (previous CS, single cephalic at term), being respectively 16.4%, 5.2% and 81.1% compared to recommended rates (15) of 10%, less than 3% and less than 60%. Rate of vaginal birth after CS (VBAC) was 17.1%. Episiotomy was performed in 4213 (56.1%) of women. In terms of health outcomes, there were four cases of maternal death (0.053%). Overall 254 (3.38%) of cases were identified as maternal near-miss. Post-partum haemorrhage (any severity) occurred in 147 (1.9%) women, with 39 (0.52%) women having a severe or massive haemorrhage. Overall there were 22 (0.29%) cases of hysterectomy. During the whole study period there were no cases of uterine rupture.

Table 3. Birth process indicators and maternal outcomes

	n (N=7504)	%
Labour onset		
Spontaneous	4726	62.98
Induction	1849	24.64
Pre-labour CS	893	11.90
Missing	36	0.48
Mode of delivery		
Vaginal spontaneous	4906	65.38
Vaginal operative	310	4.13
Caesarean section	2251	30.00
Missing	37	0.49
Caesarean section		
In spontaneous labour onset	927	19.61

In induction of labour	441	28.85
Caesarean section rate by Robson groups [1]		
Group 1	246	16.42
Group 2a	257	31.18
Group 2b	120	100
Group 3	105	5.17
Group 4 a	81	11.21
Group 4b	49	100
Group 5	666	81.11
Group 6	96	81.35
Group 7	90	78.26
Group 8	63	75.0
Group 9	42	100
Group 10	258	43.87
Episiotomy	4213	56.14
Key maternal outcomes		
Maternal deaths	4	0.05
Admission to ICU	239	3.18
Near-miss cases [2]	254	3.38
PPH	147	1.96
OT after delivery	11	0.15
Hysterectomy	22	0.29
Uterine Rupture	0	0
Sepsis	29	0.39
DVT/PE	2	0.03
Abruptio placentae	21	0.38
Amniotic fluid embolisms	0	0
Perineal tears III-IV degree	17	0.23

Notes: [1] As for Robson's classification (15); [2] As for WHO classification (37)

Abbreviations: CS= caesarian section; DVT= Deep vein thrombosis; ICU= Intensive care unit; NICU= Neonatal intensive care unit; OT= operating theatre; PE= pulmonary embolism; PPH= post-partum haemorrhage.

The analysis of the newborns' characteristics and outcomes (**Table 4**) pointed out the following key indicators: 708 (9.4%) of infants were born before the 37 week of gestational age; 1243 (16.6%) had a birth weight below 2500 grams, and of these 748 (60.2%) were babies born at term; 73 (0.97%) were stillborn; 173 (2.3%) were ventilated for more than 10 seconds in the delivery room. Overall 917 (12.2%) newborns had at least one complication, of which the most frequent was the respiratory distress syndrome (3.7%).Overall, 101 (1.62) newborns had major malformations.

Overall 148 (1.98%) infants were either born dead or died during the hospitalisation; among the cases of deaths (either stillbirths or after birth), 55.1% had major malformations.

Table 4. Newborns' characteristics and outcomes

NEWBORN	n (N=7504) [1]	%
Sex		
Female	3644	48.56
Male	3792	50.83
Missing	68	0.91
Gestational age (weeks + days)		
< 33 + 6	223	2.96
34 to 36+ 6	485	6.19
37 to 40+ 6	6491	86.50
> 41	258	3.43
Missing	47	0.62
Weight at birth		
<1499	149	1.99
1500 to 1999	183	2.44
2000 to 2499	911	12.14
2500 to 3499	5365	71.50
3500 to 4000	724	9.65
>4000	104	1.39
Missing	68	0.91
Stillbirth, total	73	0.97
Macerated	42	0.56
Fresh	27	0.36
Missing	4	
Ventilated in delivery room for more than 10 seconds	173	2.34
Asphyxia	62	0.84
Post-delivery		
With mother	6164	82.14
SCBU	1105	14.73
NICU	96	1.28
Referred	9	0.12
Death	75	1
Missing	11	0.07
Neonates with any complication	917	12.22
Complications		
RDS	276	3.73

Infection, other than sepsis	121	1.35
Major malformation	101	1.62
Neurological [2]	38	0.50
Sepsis	28	0.38
Major Birth Trauma	16	0.21
Severe jaundice with ET	15	0.20
Others [3]	232	3.09
Final outcome		
Discharged	7204	96.00
Discharged with disabilities	4	0.05
Death (including stillbirths)	148	1.98
Referred	54	0.72
LAMA	15	0.20

Notes: [1] Data on multiple pregnancies were not included in this primary analysis. [2] Seizures, ventricular haemorrhage and other neurological complications. [3] Most frequent reported conditions in this class were other respiratory problems (eg, apnoea, meconium aspiration syndrome, pulmonary hypertension), gastrointestinal problems (eg, bleeding), minor jaundice.

Abbreviations: ET= exchange transfusion; LAMA= Left against medical advice; NICU=neonatal intensive care unit; RDS= respiratory distress syndrome; SCBU=semi-intensive care baby unit.

Use of data

Data entered in the database were analysed at intervals of eight months and made available to the local coordinator. Findings of the database were presented and discussed in two large workshops with staff from De Soysa Hospital and from other large maternity units in Sri Lanka. Participants to these meetings included: senior obstetricians, neonatologists, postgraduate trainees and other middle level medical personnel, nurses, midwifes and other staff).

During these meetings, key indicators suggesting possible gaps in quality of care were identified, and recommendations for improvement were discussed and agreed upon (**Table 5**). Indicators identified as requiring actions to improve quality of care were: high rate of induction of labour (24.6%), of CS (30.0%) and episiotomy (56.1%); relatively high maternal near-miss cases (3.4%); relatively high rate of preterm babies (9.4%), low-birth-weight babies (16.5%), stillbirth (0.97%), and of total deaths in newborns (1.98%). Recommendations developed focused on the key indicators identified and included the use of checklists to standardise case management, training, clinical audits, and more information for patients. Smaller meetings were also organised, in order to develop and agree specific tools and procedures to put in practices the recommendations agreed (such as for developing the information pamphlet on VBAC, and the checklists to review obstetric emergencies).

Table 5. Use of data for improving quality of care

Key Indicators identified	Agreed recommendations for quality improvement
Maternal - High rate of induction of labour (24.6%) - High rate of CS (30.0%), with high rates in Robson's group 1, 3, 5 - Low rate of VBAC (17.1%) - High rate of episiotomy (56.1%) - Relatively high rate of near-miss cases - Low reported rate 3rd-4th degree perineal tears	• Checklist to be filled by the doctor in charge for each individual case of induction of labour, specifying indications, methods, timing. Data to be reviewed regularly. Consultant to make decision on IOL • Dedicated workshops on CS, discussing local data and international recommendations (15,16,24). • Training workshops to help improve the CTG interpretation skills. Stickers to help CTG interpretation. Improved communication regarding CTG interpretation from midwifes to medical officers using "WhatsApp/Viber". • Training workshop to develop a consensus on how to manage foetal distress and poor progress of labour. • Establishment of a nurse-lead VBAC counselling clinic and development of a VBAC leaflet for patients. Education for staff, including community midwives, on methods of counselling. • Implementation of a selective episiotomy policy; training of midwives and medical staff on appropriate indication for episiotomy. • Doctors to identify clearly near-miss cases. Establishment of a system for regular internal review of near-miss cases. • Development of checklists for systematic analysis of obstetric emergencies against international standards of care. • Training of midwifes on review and reporting the perineum status after delivery.
Newborn - High rate of preterm (9.4%) - High rate of low birth weight (16.5%) - High rate of stillbirth (0.97%) - High rate of newborns with complications (12.2%) - High rate of total deaths in newborns (1.98%)	• Improve diffusion of national and international guidelines of antenatal care (38). • Improve prenatal ultrasound diagnosis of SGA and of malformation. • Development of checklist for systematic analysis of newborn care against international standards of care. • Training on newborn resuscitation.

Abbreviations: CTG: cardiotocography; SGA: small for gestational age; VBAC: vaginal birth after cesarean section.

Lessons learned

Results of this study were discussed among partners, and a series of lessons learned, and way forward were drawn (**Box 2**). Overall the key lesson was that data collection was feasible, it resulted in a large amount of data with an acceptable quality, and in the development of some recommendations for quality improvement; however, use of data could be further improved. Drawing on this experience, and on other experiences reported in literature (7,17-22), some concrete actions that may further help improving use of data in the future were discussed (**Box 2**). Although a simplified version of the Yellow Form was discussed, it was difficult to identify what variables to drop: despite the data collection form including 150 variables, when findings were discussed clinicians tended to request even more additional information.

Box 2. Lessons learned and way forward

Key lessons

1. Data collection was feasible and resulted in a large amount of data with an acceptable quality, and in the development of some recommendations for QI; however, use of data could be further improved.
2. Standard Operating procedures (SOP) and regular data monitoring and evaluation (M&E) was crucial.
3. One data collector was sufficient to collect data in the study setting, but one additional person was needed to ensure regular M&E.
4. Ensuring concrete use of data for QI is not to be taken for granted and it requires building a system of coordination to facilitate data diffusion and discussion.
5. In general, clinicians showed low interest in statistical data compared to clinical subjects. Clinicians without training or without a particular interest in QI methods, were poorly interested in using statistical data for QI purposes, and were more attracted by new technologies. Appropriate involvement of staff (eg training, participation to projects, assignment of specific responsibilities), is needed to develop a local team who will act as drivers in QI.
6. It is difficult to find the optimal golden balance between a “simple” data collection form (ie collecting few variables) and an “informative” data collection form that satisfies clinicians (ie collecting a large number of variables).

Way forward

1. The “Yellow Form” could be incorporated into the patient file; data collection could be made part of the duties of the hospital staff in charge of each single case. This should facilitate sustainability and may further improve quality of data.
2. All staff involved in data collections should be made aware of the standard case definitions.
3. Regular local M&E should be ensured to avoid drops in data quality.
4. Adding in the database functions of automatic reporting may probably increase local ownership and facilitate use of data.
5. Other forms of diffusing data, rather than workshops, may be explored, such as use of posters or newsletters.

6. With the number of recommendations increasing, the establishment of a technical group for QI within the hospital, with clear roles and responsibilities becomes mandatory to ensure their implementation.
7. To ensure translation into actions of recommendations arising from data discussion, a system for regular follow up should to be put in place. This will probably be more effective if embedded in a national system for quality assurance in maternal and child health.

Abbreviations: M&E= monitoring and evaluation; QI= quality improvement; SOP= standard operating procedures.

DISCUSSION

This is the first individual patient database established for comprehensive prospective data collection on births in Sri Lanka. From a review of existing literature, we could identify very few databases prospectively collecting a large number of individual patient variables on hospital births. Of these, most data collection systems were established in high income countries, or in upper middle-income countries such as Brazil, Peru and South Africa (17-19), while we were able to identify only two systems for prospective collection of individual maternal and newborn variables across the time of birth in low or lower middle-income countries (20,21), and both collected data from a single facility (20-22). In respect of the average hospital administrative data, even in high income countries, the dataset implemented in this pilot study contains a large number of variables, such as maternal risk factors, that can be used for evaluating the case mix and for adjusting for confounders (7,19).

Most importantly, routine use of data to improve case management and organization of care is still not a common practice, even in countries with well-established data collection systems (7). Despite there being some good examples of how routine data collection systems are used to shape policies in low and middle-income countries (LMIC), for example in the paediatric field (23), these are very limited in number. As such, the main value of this study is that it provides an example of how data can be used for discussing and agreeing on recommendations for improving the quality of care.

This study aimed at reporting the feasibility of implementing an accurate system of data collection and not at presenting extensively the database findings. Additional analyses (such as a detailed analysis of practices and outcomes related to CS according to the Robson Groups (24), and other multivariate and sub-group analyses) will be the object of future publications. Many of the findings of the descriptive analysis reported in this paper - such as the rate of maternal deaths, induction of

labour and low birth weight babies - are not overall surprising and rather in line with other country reports (5,8-13,22,25-29). Results reflect the specificity of the setting: De Soysa Hospital is the largest referral maternity hospital in Sri Lanka, and case mix, as well as local practices, do not necessarily represent the average in the country. For example, the rate of induction of labour, CS and near-miss cases, although being relatively high compared to international standards, actually are below the national reported average (12,13,25,28). Rate of stillbirth and newborn deaths after birth may appear high when compared to national statistics (the most recent national report provides a figure of stillbirth rate of 5.9/1000 (30)), and this may due both to the case mix (55.7% of pregnancies at the De Soysa Hospital had at least one risk factor, and about half of cases of stillbirth had a major malformation), and to the fact that medical termination of pregnancy Sri Lanka is allowed only to save the life of the mother, but not for any condition of foetal impairment, not even major malformations (31). The rate of post-partum haemorrhage, appeared to be lower than what expected for LMIC according to international literature (32), but it was double checked in the hospital registers and found to be correct (Table 1). The low prevalence of DVT and PE may be due to the fact that these events are less frequent in the Asian population compared to others, or to under-reporting (33,34). It must be acknowledged that for most of the variables collected - such as risk factors, episiotomy, reasons for induction of labour/operative deliveries, newborn complications, etc, there is no other system of official data in the whole country. The main merit of the database was that it provided to hospital staff, for the first time in Sri Lanka, a large number of objective indicators on local practices and outcomes, thus providing the evidence base for discussing the appropriateness of the care delivered at the facility level. Although recommendations developed may not cover all actions needed to improve quality of care, they were agreed locally, and as such they represent an important step forward in the local culture of quality improvement and in the local ownership of the whole quality improvement process.

In the future, the database may help answering more questions (such as appropriateness of hospital practises related to CS or to induction of labour); it may inform the development of additional recommendations to improve quality of care, and it may provide a way of monitoring trends over time of patient characteristics, hospital practices and health outcomes.

Given the paucity of efficient data collection systems in LMIC (6,7), lessons from this study may be of interest to other researchers and policy makers. However, in generalising the finding of this study to other settings, key characteristics of this project must be acknowledged. First, in this study dedicated staff was appointed for data collection and entry. Second, supervision was provided, and data collection was monitored regularly. Data collection that proved accurate under these conditions may fail to have good results if these minimum conditions are not guaranteed, especially if monitoring is not ensured.

The experience accumulated so far in this pilot experience at De Soysa Hospital may help scaling up the data collection system in other maternity units in the country. The Sustainable Development Goals (SDG) in countries with low baseline maternal mortality, such as Sri Lanka, include "achieving access to quality essential health-care services" (35). Target-setting is accompanied by the need for improving measurement approaches and data quality to allow more accurate tracking of country progress as well as causes of death (36). The implementation of a system for individual patient data collection on hospital deliveries in other maternities in Sri Lanka will allow comparing several variables (patient characteristics, process outcomes and health outcomes) among different geographical regions, settings, and over time, and data generated could be used to improve overall national practices. The data collection form utilised in this project was designed together with professionals from different maternity unit in Sri Lanka, therefore, when adapting it to other facilities, only minor adaptations may be required. However, scaling up will require a good mechanism for coordination, beside further testing to identify the optimal methods for data collection in other settings (such as smaller maternity units). Furthermore, it will be crucial to establish functional mechanisms (such as regular data audits) to ensure that information generated from the database are actually used in practice to improve quality of health care. As for many other types of data collection, the main problem may be that data are not actually utilised (7).

Limitations of this study include that, within the project timelines, it did not aim at following up the impact of the recommendations developed. Future longer-term studies will be needed to assess changes in key indicators over time. Although the study was single-centre, it has the merit of reporting both technical feasibility related to the database implementation, quality of data (completeness and accuracy), lessons learned, and, actual use of data – the latter three being often neglected issues-.

CONCLUSIONS

This pilot study on the implementation of an individual patient database on hospital deliveries in Sri Lanka proved that in this setting a large quantity of data could be collected in an accurate way. The study is an example on how data can be used to discuss hospital practices, identify gaps in quality of care, and agree recommendations for improving the quality of hospital case management. More implementation research is needed to identify the best model for scaling up data collection to other maternities in Sri Lanka and in other low-middle income countries. More research in general should report on the actual use of data.

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Author contributions

ML, HS and MP conceived the study and procured funds

ML, HS, NG, RVG, MJ, NS, and MP developed the data collections tools

RF, AS and FRI collected data

BC, HW 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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Supplementary files

Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care

List of files

Appendix 1. YELLOW FORM

Complete this chart AT DELIVERY (white part) and AT DISCHARGE (dotted part) □**Soysa** □**Other**
If other hosp, add name:_____

Adm (dd/mm/yy) ☐☐☐☐☐☐ **Deliv** ☐☐☐☐☐☐ **Disch** ☐☐☐☐☐☐ **BHT 15-** ☐☐☐☐☐

Age (years) ☐☐ **Education** ☐No schooling ☐Primary (Grades 1-6) ☐Secondary (Grades 6-10) ☐Higher
Working status □ No data □ Working □ Housewife **Marital status** □ Married □ Unmarried □ Unmarried living together

GA at delivery (wks/days) ☐☐/☐ **GA estimated with US** ☐N ☐Y ☐Missing

Gravida (pregnancies)[1] ☐☐ **Para**[1] ☐☐ **Born alive**[1] ☐☐ ([1] For para / born alive – exclude current pregnancy)

BMI at booking □ Underweight (< 18.4) □ Normal (18.5 - 22.9) □ Overweight (23 - 27.4) □ Obese (> 27.5)

(Risk factors at time of delivery-check all) [2]

Multiple pregn	□N □Y	**PreGes Hyperten**[3]	□N □Y	**Ges Hyperten**[3] **no proteinur**	□N □Y
Pre-ecl NOT SEV	□N □Y	**Pre-ecl SEV**	□N □Y	**Eclampsia**	□N □Y
Chorioamnionitis	□N □Y	**Major fetal malformation/s**	□N □Y	**IUGR/SGA**[4]	□N □Y
Pregeste Diab	□N □Y	**GDM in diet**	□N □Y	**GDM, in drug therapy**	□N □Y
Maternal-cardiac disease[2]	□N □Y	**Maternal hypothiroidism**	□N □Y	**Polihydramnios**	□N □Y
Olidramnion	□N □Y	**APH/major plac previa/accret**	□N □Y	**Severe Anaemia (Hb<7)**	□N □Y
Other	□N □Y				

If Other maternal conditions, specify_____
If Other fetal conditions, specify_____
If Other, specify_____

One tick only

Steroids[5]	□ N	□ complete	□ incomplete	□ dose unclear
Previous CS	□ N	□ Y	□ Missing	Number_____
If prev CS, trial of labour	□ No previous CS	□ N	□ Y	
Presentation	□ Cephalic	□ Breech	□ Other	□ Missing
Labour onset	□ Spont	□ Induc (even if failed)[6]	□ PreLabCS[6]	□ Missing
Delivery mode	□ Vag spont	□ Vag forcep/ventuse	□ CS	□ Missing
If CS, type	□ No CS	□ Emerg	□ Elect	□ Missing

If IOL, main indication given (one tick only)

□ 1 No IOL	□ 2 Post-term	□ 3 Prelab rupture membs	□ 4 Diabetes on diet
□ 5 Diabet on insulin/metform	□ 6 Macrosomy at US[7]	□ 7 IUGR/SGA [4]	□ 8 Multiple pregnancies
□ 9 Maternal Age > 40 y	□ 10 Hypert/Preecl/Eclam	□ 11 Cardiac disease	□ 12 Oligoidramn
□ 13 Other add_____	□ 14 Prolonged latent phase/ painful contractions not in labour		□ 0 Missing

If IOL, mode of induction (one tick only) [8]

□ 1 No IOL	□ 2 PGE	□ 3 Oxytocin	□ 4 Foley
□ 5 ARM	□ 6 PGE+ oxytocin ± ARM	□ 7 Foley+ARM/oxytocin	□ 8 Foley + PGE
□ 9 ARM + oxytocin	□ 10 Other add: _____		□ 0 Missing

If operative delivery, main indication (one tick only)

□ 1 No operative del	□ 2 CTG anom/suspected fetal distress	□ 3 Failed induction
□ 4 Distocya 1st	□ 5 Distocya 2nd stage[10]	□ 6 Past CS
□ 7 Breech/abnormal lie	□ 8 History of subfertility	□ 9 APH/major placenta previa
□ 10 Cardiac disease	□ 11 Prelab diagn CPD/short mother	□ 12 Multiple pregnancies
□ 13 IUGR	□ 14 Pre term	□ 15 Diab
□ 16 Hypert/Precl/Eclam	□ 17 Maternal request	□ 18 Other
□ 0 Missing		

If other fetal cause specify _____
If other maternal specify_____
If other cause_____

Episiotomy	□ N	□ Y	□ Missing			
Analges in labour[9]	□ N	□ Petidine	□ Epid	□ Spin	□ Mix	□ Other
If CS, anaestesia	□ No CS	□ Spinal/epid	□ General			
3rd Stage manag	□ Active	□ No active	□ Missing			
Removal placenta	□ Spont	□ Manual	□ ERPC	□ Missing		
Operator del	□ Nurse	□ MW	□ HO	□ SHO	□ Reg	□ Con □ Missing

PTO

Complications (one tick)

Perineal tears	□ N/I-II d	□ III d	□ IV d	□ Missing	
PPH [11]	□ N	□ Minor	□ Severe	□ Massive	
Blood transfusion	□ N	□ Y	**Units (#)**	_____	
Cord prolapse	□ N	□ Y	**Abruptio placentae**	□ N	□ Y
Uterine rupture	□ N	□ Y	**Amn fluid embol**	□ N	□ Y
Admission to ICU/HDO	□ N	□ Y	**Major organ dys** [12]	□ N	□ Y
OT after deliv	□ N	□ Y	**Hysterectomy**	□ N	□ Y
Sepsis/sev infect	□ N	□ Y	**DVT/PE**	□ N	□ Y
Other Complications	□ N	□ Y	**Other infections**	□ N	□ Y

Final outcome (one tick)

□ Discharged □ Disc with disab due to preg complic [13] □ Death □ Referred □ LAMA

Near Miss [14] □ N □ Y

If NM or death, cause (select main; if more than one, write in Notes)

□ 1 Pre-exist cardiac dis	□ 2 Other pre-existing medic con	□ 3 Suicide
□ 4 Hypertension	□ 5 Preeclampsia/Eclampsia	□ 6 PPH
□ 7 Amniotic fluid embolism	□ 8 Sepsis/infection	□ 9 DVT/PE
□ 10 Complic anaesthesia	□ 11 Other	□ 0 Missing

If Others specify_____

Notes_____

Post delivery duration stay (days) [15] ☐☐

If stay >24 h, reason ☐ maternal ☐ newborn ☐ both ☐ hospital regulations ☐ Missing

----------**NEWBORN (N1)**----------

Born □ Alive [1] □ Dead [2] **If stillbirth**[3] □ noSB □ Macerated □ Fresh □ Intrapartum □ Missing

Sex □ Female □ Male □ Missing **BW** (gr) [4] ☐☐☐☐ **Apgar1/5 /10** ☐☐/☐☐/☐☐

Ventilated in delivery room [5] □ N □ Y □ Missing **Asphyxia** [6] □ N □ Y □ Missing

Postdelivery □With mother □ SCBU □ NICU □ Referred □ Obitorio □ Missing

Reason for referral □ medical complication □ surgical complication □No beds □ Other □ Missing

If baby in NICU /SCBU, add here BHT code ☐☐☐☐☐

COMPLICATIONS

RDS [7] □N □Y **Jaundice with ET** □N □Y **Sepsis** □N □Y

Other Infect(incl NEC) □N □Y **Major birth trauma** [8] □N □Y **Major malformation**[9] □N □Y

Neurol (seizure,IVH,HIE) □N □Y **Phototherapy > 24 h** □N □Y **Other** □N □Y

If other, add_____

Final □ Discharged □Disc with disabilities □ Death □ Referred □ LAMA

----------**NEWBORN (N2 if twins)**----------

Born □ Alive [1] □ Dead [2] **If stillbirth**[3] □ noSB □ Macerated □ Fresh □ Intrapartum □ Missing

Sex □ Female □ Male □ Missing **BW** (gr) [4] ☐☐☐☐ **Apgar1/5 /10** ☐☐/☐☐/☐☐

Ventilated in delivery room [5] □ N □ Y □ Missing **Asphyxia** [6] □ N □ Y □ Missing

Postdelivery □With mother □ SCBU □ NICU □ Referred □ Obitorio □ Missing

Reason for referral □ medical complication □ surgical complication □No beds □ Other □ Missing

If baby in NICU /SCBU, add here BHT code ☐☐☐☐☐

COMPLICATIONS

RDS [7] □N □Y **Jaundice with ET** □N □Y **Sepsis** □N □Y

Other Infect(incl NEC) □N □Y **Major birth trauma** [8] □N □Y **Major malformation**[9] □N □Y

Neurol (seizure,IVH,HIE) □N □Y **Phototherapy > 24 h** □N □Y **Other** □N □Y

If other, add_____

Final □ Discharged □ Disc with disabilities □ Death □ Referred □ LAMA

***DEFINITIONS (WOMAN)**

[1] **Gravida /Para/ Born alive:** fill this excluding current pregnancy/delivery (example: 3 pregnancies, 2 children, 1 stillbirth will be gravida 3, para 2, born alive 1)

[2] **Risk factors at time of delivery:** consider here the risk factors present at time of delivery and that can affect the delivery outcome. Examples:

- If the mother had severe anaemia but this was corrected before delivery, do not tick the severe anaemia box).
- If the mother had hypertension, pre-eclampsia, eclampsia, or hypothyroidism during current pregnancy , still tick the box even if the situation is under control
- If relevant cardiac problems present or even in the past, still tick the box.

[3] **Hypertension:** this is defined with a BP > 140/90

[4] **IUGR/SGA:** defined as weight < 10 centile of estimated weight-for-GA or < 10 centile for abdominal circumference (Bangladesh growth chart). IUGR/SGA is based on US estimate (if there was an indication for US, such as clinical signs suggesting IUGR, but US was not performed or uncertain, collect this information under “other or uncertain”.

[5] **Steroids:** Complete dose is Dexametason 8 mg /12 hrs for 3 doses –can you double if this is you national standard ? (last GL 6mg/ 12 h 48 h)

[6] **Induction**: as labour onset should be selected even in the case of **failed IOL** and subsequent CS, not "prelabour caesarean section" (note that this is accordingly to Robson classification)

[7] **Macrosomy at US:** defined as weight > 3500 grams or 90 Centile weight-for-GA

[8] **If IOL, mode of induction:** record here only procedures for IOL,i.e. until 4 cm dilatation

[9] **Analg:** record only drugs actually given (not just prescribed). Record paracetamol under “other”

[10] **Distocya 2nd stage**: CS at full dilatation

[11] **PPH** Minor (not severe not massive) Severe PPH (≥ 1000 ml *or* any bleeding with hypotension or tachycardia *or* blood transfusion) Massive (lost of ≥40% of blood volume, blood volume= body weight(kg)/12)

[12] **Major organ dysfunction:** as for Near miss definition **-**do not consider diabetes as major organ dysfunction (see following ANNEX 1)

[13] **Disabilities from pregnancy complications:** include here stroke, anaemia, post partum depression or other psychiatric disorders and other disabilities (not include preexisting problems such as GDM, hypertension, or hysterectomy)

[14] **Near Miss=** A maternal near-miss case is defined as “a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy” (*WHO 2011*). This implies either severe disease (severe PPH, severe pre-eclampsia, Eclampsia, sepsis, uterine rupture, severe complications of abortion), or critical interventions (admission UTI, intervention radiology, laparotomy, blood transfusion) or organ dysfunction (see ANNEX 1)

[15] **Post delivery duration stay:** count this in days. If admitted on 2 April and out day 3 April count this as 1 day if it is less than 24 h. If more than 24h , count this as 2 days

DEFINITIONS (NEWBORN)

[1] **Born alive**= fetus/baby of any GA and any birth weight showing any sign of vital activity (breath, cardiac, movements)

[2] **Born dead**= when not born alive; it includes stillbirth

[3] **Stillbirth** = macerated are fresh are based on clinical evaluation; intrapartum is a fetus where heart rate was perceived before delivery (and than lost after delivery)

[4] **Birth weight**=avoid approximation (use weight in grams)

[5] **Ventilated in delivery room=** not just stimulated, but ventilated (with bag or CPAP) for more than *10 seconds*

[6] **Asphyxia**= no spontaneous start of breathing, ventilation for at least *30 sec* and/or thoracic compressions as in international guidelines or any drug

[7] **RDS (Respiratory Distress Syndrome)**= tick this box for a baby with respiratory distress lasting more than 24 hours

[8] **Major birth trauma**= include here brachial plexus injury/arm palsy, fractures at any site, sub-aponeurotic (subgaleal) hemorrhage. Do NOT include here cephaloaematoma and caput succedaneum

[9] **Major Malformation**= do not include here minor malformation such as skin tags and pits, syndactyly, polydactyly, additional finger, PDA even if persistent.

[10] **Day of death**= for still birth use day zero

[12] **ANNEX 1 DEFINITIONS ORGAN DISFUNCTION (SOURCE: WHO MANUAL)**

Organ dysfunction / life-threatening conditions

☐ C0 **Cardiovascular dysfunction**
[shock, use of continuous vasoactive drugs, cardiac arrest, cardio-pulmonary resuscitation, severe hypoperfusion (lactate >5 mmol/L or >45mg/dL) or severe acidosis (pH<7.1)]

☐ C1 **Respiratory dysfunction**
[acute cyanosis, gasping, severe tachypnea (respiratory rate>40 bpm), severe bradypnea (respiratory rate<6 bpm), severe hypoxemia (PAO2/FiO2<200 O2 saturation <90% for ≥60min) or intubation and ventilation not related to anaesthesia]

☐ C2 **Renal dysfunction**
[oliguria non responsive to fluids or diuretics, dialysis for acute renal failure or severe acute azotemia (creatinine ≥300umol/ml or ≥3.5mg/dL)]

☐ C3 **Coagulation/hematologic dysfunction**
[failure to form clots, massive transfusion of blood or red cells (≥ 5 units) or severe acute thrombocytopenia (<50,000 platelets/ml)]

☐ C4 **Hepatic dysfunction**
[jaundice in the presence of pre-eclampsia, severe acute hyperbilirubinemia (bilirubin>100umol/L or >6.0mg/dL)]

☐ C5 **Neurologic dysfunction**
[prolonged unconsciousness / coma (lasting >12 hours), stroke, status epilepticus / uncontrollable fits, total paralysis]

☐ C6 **Uterine dysfunction / Hysterectomy**
[haemorrhage or infection leading to hysterectomy]

Appendix 2. Missing variables

	Total	Missing	% Missing
Maternal variables			
Age	7504	34	0.4
Work	7504	38	0.5
Education	7504	37	0.4
Para (number of children)	7504	34	0.4
Marital status	7504	38	0.5
Gravidas (pregnancies, including the ongoing)	7504	34	0.4
Born alive	7504	34	0.4
Gestational age at delivery	7504	47	0.6
Gestational age estimated with ultrasounds	7504	53	0.7
BMI	7504	53	0.7
Discharge	7504	35	0.4
Delivery	7504	32	0.4
Multiple pregnancies	7504	34	0.4
Pregestetional hypertension	7504	33	0.4
Gestetional 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
Chorionamnionitis	7504	36	0.4
Major fetal malformation	7504	36	0.4
IUGR/SGA	7504	36	0.4
Pregestetional diabetes	7504	35	0.4
Gestetional diabetes mellitus in diet	7504	35	0.4
Gestetional diabetes mellitus in drug therapy	7504	36	0.4
Maternal cardiac disease	7504	34	0.4
Maternal hypothiroidism	7504	37	0.4
Polihydramnios	7504	36	0.4
Oligohydramnios	7504	38	0.4
APH/major placentia previa	7504	37	0.4
Severe anaemia	7504	38	0.5
Other (risk factors)	7504	63	0.8
Steroids	7504	37	0.4

Previous CS	7504	38	0.5
If previous CS, trial of labour	7504	39	0.4
Presentation	7504	37	0.4
Labour onset	7504	36	0.4
Delivery mode	7504	37	0.4
If CS, type	7504	37	0.4
Indication of labour	7504	36	0.4
Mode of induction	7504	42	0.5
If operative delivery, indication	7504	38	0.5
Episiotomy	7504	43	0.5
Analgesia in labour	7504	43	0.5
3rd stage management	7504	39	0.5
Removal of placenta	7504	39	0.5
Operator delivery	7504	41	0.5
Perineal tears	7504	36	0.4
PPH	7504	38	0.5
Blood transfusion	7504	36	0.4
Cord collapse	7504	42	0.5
Uterine rupture	7504	42	0.5
Admission to ICU	7504	22	0.2
OT after delivery	7504	43	0.5
Sepsis/several infections	7504	44	0.5
Other complications	7504	45	0.6
Abruption placentae	7504	42	0.5
Amniotic fluid embolism	7504	42	0.5
Major organ dysfunction	7504	37	0.4
Hysterectomy	7504	36	0.4
DVT	7504	46	0.6
Final outcome	7504	42	0.5
Near miss	7504	20	0.2
Newborn variables ¶			
Born	7504	43	0.5
If stillbirth, fresh or macerated	7504	75	1.0

Sex	7504	51	0.6
Birth weight	7504	68	0.9
Apgar at 1’	7504	168	2.2
Apgar at 5’	7504	168	2.2
Apgar at 10’	7504	166	2.2
Ventilated in delivery room	7504	119	1.5
Asphyxia	7504	124	1.6
Post-delivery	7504	44	0.5
Respiratory distress syndrome	7504	114	1.5
Other infections	7504	110	1.4
Neurological complications (seizure, IVH, HIE)	7504	114	1.5
Jaundice with ET	7504	112	1.4
Major birth trauma	7504	120	1.6
Phototherapy for over 24 hours	7504	121	1.6
Sepsis	7504	113	1.5
Major malformation	7504	120	1.6
Other complications	7504	172	2.3
Final	7504	108	1.4

Abbreviations: APH= ante-partum haemorrhage; BMI= body Mass index; CS= caesarian section; DVT= deep vein thrombosis; ET= exchange transfusion; HIE= Hypoxic Ischemic Encephalopathy; ICU= Intensive care unit; IUGR=Intra-uterine growth restriction; IVH= intra-ventricular haemorrhage; OT=operating theatre; PPH= post-partum haemorrhage; SGA= small for gestational age.

¶ For multiple pregnancies, only data on the first newborn provided

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Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care

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Complete List of Authors:	Lazzerini, Marzia; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Senanayake, H.; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Mohamed , Rishard ; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Kaluarachchi, Athula; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Fernando , Roshini; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Sakalasuriya , Anshumalie; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Ihsan , Fathima Reshma; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Saravanabhava , Namasivayam; District Hospital Thellippalai, Thellippalai, Sri Lanka Gamaathige , Nalin; De Soysa Hospital for Women, Colombo, Sri Lanka, Neonatology Unit Jayawardena , Madura ; Department of Obstetrics & Gynaecology, Faculty of Medical Sciences, University of Sri Jayawardenapura Gamage, Ruwan Vidana; Base Hospital, Balangoda Covi, Benedetta; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Wanzira, Humphey; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Businelli, Caterina; Institute for Maternal and Child Health IRCCS Burlo Garofolo, Department of Maternal and Newborn Health Piccoli, Monica ; Institute for Maternal and Child Health IRCCS Burlo Garofolo, Department of Maternal and Newborn Health
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Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care

Short title: Individual patient maternal and newborn database to improve quality of care in Sri Lanka

Marzia Lazzerini,[1] Hematha Senanayake,[2,3] Rishard Mohamed,[2,3] Athula Kaluarachchi,[2,3,] Roshini Fernando,[3] Anshumalie Sakalasuriya,[3] Fathima Reshma Ihsan,[3] Namasivayam Saravanabhava,[4] Nalin Gamaathige,[5] Madura Jayawardena,[6] Ruwan Vidana Gamage,[7] Benedetta Covi,[1] Humphrey Wanzira,[1] Caterina Businelli,[1] Monica Piccoli.[1]

[1] Institute for Maternal and Child Health IRCCS Burlo Garofolo, Trieste, Italy.
[2] University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka
[3] Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo, Colombo, Sri Lanka.
[4] District Hospital Thellippalai, Thellippalai, Sri Lanka.
[5] Neonatology Unit, De Soysa Hospital for Women, Colombo, Sri Lanka
[6] Department of Obstetrics & Gynaecology, Faculty of Medical Sciences, University of Sri Jayawardenapura, Nugegoda 10250, Sri Lanka
[7] Base Hospital, Balangoda, Sri Lanka

Authors' e-mail contacts

ML: marzia.lazzerini@burlo.trieste.it
HS: senanayakeh@gmail.com
RM: mrishard@obg.cmb.ac.lk
AK: akaluarachchi@obg.cmb.ac.lk
RF: ragynobs2009@gmail.com
AS: sakalasuriyasaritha43@gmail.com
FRI: resh.ihsan798@gmail.com
NS: sarabhava@yahoo.com
NG: nalinnicu@gmail.com
MJ: madurammj@yahoo.com
RVG: ruwangamage21@yahoo.com
BC: benedetta.covi@burlo.trieste.it
HW: humphey.wanzira@burlo.trieste.it
CB: caterina.businelli@burlo.trieste.it
MP: monica.piccoli@burlo.trieste.it

Corresponding author
Marzia Lazzerini DTMH, MSc, PhD
WHO Collaborating Centre for Maternal and Child Health
Institute for Maternal and Child Health IRCCS Burlo Garofolo
Via dell'Istria 65/1, 34137, Trieste, ITALY
Email: marzia.lazzerini@burlo.trieste.it

ABSTRACT

Objectives This study aimed at piloting a prospective individual patient database on hospital deliveries in Colombo, Sri Lanka, and at exploring it use for developing recommendations for improving the quality of care (QoC).

Design Observational study.

Setting De Soysa Teaching Hospital for Women, the largest referral hospital for maternity care in Sri Lanka.

Data collection and analysis From July 2015 to June 2017 for each delivery 150 variables were collected in a standardised form and entered in a database. Data were analysed every eight months and results were made available to local staff. Outcomes of the study included: technical problems; data completeness; data accuracy; key database findings; use of data .

Results 7504 deliveries were recorded. No technical problem was reported. Data completeness exceeded that of other existing hospital recording systems. Missing data were less than 1% for maternal variables, and less than 3% for newborn variables. Mistakes in data collection and entry occurred in 0.01% and 0.09% of cases respectively. Key QoC indicators identified in comparison to international standards were: relatively low maternal mortality (0.053%); relatively high maternal near-miss cases (3.4%); high rate of induction of labour (24.6%), caesarean section (30.0%) and episiotomy (56.1%); relatively high rate of preterm babies (9.4%), low-birth-weight babies (16.5%), stillbirth (0.97%), and of total deaths in newborn (1.98%). Recommendations developed focused on the key indicators identified and included the use of checklist to standardise case management, training, clinical audits, and more information for patients. Based on this pilot experience, a list of lessons learned was drawn.

Conclusions The study shows that the implemented system of data collection can produce a large quantity of reliable information. Most importantly, this experience provides an example on how database findings can be used for discussing hospital practices, identifying gaps, and agree recommendations for improving the QoC.

Article summary: strengths and limitations of this study

- The study reports on the first individual patient database for comprehensive prospective data collection on births in Sri Lanka. Very few individual patient databases exist in general in low and middle-income countries (LMIC).
- The study showed that implemented data collection system can produce a large quantity of reliable information that can be used for quality improvement purposes, thus providing a model that can be adopted by policy makers in other similar settings.
- Although the study was single-centre, it has the merit of reporting both technical feasibility related to the database implementation, quality of data (ie, data completeness and accuracy), lessons learned, and, actual use of data – the latter three being often neglected issues -.

Keywords

Quality of care; Health Information system; mothers and newborns.

Disclosure of interests

None competing interest

List of abbreviations

LMIC = low and middle-income countries

MM= maternal mortality ratio

QoC= Quality of Care

WHO = World Health Organization

BACKGROUND

The availability of an actionable health information system is one of the key components of the World Health Organisation (WHO) framework for improving the quality of maternal and newborn health care (1,2) and one of the recommended cross-cutting actions in the WHO Strategy for Ending Preventable Maternal Mortality (EPMM) (3). According to WHO standards (2), "the health information systems should enable using data to ensure timely actions to improve the care of every woman and newborn". More specifically, a health facility should have mechanisms for data collection, analysis and feedback as part of the activities for monitoring and improving performance around the time of childbirth (2).

However, estimates have highlighted major gaps in data collection even on key indicators: only one third of countries have the capacity to count or register maternal deaths (3,4) and less than two fifths of all countries have a complete civil registration system with accurate attribution of the cause of death (3,5). Quality of data is also an area of significant concern: according to a WHO review, although most countries are using some core indicators to monitor performance in maternal and newborn care, virtually no low- or lower-middle-income country has a full system of data sharing and transparent quality control in place (6). 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 outcomes (7).

Sri Lanka is a lower middle-income country (8). Since the civil war ended in 2009, the economy has grown on average at 6.2% per year (8), in transition from being predominantly rural-based to one that is urban-oriented around manufacturing and services. Major progresses have been made in maternal healthcare in past decades: according to the last estimates the reported maternal mortality ratio (MMR) is relatively low (33.7/100.000) (9). However, no significant improvement in the MMR has been observed in the last 10 years (8-11). The latest national Maternal Mortality Review have shown that 50% of maternal deaths are from direct causes, with preventable causes, such as post-partum haemorrhage and sepsis, being among the top five causes of death (9). Almost 80% of all women died in hospitals (9), where specialized facilities are available, thus suggesting possible gaps in the quality of care provided (9). Inappropriate practices are suggested also by other indicators, such as the rising rate of caesarean section (CS) (12), peaking above 50% in selected facilities (12). The estimated rate of induction of labour in Sri Lanka is currently among the highest in Asia (35.5%) and the rate of inductions without medical indication is reported to be 27.8% (13).

Presently in Sri Lanka the health information system collects data only on selected maternal and newborn indicators, in an aggregate form. The objective of this study was to pilot, in the largest maternity unit in Sri Lanka, a system for collecting prospectively, for each case of delivery, a large number of maternal and newborn variables. The paper also aimed at reporting on the use of data for developing recommendations to improve the quality of hospital care, in a participatory manner.

METHODS

Population and setting

The study was conducted at the De Soysa Hospital for Women in Colombo, the largest referral hospital for maternity care in Sri Lanka. Previous collaborations among the involved institutions provided the opportunity to establish an international working group dedicated to improve the quality of maternal hospital care. It was agreed that establishing a system of data collection and fostering data use were two necessary steps toward this direction. In June 2015, a database for routinely collecting individual patient data was implemented in wards 3 and 15, the two wards of the University Obstetrics Unit in the hospital, where about half of the total deliveries of the hospital take place. All deliveries occurring in these two wards, with no exclusions, were to be entered in the database. This paper reports findings of the first 24 months of data collection, from July 2015 to June 2017.

Data collection tools

For each delivery, data were collected in a standardised form ("Yellow Form") and entered in a database. The "Yellow Form" was two pages long (**Appendix 1**), and recorded 150 variables for each delivery: demographic and socio-economic data of the woman (8 variables); characteristics of pregnancy and risk factors (28 variables); process of care during birth (60 variables); maternal health outcomes (31 variables); newborn health at birth and during hospitalisation, process of care and health outcomes (23 variables). The database was developed using Epidata (14), a free software that allows for inclusion of internal checks. Data were collected and entered in the database by dedicated trained data collectors.

Data quality assurance procedures

The Yellow Form was developed through a participatory approach with local staff. The team involved included: six senior obstetricians from De Soysa Hospital and other hospitals in Sri Lanka, eight midwifery-qualified nurses, two registrars in obstetrics and gynaecology, one neonatologist, one registrar in neonatology, two data collectors. Two external researchers (one obstetrician and one epidemiologist) participated as facilitators. Variables were selected based on the experience reported in the literature (1,2,6,7) and on previous experience of the team, so that it could allow

answering different research questions and monitoring trends over time. Case-definitions were derived from international literature (15-17). Instructions on how to fill the form, and specific case definitions were developed in parallel with the development of the form and embedded into it (Appendix 1).

All relevant information were to be extracted from the medical files. The use of an intermediate paper based system of data collection was agreed at the beginning of the project based on the following consideration: using a paper-based form to collect data allows to check for internal consistency in the data collected, before entering them in the database.

Both the data collection form, the instructions on how to fill it, and how to transfer information in the database were field-tested. Procedures of data collection were field tested to evaluate the following domains: if the sequence of data in the form was appropriate; if case definitions were clear; if data collectors were able to fill the form and enter data in the database; if time needed to fill the form and enter data in the database was acceptable to allow routine data collection; if there were sources of systematic error or bias; if there was any technical problem. Data collectors were young medical doctors who were trained on the standard operating procedures (SOP) of data collection and data entry and supervised over time.

The database was designed in a way that the interface for data entry was almost identical to the "Yellow Form". To further minimise data-entry errors, the database contained 137 internal automatic validation rules, aiming at minimising errors in biological plausibility of data (i.e. normal ranges), data completeness and internal consistency.

For the initial period of data collection for each case of delivery two data collectors independently filled a Yellow Form and data were cross-checked to evaluate consistency. This procedure was continued until when errors in data collection were consistently low (ie. below 0.02%; this was achieved in the time period of about 1 month). Subsequently, data completeness and accuracy in data collection and data entry were monitored by an external independent data monitor who randomly reviewed 5% of forms and 5% of the entered cases. Missing cases or errors in data collection/entry were corrected in real time. Data were also externally monitored for completeness and internal consistency at about four months intervals.

Data analysis and use

Data were analysed at intervals of eight months using a standardized plan for analysis, pre-defined and agreed among partners. This included: a descriptive analysis of all the key variables in the database; an analysis of CS groups according to Robson Classification (16,17) and other minor

secondary analyses as suggested by the finding of the primary analysis and as requested by partners. Data were analysed by the external team (WHO Collaborating Centre) and made available as tables and graphs to the local staff (De Soysa hospital) in the format of a power point presentation. Data were provided with the purpose of being locally discussed in dedicated workshops, and used to develop recommendations to improve the quality of care at hospital level

Outcomes

Outcomes of the study are reported in Box 1 and further described below. Technical problems in data collection were defined as any technical problem occurring with the use of the database (either with the software or with the computer). These had to be notified by data collectors in real time to the local coordinator and to the external team.

Database completeness was checked by an independent assessor by comparing the number of cases entered in the database with data in the official hospital registers and specifically with the following eight data sources: i) birth register; ii) intensive care unit (ICU) admissions register; iii) operating theatre (OT) register; iv) neonatal intensive care unit (NICU) admissions register; v) Special Care Baby Unit (SCBU) admissions register; vi) maternal death reviews; vii) perinatal mortality and morbidity statistics; viii)) monthly reports.

The number of missing cases for each variable was calculated as the number of missing cases in the database out of the total expected entries for that variable.

Accuracy in data collection was measured by the number of variables correctly recorded in the yellow form when compared to the original medical files. Accuracy in data entry was measured by the number of variables correctly recorded in the database compared to the yellow forms. Both accuracy in data collection and data entry were assessed by an external independent data collector who randomly checked 5% of forms and 5% of entered cases, respectively.

Database findings included a descriptive analysis of the key variables as agreed among partners. Data on multiple pregnancies were not included in this primary descriptive analysis of newborn outcomes. Use of data for quality improvement purposes included any action-oriented recommendation generated from review of the data outcomes by researchers and partners

Box 1. Outcomes of the study

i)	**Technical problems:** - any type of technical problem in implementing and using the database.

ii) **Data completeness:**
- number of cases entered in the database versus data in the official registers;
- number of missing cases for each variable in the database.

iii) **Data accuracy:**
- number of correct variables in the yellow form versus the original medical files;
- number of correct variables in the database compared to the yellow forms.

iv) **Database findings:**
- descriptive analysis of the key variables as agreed among partners.

v) **Use of data for quality improvement purposes:**
- any action-oriented recommendation generated from review of the data outcomes by researchers and partners.

Ethical considerations

The study 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. Informed consent was not requested by the Ethics Review Committee.

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 (16) The development of recommendations for improving the quality of care took into account the importance of effective communication with patients.

RESULTS

Technical problems

No technical problems occurred. The data collectors reported that there were no technical difficulties in managing the database.

Data completeness

Table 1 reports the number of total cases in the database when compared to other official hospital data sources. Numbers were matching, except for the cases of hysterectomies, for which the database appear to contain one additional case (verified as actually being a real case).

Table 1. Number of cases in the database compared to hospital registers and other official sources of data

	Database	Hospital registers	Source of data for comparison
Maternal indicators			
Total deliveries	7504	7504	Birth register
Maternal deaths	4	4	Maternal deaths reviews
Admission to ICU	239	239	ICU register
PPH	147	147	Birth register
OT after delivery	11	11	OT register
Hysterectomy	22	21	OT register
Newborn indicators [1]			
Stillbirth	82	82	Birth register, monthly reports
Admission to NICU	105	105	NICU register
Admission to SCBU	1121	1121	SCBU register
Neonatal deaths after birth	81	81	Birth register + NICU and SCBU registers + perinatal mortality and morbidity statistics

Notes: [1] Including also the second twin in multiple pregnancies.

Abbreviation: ICU= Intensive care unit; NICU= Neonatal intensive care unit; OT= operating theatre; PPH= post-partum haemorrhage; SCBU= semi-intensive baby unit

Number of missing variables is reported in **Appendix 2**. Missing data were less than 1% for all maternal variables, and less than 2% in all but two newborn variables.

Data accuracy

Random checks by an independent data monitor on 5% of Yellow Forms and 5% of entered cases revealed that mistakes in data collection in the forms occurred in 0.01% of cases, while mistakes in data entry in the database occurred in 0.09% of cases.

Database findings

Tables 2,3 and 4 report the descriptive analysis of key indicators in the database. Overall, during the two years of the study period, 7504 deliveries were entered (Table 2). In terms of socio-demographic characteristics, most women belonged to the following categories: 4253 (56.7%) were 25 to 34 years old; 6028 (80.3%) had secondary education; 6253 (83.3%) were housewives;

5231 (69.7%) had a normal nutritional status. Overall, in 4182 (55.7%) of deliveries there was a maternal or foetal medical condition or a risk factor for operative delivery/ negative outcome, the most prevalent being: gestational diabetes (13.4%), pre or post-term delivery (12.9%), and previous CS (12.7%). Overall 2870 (38.2%) were primigravidae.

Analysing the population according to Robson classification, the most prevalent groups were: group 3 (multiparous, single cephalic, at term in spontaneous labour), accounting for 27.1% of total case; group 1 (nulliparous, single cephalic, at term, in spontaneous labour) accounting for 23.2% of cases; group 2a (nulliparous, single cephalic, at term, induced), 12.8% of cases; group 5 (previous CS, single cephalic at term), 10.9% of the population.

Table 2. Maternal characteristics

	n (N=7504)	%
Age categories		
< 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
Missing		
Number of pregnancies [1]		
1	2870	38.24
2	2313	30.82
≥3	2285	30.47
Missing	34	0.45
Education		
None	23	0.31
Primary	235	3.13
Secondary	6028	80.33
Higher	1181	15.74
Missing	37	0.49
Work		
Not reported by the mother	77	1.03
Working	1136	15.14
Housewife	6253	83.33
Missing	38	0.51
Marital status		
Married	7350	97.95
Unmarried	96	1.28
Living together		

Missing	20	0.27
	38	0.51
Nutritional status [2]		
Underweight	670	8.93
Normal	5231	69.71
Overweight	1110	14.79
Obese	440	5.86
Missing	53	0.71
Medical conditions /risk factors (any) [3]	4182	55.73
Gestational diabetes, total	1002	13.36
On diet	417	5.56
On drug therapy	585	7.80
Gestational age <37 >= 41	966	12.87
Previous CS	956	12.74
Hypertensive disorders of pregnancy, any	506	6.74
Pre-gestational hypertension	168	2.24
Gestational hypertension	179	2.39
Pre-eclampsia not severe	78	1.04
Pre-eclampsia severe	69	0.92
Eclampsia	12	0.16
IUGR at ultrasound	504	6.72
Obesity	440	5.86
Breech/transverse/oblique lie	339	4.52
Pre-gestational diabetes	266	3.54
Maternal cardiac disease	234	3.12
Fetal conditions, other	223	3.10
Maternal hypothyroidism	219	2.92
Maternal age >40	224	2.9
Oligohydramnios	131	1.75
APH	112	1.49
Polyhydramnios	96	1.28
Multiple pregnancies	84	1.12
Severe anaemia	40	0.53
Chorioamnionitis	11	0.15

Notes: [1] Including the opngoing pregnancy. [2] As defined by National Guidelines in Sri Lanka. [3] Any of the medical conditions/risk factors described in the following raws.

Abbreviations: APH= ante-partum haemorrhage; CS= caesarian section; IUGR= intra-uterine growth retardation.

In terms of process indicators and maternal outcomes (**Table 3**), 1849 (24.6%) of women had their labour induced, and 2251 (30.0%) had a CS. Rate of vaginal birth after CS (VBAC) was 17.1%. Episiotomy was performed in 4213 (56.1%) of women. In terms of health outcomes, there were four cases of maternal death (0.053%). Overall 254 (3.38%) of cases were identified as maternal near miss. Post-partum haemorrhage (any severity) occurred in 147 (1.9%) women, with 39 (0.52%) women having a severe or massive haemorrhage. Overall there were 22 (0.29%) cases of hysterectomy. During the whole study period there were no cases of uterine rupture.

Table 3. Birth process indicators and maternal outcomes

	n (N=7504)	%
Labour onset		
Spontaneous	4726	62.98
Induction	1849	24.64
Pre-labour CS	893	11.90
Missing	36	0.48
Mode of delivery		
Vaginal spontaneous	4906	65.38
Vaginal operative	310	4.13
Caesarean section	2251	30.00
Missing	37	0.49
Caesarean section		
In spontaneous labour onset	927	19.61
In induction of labour	441	28.85
Episiotomy	4213	56.14
Key maternal outcomes		
Maternal deaths	4	0.05
Admission to ICU	239	3.18
Near-miss cases [2]	254	3.38
PPH	147	1.96
OT after delivery	11	0.15
Hysterectomy	22	0.29
Uterine Rupture	0	0
Sepsis	29	0.39
DVT/PE	2	0.03
Abruptio placentae	21	0.38
Amniotic fluid embolisms	0	0
Perineal tears III-IV degree	17	0.23

Notes: [1] As for Robson's classification (17); [2] As for WHO classification (15)

Abbreviations: CS= caesarian section; DVT= Deep vein thrombosis; ICU= Intensive care unit; NICU= Neonatal intensive care unit; OT= operating theatre; PE= pulmonary embolism; PPH= post-partum haemorrhage.

The analysis of the newborns' characteristics and outcomes (**Table 4**) pointed out the following key indicators: 73 (0.97%) were stillborn; 708 (9.4%) were born pre-term (ie, before 37 weeks of gestational age); 1243 (16.6%) had a low birth-weight (ie, below 2500 grams), ; 173 (2.3%) were ventilated for more than 10 seconds in the delivery room. Overall 917 (12.2%) newborns had at least one complication during their hospital stay, and among these the most frequent was the respiratory distress syndrome (3.7%). Overall, 101 (1.62) newborns had major malformations. Overall 148 (1.98%) were either born dead or died during the hospitalisation; among these cases (death either before or after birth), 55.1% had major malformations.

Table 4. Newborns' characteristics and outcomes

NEWBORN	n (N=7504) [1]	%
Sex		
Female	3644	48.56
Male	3792	50.83
Missing	68	0.91
Gestational age (weeks + days)		
< 33 + 6	223	2.96
34 to 36+ 6	485	6.19
37 to 40+ 6	6491	86.50
> 41	258	3.43
Missing	47	0.62
Weight at birth		
<1499	149	1.99
1500 to 1999	183	2.44
2000 to 2499	911	12.14
2500 to 3499	5365	71.50
3500 to 4000	724	9.65
>4000	104	1.39
Missing	68	0.91
Stillbirth, total	73	0.97
Macerated	42	0.56
Fresh	27	0.36
Missing	4	
Ventilated in delivery room for more than 10 seconds	173	2.34
Asphyxia	62	0.84

Post-delivery		
With mother	6164	82.14
SCBU	1105	14.73
NICU	96	1.28
Referred	9	0.12
Death	75	1
Missing	11	0.07
Neonates with any complication	917	12.22
Complications		
RDS	276	3.73
Infection, other than sepsis	121	1.35
Major malformation	101	1.62
Neurological [2]	38	0.50
Sepsis	28	0.38
Major Birth Trauma	16	0.21
Severe jaundice with ET	15	0.20
Others [3]	232	3.09
Final outcome		
Discharged	7204	96.00
Discharged with disabilities	4	0.05
Death (including stillbirths)	148	1.98
Referred	54	0.72
LAMA	15	0.20

Notes: [1] Data on multiple pregnancies were not included in this primary analysis. [2] Seizures, ventricular haemorrhage and other neurological complications. [3] Most frequent reported conditions in this class were other respiratory problems (eg, apnoea, meconium aspiration syndrome, pulmonary hypertension), gastrointestinal problems (eg, bleeding), minor jaundice.

Abbreviations: ET= exchange transfusion; LAMA= Left against medical advice; NICU=neonatal intensive care unit; RDS= respiratory distress syndrome; SCBU=semi-intensive care baby unit.

Use of data

Data entered in the database were timely analysed at intervals of eight months and made available to the local coordinator. Findings of the database were presented and discussed in two large workshops with staff from De Soysa Hospital and from other large maternity units in Sri Lanka. Participants to these meetings included: senior obstetricians, neonatologists, postgraduate trainees and other middle level medical personnel, nurses, midwifes and other staff. About 50 people participated to each workshop.

During these meetings, key indicators suggesting possible gaps in quality of care were identified, and recommendations for improvement were discussed and agreed upon (**Table 5**). Indicators identified as requiring actions to improve quality of care were: high rate of induction of labour (24.6%), of CS (30.0%) and episiotomy (56.1%); relatively high maternal near-miss cases (3.4%); relatively high rate of preterm babies (9.4%), low-birth-weight babies (16.5%), stillbirth (0.97%), and of total deaths in newborns (1.98%). Recommendations developed focused on the key indicators identified and included the use of checklists to standardise case management, training, clinical audits, and more information for patients.

Smaller meetings of technical working groups were also organised, in order to develop and agree specific tools and procedures to put in practice the recommendations agreed (such as: developing the information pamphlet on VBAC, and the checklists to review obstetric emergencies).

Table 5. Use of data for improving quality of care

Key Indicators identified	Agreed recommendations for quality improvement
Maternal - High rate of induction of labour (24.6%), with many woman in Robson gropup 2a (nulliparous, single cephalic, at term, induced) - High rate of CS (30.0%), relatively high prevalence of group 5 (multiparous with previous CS) - Low rate of VBAC (17.1%) - High rate of episiotomy (56.1%) - Relatively high rate of near-miss cases - Low reported rate 3rd-4th degree perineal tears	• Checklist to be filled by the doctor in charge for each individual case of induction of labour, specifying indications, methods, timing. Data to be reviewed regularly. Consultant to make decision on IOL • Dedicated workshops on CS, discussing local data and international recommendations (16,17). • Training workshops to help improve the CTG interpretation skills. Stickers to help CTG interpretation. Improved communication regarding CTG interpretation from midwives to medical officers using "WhatsApp/Viber". • Training workshop to develop a consensus on how to manage foetal distress and poor progress of labour. • Establishment of a nurse-lead VBAC counselling clinic and development of a VBAC leaflet for patients. Education for staff, including community midwives, on methods of counselling. • Implementation of a selective episiotomy policy; training of midwives and medical staff on appropriate indication for episiotomy. • Doctors to identify clearly near-miss cases. Establishment of a system for regular internal review of near-miss cases. • Development of checklists for systematic analysis of obstetric emergencies against international standards of

	care. • Training of midwifes on checking and reporting the perineum status after delivery.
Newborn - High rate of preterm (9.4%) - High rate of low birth weight (16.5%) - High rate of stillbirth (0.97%) - High rate of newborns with complications (12.2%) - High rate of total deaths in newborns (1.98%)	• Improve diffusion of national and international guidelines of antenatal care.. • Improve prenatal ultrasound diagnosis of SGA and of malformation. • Development of checklist for systematic analysis of newborn care against international standards of care. • Training on newborn resuscitation.

Abbreviations: CTG: cardiotocography; SGA: small for gestational age; VBAC: vaginal birth after cesarean section.

Lessons learned

Results of this study were discussed among partners and lessons learned and future actions were articulated (**Box 2**). Overall the key lesson was that data collection was feasible, it resulted in a large amount of data with an acceptable quality, and in the development of some recommendations for quality improvement; however, use of data could be further improved. Drawing on this experience and on other experiences reported in literature (7,18-23), some concrete actions that may further help improving use of data in the future were discussed (**Box 2**). Although a simplified version of the Yellow Form was discussed, it was difficult to identify what variables to exclude: despite the data collection form including 150 variables, when findings were discussed clinicians tended to request even more additional information.

Box 2. Lessons learned and way forward

Key lessons

1. Data collection was feasible and resulted in a large amount of data with an acceptable quality and in the development of some recommendations for quality Improvement (QI); however, use of data could be further improved.
2. Standard Operating procedures (SOP) and regular data monitoring and evaluation (M&E) was crucial.
3. One data collector was sufficient to collect data in the study setting, but one additional person was needed to ensure regular M&E.
4. Ensuring concrete use of data for QI should not be taken for granted and it requires building a system of coordination to facilitate data diffusion and discussion.
5. In general, clinicians showed low interest in statistical data compared to clinical subjects. Clinicians without training or without a particular interest in QI methods, were poorly interested in using statistical

data for QI purposes, and were more attracted by new technologies. Appropriate involvement of staff (e.g. training, participation to projects, assignment of specific responsibilities), is needed to develop a local team who will act as drivers in QI.

6. It is difficult to find the golden balance between a "simple" data collection form (i.e. collecting few variables) and an "informative" data collection form that satisfies clinicians (i.e. collecting a large number of variables).

Way forward

1. The "Yellow Form" could be incorporated into the patient file; data collection could be made part of the duties of the hospital staff in charge of each single case. This should facilitate sustainability and may further improve quality of data.
2. All staff involved in data collections should be made aware of the standard case definitions.
3. Regular local M&E should be ensured to avoid drops in data quality.
4. Adding in the database functions of automatic reporting may probably increase local ownership and facilitate use of data.
5. Other forms of diffusing data, rather than workshops, may be explored, such as use of posters or newsletters.
6. With the number of recommendations increasing, the establishment of a technical group for QI within the hospital, with clear roles and responsibilities becomes mandatory to ensure their implementation.
7. To ensure translation into actions of recommendations arising from data discussion, a system for regular follow up should be put in place. This will probably be more effective if embedded in a national system for quality assurance in maternal and child health.

Abbreviations: M&E= monitoring and evaluation; QI= quality improvement; SOP= standard operating procedures.

DISCUSSION

This is the first individual patient database established for comprehensive prospective data collection on births in Sri Lanka. From a review of existing literature, we could identify very few databases prospectively collecting a large number of individual patient variables on hospital births. Of these, most data collection systems were established in high-income countries, or in upper middle-income countries such as Brazil, Peru and South Africa (19-21). We were able to identify only two systems for prospective collection of individual maternal and newborn variables across the time of birth in low or lower middle-income countries (22,23) and both collected data from a single facility (22-24). In respect to the average hospital administrative data, even in high income countries, the dataset implemented in this pilot study contains a large number of variables, such as maternal risk factors, that can be used for evaluating the case mix and for adjusting for confounders (7,21).

Most importantly, routine use of data to improve case management and organization of care is still not a common practice, even in countries with well-established data collection systems (7). Despite there being some good examples of how routine data collection systems are used to shape policies in low and middle-income countries (LMIC), for example in the paediatric field (24), these are very limited in number. As such, the main value of this study is that it provides an example of how data can be used for discussing and agreeing on recommendations for improving the quality of care.

This study was aimed at reporting the feasibility of implementing an accurate system of data collection and not at an extensive presentation of the database findings. Additional analyses (such as a detailed analysis of practices and outcomes related to CS according to the Robson Groups (25), and other multivariate and sub-group analyses) will be the object of future publications. Many of the findings of the descriptive analysis reported in this paper - such as the rate of maternal deaths, induction of labour and low birth weight babies - are not overall surprising and rather in line with other country reports (5,8-13,24,27-31). Results reflect the specificity of the setting: De Soysa Hospital is the largest referral maternity hospital in Sri Lanka, and case mix, as well as local practices, do not necessarily represent the average in the country. For example, the rate of induction of labour, CS and near-miss cases, although being relatively high when compared to other reports in international literature , actually are below the national reported average (12,13,27,30). Rate of stillbirth and newborn deaths after birth may appear high when compared to national statistics (the most recent national report provides a figure of stillbirth rate of 5.9/1000 (32)). This may be due to the case mix, with 55.7% of pregnancies at the De Soysa Hospital presenting at least one medical condition/risk factor for operative delivery/negative outcome. Additionally, about half of cases of stillbirth had a major malformation. Of notice, medical termination of pregnancy in Sri Lanka is allowed only to save the life of the mother, but not for any condition of foetal impairment, not even major malformations (33). The rate of post-partum haemorrhage, appeared to be lower than what would be expected for LMIC according to international literature (34), but it was double checked in the hospital registers and found to be correct (Table 1). The low prevalence of DVT and PE may be due to the fact that these events are less frequent in the Asian population compared to others, or to under-reporting (35,36). It must be acknowledged that for most of the variables collected - such as risk factors, episiotomy, reasons for induction of labour/operative deliveries, newborn complications, etc, there is no other system of official data in the whole country. The main merit of the database was that it provided to hospital staff, for the first time in Sri Lanka, a large number of objective indicators on local practices and outcomes, thus providing the evidence base for discussing the appropriateness of the care delivered at the facility level. Although recommendations developed may not cover all actions needed to improve quality of care, they were agreed locally, and as such they represent an

important step forward in the local culture of quality improvement and in the local ownership of the whole quality improvement process.

In the future, the database will be used to analyse more specific topics, such as the appropriateness of hospital practises related to CS or to induction of labour (these analyses are already ongoing, and will be reported in future publications. Findings of such analyses may inform the development of additional and mores specific recommendations to improve quality of care. Additionally, the database may provide a way of monitoring trends over time regarding patients' characteristics, hospital practices (ie, CS rates, and indications to CS) and health outcomes.

Given the paucity of efficient data collection systems in LMIC (6,7), lessons from this study may be of interest to other researchers and policy makers. However, in generalising the findings of this study to other settings, key characteristics of this project must be acknowledged. First, in this study dedicated staff was appointed for data collection and entry. Second, supervision was provided, and data collection was monitored regularly. Data collection that proved accurate under these conditions may fail to have good results if these minimum conditions are not guaranteed, especially if monitoring is not ensured.

The experience accumulated so far in this pilot experience at De Soysa Hospital may help scaling up the data collection system in other maternity units in the country. The Sustainable Development Goals (SDG) in countries with low baseline maternal mortality, such as Sri Lanka, include "achieving access to quality essential health-care services" (37). Target-setting is accompanied by the need for improving measurement approaches and data quality to allow more accurate tracking of country progress as well as causes of death (38). The implementation of a system for individual patient data collection on hospital deliveries in other maternity units in Sri Lanka will allow comparison of several variables (patient characteristics, process outcomes and health outcomes) among different geographical regions, settings, over time. Data generated could be used to improve overall national practices. The data collection form utilised in this project was designed together with professionals from different maternity units in Sri Lanka, therefore, when adapting it to other facilities, only minor adaptations may be required. However, scaling up will require a good mechanism for coordination, beside further testing to identify the optimal methods for data collection in other settings (such as smaller maternity units). Furthermore, it will be crucial to establish functional mechanisms (such as regular data audits) to ensure that information generated from the database are actually used in practice to improve quality of health care. As for many other types of data collection, the main problem may be that data are not actually utilised (7).

Limitations of this study include that, 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 assess changes in key indicators over time. Although the study was single-centre, it has the merit of reporting both technical feasibility related to the database implementation, quality of data (completeness and accuracy), lessons learned, and, actual use of data – the latter three being often neglected issues-.

CONCLUSIONS

This pilot study on the implementation of an individual patient database on hospital deliveries in Sri Lanka proved that in this setting a large quantity of data could be collected in an accurate way. The study is an example on how data can be used to discuss hospital practices, identify gaps in quality of care, and agree recommendations for improving the quality of hospital case management. More implementation research is needed to identify the best model for scaling up data collection to other maternities in Sri Lanka and in other low-middle income countries. More research in general should report on the actual use of data, and should aim at identifying effective ways of translating into practice recommendations generated from data.

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Data sharing statement

All key data are provided in the paper. Additional details can be provided by the contact author on request.

Author contributions

ML, HS and MP conceived the study and procured funds

ML, HS, RM, NS,NG,MJ, RVG, and MP developed the data collections tools

AK, RF, AS and FRI collected data

BC, HW, CB 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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Supplementary files

Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care

List of files

Appendix 1. YELLOW FORM

Complete this chart AT DELIVERY (white part) and AT DISCHARGE (dotted part) □**Soysa** □**Other**
If other hosp, add name:_____

Adm (dd/mm/yy) ☐☐☐☐☐☐ **Deliv** ☐☐☐☐☐☐ **Disch** ☐☐☐☐☐☐ **BHT 15-** ☐☐☐☐☐

Age (years) ☐☐ **Education** ☐No schooling ☐Primary (Grades 1-6) ☐Secondary (Grades 6-10) ☐Higher

Working status □ No data □ Working □ Housewife **Marital status** □ Married □ Unmarried □ Unmarried living together

GA at delivery (wks/days) ☐☐/☐ **GA estimated with US** ☐N ☐Y ☐Missing

Gravida (pregnancies)[1] ☐☐ **Para**[1] ☐☐ **Born alive**[1] ☐☐ ([1] For para / born alive – exclude current pregnancy)

BMI at booking □ Underweight (< 18.4) □ Normal (18.5 - 22.9) □ Overweight (23 - 27.4) □ Obese (> 27.5)

(Risk factors at time of delivery-check all) [2]

Multiple pregn	□N □Y	**PreGes Hyperten**[3]	□N □Y	**Ges Hyperten**[3] **no proteinur**	□N □Y
Pre-ecl NOT SEV	□N □Y	**Pre-ecl SEV**	□N □Y	**Eclampsia**	□N □Y
Chorioamnionitis	□N □Y	**Major fetal malformation/s**	□N □Y	**IUGR/SGA**[4]	□N □Y
Pregeste Diab	□N □Y	**GDM in diet**	□N □Y	**GDM, in drug therapy**	□N □Y
Maternal-cardiac disease[2]	□N □Y	**Maternal hypothiroidism**	□N □Y	**Polihydramnios**	□N □Y
Olidramnion	□N □Y	**APH/major plac previa/accret**	□N □Y	**Severe Anaemia (Hb<7)**	□N □Y
Other	□N □Y				

If Other maternal conditions, specify_____
If Other fetal conditions, specify_____
If Other, specify_____

One tick only

Steroids[5]	□ N	□ complete	□ incomplete	□ dose unclear
Previous CS	□ N	□ Y	□ Missing	Number_____
If prev CS, trial of labour	□ No previous CS	□ N	□ Y	
Presentation	□ Cephalic	□ Breech	□ Other	□ Missing
Labour onset	□ Spont	□ Induc (even if failed)[6]	□ PreLabCS[6]	□ Missing
Delivery mode	□ Vag spont	□ Vag forcep/ventuse	□ CS	□ Missing
If CS, type	□ No CS	□ Emerg	□ Elect	□ Missing

If IOL, main indication given (one tick only)

□ 1 No IOL	□ 2 Post-term	□ 3 Prelab rupture membs	□ 4 Diabetes on diet
□ 5 Diabet on insulin/metform	□ 6 Macrosomy at US[7]	□ 7 IUGR/SGA [4]	□ 8 Multiple pregnancies
□ 9 Maternal Age > 40 y	□ 10 Hypert/Preecl/Eclam	□ 11 Cardiac disease	□ 12 Oligoidramn
□ 13 Other add_____	□ 14 Prolonged latent phase/ painful contractions not in labour		□ 0 Missing

If IOL, mode of induction (one tick only) [8]

□ 1 No IOL	□ 2 PGE	□ 3 Oxytocin	□ 4 Foley
□ 5 ARM	□ 6 PGE+ oxytocin ± ARM	□ 7 Foley+ARM/oxytocin	□ 8 Foley + PGE
□ 9 ARM + oxytocin	□ 10 Other add: _____		□ 0 Missing

If operative delivery, main indication (one tick only)

□ 1 No operative del	□ 2 CTG anom/suspected fetal distress	□ 3 Failed induction
□ 4 Distocya 1st	□ 5 Distocya 2nd stage[10]	□ 6 Past CS
□ 7 Breech/abnormal lie	□ 8 History of subfertility	□ 9 APH/major placenta previa
□ 10 Cardiac disease	□ 11 Prelab diagn CPD/short mother	□ 12 Multiple pregnancies
□ 13 IUGR	□ 14 Pre term	□ 15 Diab
□ 16 Hypert/Precl/Eclam	□ 17 Maternal request	□ 18 Other
□ 0 Missing		

If other fetal cause specify _____
If other maternal specify_____
If other cause_____

Episiotomy	□ N	□ Y	□ Missing			
Analges in labour[9]	□ N	□ Petidine	□ Epid	□ Spin	□ Mix	□ Other
If CS, anaestesia	□ No CS	□ Spinal/epid	□ General			
3rd Stage manag	□ Active	□ No active	□ Missing			
Removal placenta	□ Spont	□ Manual	□ ERPC	□ Missing		
Operator del	□ Nurse	□ MW	□ HO	□ SHO	□ Reg	□ Con □ Missing

PTO

Complications (one tick)

Perineal tears	□ N/I-II d	□ III d	□ IV d	□ Missing	
PPH [11]	□ N	□ Minor	□ Severe	□ Massive	
Blood transfusion	□ N	□ Y	**Units (#)**	_____	
Cord prolapse	□ N	□ Y	**Abruptio placentae**	□ N	□ Y
Uterine rupture	□ N	□ Y	**Amn fluid embol**	□ N	□ Y
Admission to ICU/HDO	□ N	□ Y	**Major organ dys** [12]	□ N	□ Y
OT after deliv	□ N	□ Y	**Hysterectomy**	□ N	□ Y
Sepsis/sev infect	□ N	□ Y	**DVT/PE**	□ N	□ Y
Other Complications	□ N	□ Y	**Other infections**	□ N	□ Y

Final outcome (one tick)

□ Discharged □ Disc with disab due to preg complic [13] □ Death □ Referred □ LAMA

Near Miss [14] □ N □ Y

If NM or death, cause (select main; if more than one, write in Notes)

□ 1 Pre-exist cardiac dis	□ 2 Other pre-existing medic con	□ 3 Suicide
□ 4 Hypertension	□ 5 Preeclampsia/Eclampsia	□ 6 PPH
□ 7 Amniotic fluid embolism	□ 8 Sepsis/infection	□ 9 DVT/PE
□ 10 Complic anaesthesia	□ 11 Other	□ 0 Missing

If Others specify_____

Notes_____

Post delivery duration stay (days) [15] ☐☐

If stay >24 h, reason ☐ maternal ☐ newborn ☐ both ☐ hospital regulations ☐ Missing

----------**NEWBORN (N1)**----------

Born □ Alive [1] □ Dead [2] **If stillbirth**[3] □ noSB □ Macerated □ Fresh □ Intrapartum □ Missing

Sex □ Female □ Male □ Missing **BW** (gr) [4] ☐☐☐☐ **Apgar1/5 /10** ☐☐/☐☐/☐☐

Ventilated in delivery room [5] □ N □ Y □ Missing **Asphyxia** [6] □ N □ Y □ Missing

Postdelivery □With mother □ SCBU □ NICU □ Referred □ Obitorio □ Missing

Reason for referral □ medical complication □ surgical complication □No beds □ Other □ Missing

If baby in NICU /SCBU, add here BHT code ☐☐☐☐☐

COMPLICATIONS

RDS [7] □N □Y **Jaundice with ET** □N □Y **Sepsis** □N □Y

Other Infect(incl NEC) □N □Y **Major birth trauma** [8] □N □Y **Major malformation**[9] □N □Y

Neurol (seizure,IVH,HIE) □N □Y **Phototherapy > 24 h** □N □Y **Other** □N □Y

If other, add_____

Final □ Discharged □Disc with disabilities □ Death □ Referred □ LAMA

----------**NEWBORN (N2 if twins)**----------

Born □ Alive [1] □ Dead [2] **If stillbirth**[3] □ noSB □ Macerated □ Fresh □ Intrapartum □ Missing

Sex □ Female □ Male □ Missing **BW** (gr) [4] ☐☐☐☐ **Apgar1/5 /10** ☐☐/☐☐/☐☐

Ventilated in delivery room [5] □ N □ Y □ Missing **Asphyxia** [6] □ N □ Y □ Missing

Postdelivery □With mother □ SCBU □ NICU □ Referred □ Obitorio □ Missing

Reason for referral □ medical complication □ surgical complication □No beds □ Other □ Missing

If baby in NICU /SCBU, add here BHT code ☐☐☐☐☐

COMPLICATIONS

RDS [7] □N □Y **Jaundice with ET** □N □Y **Sepsis** □N □Y

Other Infect(incl NEC) □N □Y **Major birth trauma** [8] □N □Y **Major malformation**[9] □N □Y

Neurol (seizure,IVH,HIE) □N □Y **Phototherapy > 24 h** □N □Y **Other** □N □Y

If other, add_____

Final □ Discharged □ Disc with disabilities □ Death □ Referred □ LAMA

***DEFINITIONS (WOMAN)**

[1] **Gravida /Para/ Born alive:** fill this excluding current pregnancy/delivery (example: 3 pregnancies, 2 children, 1 stillbirth will be gravida 3, para 2, born alive 1)

[2] **Risk factors at time of delivery:** consider here the risk factors present at time of delivery and that can affect the delivery outcome. Examples:

- If the mother had severe anaemia but this was corrected before delivery, do not tick the severe anaemia box).
- If the mother had hypertension, pre-eclampsia, eclampsia, or hypothyroidism during current pregnancy , still tick the box even if the situation is under control
- If relevant cardiac problems present or even in the past, still tick the box.

[3] **Hypertension:** this is defined with a BP > 140/90

[4] **IUGR/SGA:** defined as weight < 10 centile of estimated weight-for-GA or < 10 centile for abdominal circumference (Bangladesh growth chart). IUGR/SGA is based on US estimate (if there was an indication for US, such as clinical signs suggesting IUGR, but US was not performed or uncertain, collect this information under “other or uncertain”.

[5] **Steroids:** Complete dose is Dexametason 8 mg /12 hrs for 3 doses –can you double if this is you national standard ? (last GL 6mg/ 12 h 48 h)

[6] **Induction**: as labour onset should be selected even in the case of **failed IOL** and subsequent CS, not "prelabour caesarean section" (note that this is accordingly to Robson classification)

[7] **Macrosomy at US:** defined as weight > 3500 grams or 90 Centile weight-for-GA

[8] **If IOL, mode of induction:** record here only procedures for IOL,i.e. until 4 cm dilatation

[9] **Analg:** record only drugs actually given (not just prescribed). Record paracetamol under “other”

[10] **Distocya 2nd stage**: CS at full dilatation

[11] **PPH** Minor (not severe not massive) Severe PPH (≥ 1000 ml *or* any bleeding with hypotension or tachycardia *or* blood transfusion) Massive (lost of ≥40% of blood volume, blood volume= body weight(kg)/12)

[12] **Major organ dysfunction:** as for Near miss definition **-**do not consider diabetes as major organ dysfunction (see following ANNEX 1)

[13] **Disabilities from pregnancy complications:** include here stroke, anaemia, post partum depression or other psychiatric disorders and other disabilities (not include preexisting problems such as GDM, hypertension, or hysterectomy)

[14] **Near Miss=** A maternal near-miss case is defined as “a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy” (*WHO 2011*). This implies either severe disease (severe PPH, severe pre-eclampsia, Eclampsia, sepsis, uterine rupture, severe complications of abortion), or critical interventions (admission UTI, intervention radiology, laparotomy, blood transfusion) or organ dysfunction (see ANNEX 1)

[15] **Post delivery duration stay:** count this in days. If admitted on 2 April and out day 3 April count this as 1 day if it is less than 24 h. If more than 24h , count this as 2 days

DEFINITIONS (NEWBORN)

[1] **Born alive**= fetus/baby of any GA and any birth weight showing any sign of vital activity (breath, cardiac, movements)

[2] **Born dead**= when not born alive; it includes stillbirth

[3] **Stillbirth** = macerated are fresh are based on clinical evaluation; intrapartum is a fetus where heart rate was perceived before delivery (and than lost after delivery)

[4] **Birth weight**=avoid approximation (use weight in grams)

[5] **Ventilated in delivery room=** not just stimulated, but ventilated (with bag or CPAP) for more than *10 seconds*

[6] **Asphyxia**= no spontaneous start of breathing, ventilation for at least *30 sec* and/or thoracic compressions as in international guidelines or any drug

[7] **RDS (Respiratory Distress Syndrome)**= tick this box for a baby with respiratory distress lasting more than 24 hours

[8] **Major birth trauma**= include here brachial plexus injury/arm palsy, fractures at any site, sub-aponeurotic (subgaleal) hemorrhage. Do NOT include here cephaloaematoma and caput succedaneum

[9] **Major Malformation**= do not include here minor malformation such as skin tags and pits, syndactyly, polydactyly, additional finger, PDA even if persistent.

[10] **Day of death**= for still birth use day zero

[12] **ANNEX 1 DEFINITIONS ORGAN DISFUNCTION (SOURCE: WHO MANUAL)**

Organ dysfunction / life-threatening conditions

☐ C0 **Cardiovascular dysfunction**
[shock, use of continuous vasoactive drugs, cardiac arrest, cardio-pulmonary resuscitation, severe hypoperfusion (lactate >5 mmol/L or >45mg/dL) or severe acidosis (pH<7.1)]

☐ C1 **Respiratory dysfunction**
[acute cyanosis, gasping, severe tachypnea (respiratory rate>40 bpm), severe bradypnea (respiratory rate<6 bpm), severe hypoxemia (PAO2/FiO2<200 O2 saturation <90% for ≥60min) or intubation and ventilation not related to anaesthesia]

☐ C2 **Renal dysfunction**
[oliguria non responsive to fluids or diuretics, dialysis for acute renal failure or severe acute azotemia (creatinine ≥300umol/ml or ≥3.5mg/dL)]

☐ C3 **Coagulation/hematologic dysfunction**
[failure to form clots, massive transfusion of blood or red cells (≥ 5 units) or severe acute thrombocytopenia (<50,000 platelets/ml)]

☐ C4 **Hepatic dysfunction**
[jaundice in the presence of pre-eclampsia, severe acute hyperbilirubinemia (bilirubin>100umol/L or >6.0mg/dL)]

☐ C5 **Neurologic dysfunction**
[prolonged unconsciousness / coma (lasting >12 hours), stroke, status epilepticus / uncontrollable fits, total paralysis]

☐ C6 **Uterine dysfunction / Hysterectomy**
[haemorrhage or infection leading to hysterectomy]

Appendix 2. Missing variables

	Total	Missing	% Missing
Maternal variables			
Age	7504	34	0.4
Work	7504	38	0.5
Education	7504	37	0.4
Para (number of children)	7504	34	0.4
Marital status	7504	38	0.5
Gravidas (pregnancies, including the ongoing)	7504	34	0.4
Born alive	7504	34	0.4
Gestational age at delivery	7504	47	0.6
Gestational age estimated with ultrasounds	7504	53	0.7
BMI	7504	53	0.7
Discharge	7504	35	0.4
Delivery	7504	32	0.4
Multiple pregnancies	7504	34	0.4
Pregestetional hypertension	7504	33	0.4
Gestetional 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
Chorionamnionitis	7504	36	0.4
Major fetal malformation	7504	36	0.4
IUGR/SGA	7504	36	0.4
Pregestetional diabetes	7504	35	0.4
Gestetional diabetes mellitus in diet	7504	35	0.4
Gestetional diabetes mellitus in drug therapy	7504	36	0.4
Maternal cardiac disease	7504	34	0.4
Maternal hypothiroidism	7504	37	0.4
Polihydramnios	7504	36	0.4
Oligohydramnios	7504	38	0.4
APH/major placentia previa	7504	37	0.4
Severe anaemia	7504	38	0.5
Other (risk factors)	7504	63	0.8
Steroids	7504	37	0.4

Previous CS	7504	38	0.5
If previous CS, trial of labour	7504	39	0.4
Presentation	7504	37	0.4
Labour onset	7504	36	0.4
Delivery mode	7504	37	0.4
If CS, type	7504	37	0.4
Indication of labour	7504	36	0.4
Mode of induction	7504	42	0.5
If operative delivery, indication	7504	38	0.5
Episiotomy	7504	43	0.5
Analgesia in labour	7504	43	0.5
3rd stage management	7504	39	0.5
Removal of placenta	7504	39	0.5
Operator delivery	7504	41	0.5
Perineal tears	7504	36	0.4
PPH	7504	38	0.5
Blood transfusion	7504	36	0.4
Cord collapse	7504	42	0.5
Uterine rupture	7504	42	0.5
Admission to ICU	7504	22	0.2
OT after delivery	7504	43	0.5
Sepsis/several infections	7504	44	0.5
Other complications	7504	45	0.6
Abruption placentae	7504	42	0.5
Amniotic fluid embolism	7504	42	0.5
Major organ dysfunction	7504	37	0.4
Hysterectomy	7504	36	0.4
DVT	7504	46	0.6
Final outcome	7504	42	0.5
Near miss	7504	20	0.2
Newborn variables ¶			
Born	7504	43	0.5
If stillbirth, fresh or macerated	7504	75	1.0

Sex	7504	51	0.6
Birth weight	7504	68	0.9
Apgar at 1’	7504	168	2.2
Apgar at 5’	7504	168	2.2
Apgar at 10’	7504	166	2.2
Ventilated in delivery room	7504	119	1.5
Asphyxia	7504	124	1.6
Post-delivery	7504	44	0.5
Respiratory distress syndrome	7504	114	1.5
Other infections	7504	110	1.4
Neurological complications (seizure, IVH, HIE)	7504	114	1.5
Jaundice with ET	7504	112	1.4
Major birth trauma	7504	120	1.6
Phototherapy for over 24 hours	7504	121	1.6
Sepsis	7504	113	1.5
Major malformation	7504	120	1.6
Other complications	7504	172	2.3
Final	7504	108	1.4

Abbreviations: APH= ante-partum haemorrhage; BMI= body Mass index; CS= caesarian section; DVT= deep vein thrombosis; ET= exchange transfusion; HIE= Hypoxic Ischemic Encephalopathy; ICU= Intensive care unit; IUGR=Intra-uterine growth restriction; IVH= intra-ventricular haemorrhage; OT=operating theatre; PPH= post-partum haemorrhage; SGA= small for gestational age.

¶ For multiple pregnancies, only data on the first newborn provided

BMJ Open

Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care

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Complete List of Authors:	Lazzerini, Marzia; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Senanayake, H.; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Mohamed , Rishard ; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Kaluarachchi, Athula; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo; University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka Fernando , Roshini; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Sakalasuriya , Anshumalie; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Ihsan , Fathima Reshma; Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo Saravanabhava , Namasivayam; District Hospital Thellippalai, Thellippalai, Sri Lanka Gamaathige , Nalin; De Soysa Hospital for Women, Colombo, Sri Lanka, Neonatology Unit Jayawardena , Madura ; Department of Obstetrics & Gynaecology, Faculty of Medical Sciences, University of Sri Jayawardenapura Gamage, Ruwan Vidana; Base Hospital, Balangoda Covi, Benedetta; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Wanzira, Humphey; WHO Collaborating Centre Trieste, Institute for Maternal and Child Health IRCCS Burlo Garofolo Businelli, Caterina; Institute for Maternal and Child Health IRCCS Burlo Garofolo, Department of Maternal and Newborn Health Piccoli, Monica ; Institute for Maternal and Child Health IRCCS Burlo Garofolo, Department of Maternal and Newborn Health
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	ADMINISTRATION & MANAGEMENT, International health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care

Short title: Individual patient maternal and newborn database to improve quality of care in Sri Lanka

Marzia Lazzerini,[1] Hematha Senanayake,[2,3] Rishard Mohamed,[2,3] Athula Kaluarachchi,[2,3,] Roshini Fernando,[3] Anshumalie Sakalasuriya,[3] Fathima Reshma Ihsan,[3] Namasivayam Saravanabhava,[4] Nalin Gamaathige,[5] Madura Jayawardena,[6] Ruwan Vidana Gamage,[7] Benedetta Covi,[1] Humphrey Wanzira,[1] Caterina Businelli,[1] Monica Piccoli.[1]

[1] Institute for Maternal and Child Health IRCCS Burlo Garofolo, Trieste, Italy.

[2] University Obstetrics Unit, De Soysa Hospital for Women, Colombo, Sri Lanka

[3] Faculty of Medicine, Department of Obstetrics & Gynaecology, University of Colombo, Colombo, Sri Lanka.

[4] District Hospital Thellippalai, Thellippalai, Sri Lanka.

[5] Neonatology Unit, De Soysa Hospital for Women, Colombo, Sri Lanka

[6] Department of Obstetrics & Gynaecology, Faculty of Medical Sciences, University of Sri Jayawardenapura, Nugegoda 10250, Sri Lanka

[7] Base Hospital, Balangoda, Sri Lanka

Authors' e-mail contacts

ML: marzia.lazzerini@burlo.trieste.it

HS: senanayakeh@gmail.com

RM: mrishard@obg.cmb.ac.lk

AK: akaluarachchi@obg.cmb.ac.lk

RF: ragynobs2009@gmail.com

AS: sakalasuriyasaritha43@gmail.com

FRI: resh.ihsan798@gmail.com

NS: sarabhava@yahoo.com

NG: nalinnicu@gmail.com

MJ: madurammj@yahoo.com

RVG: ruwangamage21@yahoo.com

BC: benedetta.covi@burlo.trieste.it

HW: humphey.wanzira@burlo.trieste.it

CB: caterina.businelli@burlo.trieste.it

MP: monica.piccoli@burlo.trieste.it

Corresponding author
Marzia Lazzerini DTMH, MSc, PhD
WHO Collaborating Centre for Maternal and Child Health
Institute for Maternal and Child Health IRCCS Burlo Garofolo
Via dell'Istria 65/1, 34137, Trieste, ITALY
Email: marzia.lazzerini@burlo.trieste.it

ABSTRACT

Objectives This study was aimed at piloting a prospective individual patient database on hospital deliveries in Colombo, Sri Lanka, and at exploring its use for developing recommendations for improving quality of care (QoC).

Design Observational study.

Setting De Soysa Maternity Hospital, the largest referral hospital for maternity care in Sri Lanka.

Data collection and analysis From July 2015 to June 2017, 150 variables were collected for each delivery using a standardised form and entered into a database. Data were analysed every eight months and the results made available to local staff. Outcomes of the study included: technical problems; data completeness; data accuracy; key database findings; use of data.

Results 7504 deliveries were recorded. No technical problem was reported. Data completeness exceeded that of other existing hospital recording systems. Less than 1 % data were missing for maternal variables, and less than 3% for newborn variables. Mistakes in data collection and entry occurred in 0.01% and 0.09% of maternal and newborn data respectively. Key QoC indicators identified in comparison to international standards were: relatively low maternal mortality (0.053%); relatively high maternal near-miss cases (3.4%); high rate of induction of labour (24.6%), caesarean section (30.0%) and episiotomy (56.1%); relatively high rate of preterm births (9.4%), low-birth-weight rate (16.5%), stillbirth (0.97%), and of total deaths in newborn (1.98%). Recommendations developed focused on the key indicators identified and included the use of a checklist to standardise case management, training, clinical audits, and more information for patients. Based on this experience, a list of lessons learnt was drawn.

Conclusions The study shows that the implemented system of data collection can produce a large quantity of reliable information. Most importantly, this experience provides an example on how database findings can be used for discussing hospital practices, identifying gaps, and to agree on recommendations for improving QoC.

Article summary: strengths and limitations of this study

- The study has the strength of reporting on the first individual patient database for comprehensive prospective data collection on births in Sri Lanka. Very few individual patient databases exist in general in low and middle-income countries (LMIC).Although this is a single–center study, it has potential for use as a model for future scale up.
- As additional strengths, the study has the merit of reporting both technical feasibility related to the database implementation, quality of data (ie, data completeness and accuracy), lessons learned and actual use of data – the latter three being often neglected issues.
- Limitations of this study include that within the project timelines (2 years), it was not possible to follow up the impact of the recommendations developed.

Keywords

Quality of care; Health Information system; mothers and newborns.

Disclosure of interests

None competing interest

List of abbreviations

LMIC = low and middle-income countries

MMR= maternal mortality ratio

QoC= Quality of Care

WHO = World Health Organization

BACKGROUND

The availability of an actionable health information system is one of the key components of the World Health Organisation (WHO) framework for improving the quality of maternal and newborn health care (1,2) and one of the recommended cross-cutting actions in the WHO Strategy for Ending Preventable Maternal Mortality (EPMM) (3). According to WHO standards (2), "the health information systems should enable using data to ensure timely actions to improve the care of every woman and newborn". More specifically, a health facility should have mechanisms for data collection, analysis and feedback as part of the activities for monitoring and improving performance around the time of childbirth (2).

However, estimates have highlighted major gaps in data collection even on key indicators: only one third of countries have the capacity to count or register maternal deaths (3,4) and less than two fifths of all countries have a complete civil registration system with accurate attribution of the cause of death (3,5). Quality of data is also an area of significant concern: according to a WHO review, although most countries are using some core indicators to monitor performance in maternal and newborn care, virtually no low- or lower-middle-income country has a full system of data sharing and transparent quality control in place (6). 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 interpreting the observed outcomes (7).

Sri Lanka is a lower middle-income country (8). Since the end of the civil war in 2009, the economy has grown on average at 6.2% per year (8), transiting from a predominantly rural-based economy to one that is urban-oriented around manufacturing and services. Major progress has been made in maternal healthcare in past decades: according to the last estimates the reported maternal mortality ratio (MMR) is relatively low (33.7/100.000) (9). However, no significant improvement in the MMR has been observed in the last 10 years (8-11). The latest national Maternal Mortality Review has shown that 50% of maternal deaths are from direct causes, with preventable causes, such as post-partum haemorrhage and sepsis, being among the top five causes of death (9). Almost 80% of all women died in hospitals (9), where specialized facilities are available, thus suggesting possible gaps in the quality of care provided (9). Inappropriate practices are suggested also by other indicators, such as the rising rate of caesarean section (CS) (12), peaking above 50% in selected facilities (12). The estimated rate of induction of labour in Sri Lanka is currently among the highest in Asia (35.5%) and the rate of inductions without medical indication is reported to be 27.8% (13).

Presently in Sri Lanka the health information system collects data only on selected maternal and newborn indicators, in an aggregate form. The objective of this study was to pilot a system for collecting prospectively for each delivery, a large number of maternal and newborn variables in the largest maternity unit in Sri Lanka,. The paper also aimed at reporting on the use of data for developing recommendations to improve the quality of hospital care in a participatory manner.

METHODS

Population and setting

The study was conducted at the De Soysa Hospital for Women in Colombo, the largest referral hospital for maternity care in Sri Lanka. Previous collaborations among the involved institutions provided the opportunity to establish an international working group dedicated to improving the quality of maternal hospital care. It was agreed that establishing a system of data collection and fostering data use were two necessary steps toward this direction. In June 2015, a database for routinely collecting individual patient data was implemented in wards 3 and 15, the two wards of the University Obstetrics Unit in the hospital, where about half of the total deliveries of the hospital take place. All deliveries occurring in these two wards, with no exclusions, were to be entered in the database. This paper reports findings of the first 24 months of data collection, from July 2015 to June 2017.

Data collection tools

For each delivery, data were collected in a standardised form ("Yellow Form") and entered in a database. The "Yellow Form" was two pages long (**Appendix 1**), and recorded 150 variables for each delivery. These included demographic and socio-economic data of the woman (8 variables); characteristics of pregnancy and risk factors (28 variables); process of care during birth (60 variables); maternal health outcomes (31 variables); newborn health at birth and during hospitalisation, process of care and health outcomes (23 variables). The database was developed using Epidata (14), a free software that allows for inclusion of internal checks. Data were collected and entered in the database by trained data collectors.

Data quality assurance procedures

The Yellow Form was developed through a participatory approach with local staff. The team involved included: six senior obstetricians from De Soysa Hospital and other hospitals in Sri Lanka, eight midwifery-qualified nurses, two Registrars in obstetrics and gynaecology, one neonatologist, one Registrar in neonatology and two data collectors. Two external researchers (one obstetrician and one epidemiologist) participated as facilitators. Variables were selected based on the literature (1,2,6,7) and on previous experience of the team, so that it would allow answering

research questions and monitoring trends over time. Case-definitions were derived from international literature (15-18). Instructions on how to fill the form and specific case definitions were developed in parallel with the development of the form and embedded into it (Appendix 1).

All relevant information was extracted from the medical files. We chose to use a paper-based system of data collection since it allowed checking for internal consistency of data prior to being entered n the database.

The data collection form, the instructions on how to fill it and how to transfer information into the database were field-tested. Procedures of data collection were field tested to evaluate the following domains: if the sequence of data in the form was appropriate; if case definitions were clear; if data collectors were able to fill the form and enter data in the database; if time needed to fill the form and enter data in the database was acceptable to allow routine data collection; if there were sources of systematic error or bias; if there was any technical problem. Data collectors were young medical doctors who were trained on the standard operating procedures (SOP) of data collection and data entry and supervised over time.

The database was designed in a way that the interface for data entry was almost identical to the "Yellow Form". To further minimise data-entry errors, the database contained 137 internal automatic validation rules, aiming at minimising errors in biological plausibility of data (i.e. normal ranges), data completeness and internal consistency.

For the initial period of data collection for each case of delivery two data collectors independently filled a Yellow Form and data were cross-checked to evaluate consistency. This procedure was continued until when errors in data collection were consistently low (ie. below 0.02%; this was achieved in a period of about 1 month). Subsequently, data completeness and accuracy in data collection and data entry were monitored by an external independent data monitor who randomly reviewed 5% of forms and 5% of the entered cases. Missing cases or errors in data collection/entry were corrected in real time. Data were also externally monitored for completeness and internal consistency at about four month intervals.

Data analysis and use

Data were analysed at intervals of eight months using a standardized plan for analysis, pre-defined and agreed among partners. This included: a descriptive analysis of all the key variables in the database; an analysis of CS groups according to the Robson Classification (17,18) and other minor secondary analyses as suggested by the finding of the primary analysis and as requested by partners. Data were analysed by the external team (WHO Collaborating Centre) and made

available as tables and graphs to the local staff at the De Soysa Hospital. Data were provided with the purpose of being locally discussed in dedicated workshops and used to develop recommendations to improve the quality of care.

Outcomes

Outcomes of the study are reported in Box 1 and described below. Technical problems in data collection were defined as any technical problem occurring with the use of the database (either with the software or with the computer). These had to be notified by data collectors in real time to the local coordinator and to the external team.

Database completeness was checked by an independent assessor by comparing the number of cases entered in the database with data in the official hospital registers and specifically with the following eight data sources: i) birth register; ii) intensive care unit (ICU) admissions register; iii) operating theatre (OT) register; iv) neonatal intensive care unit (NICU) admissions register; v) Special Care Baby Unit (SCBU) admissions register; vi) maternal death reviews; vii) perinatal mortality and morbidity statistics; viii)) monthly reports.

The number of missing cases for each variable was calculated as the number of missing cases in the database out of the total expected entries for that variable.

Accuracy in data collection was measured by the number of variables correctly recorded in the yellow form when compared to the original medical files. Accuracy in data entry was measured by the number of variables correctly recorded in the database compared to the yellow forms. Both accuracy in data collection and data entry were assessed by an external independent data collector who randomly checked 5% of forms and 5% of entered cases, respectively.

Database findings included a descriptive analysis of the key variables as agreed among partners. Data on multiple pregnancies were not included in this primary descriptive analysis of newborn outcomes. Use of data for quality improvement purposes included any action-oriented recommendation generated from review of the data outcomes by researchers and partners

Box 1. Outcomes of the study

i) **Technical problems:**
   - any type of technical problem in implementing and using the database.

ii) **Data completeness:**

- number of cases entered in the database versus data in the official registers;
- number of missing cases for each variable in the database.

iii) **Data accuracy:**

- number of correct variables in the yellow form versus the original medical files;
- number of correct variables in the database compared to the yellow forms.

iv) **Database findings:**

- descriptive analysis of the key variables as agreed among partners.

v) **Use of data for quality improvement purposes:**

- any action-oriented recommendation generated from review of the data outcomes by researchers and partners.

Ethical considerations

The study 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. Informed consent was not requested by the Ethics Review Committee.

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 (16) The development of recommendations for improving the quality of care took into account the importance of effective communication with patients.

RESULTS

Technical problems

No technical problems occurred. The data collectors reported that there were no technical difficulties in managing the database.

Data completeness

Table 1 reports the number of total cases in the database when compared to other official hospital data sources. Numbers were matching, except for the cases of hysterectomies, for which the database appear to contain one additional case (verified as actually being a real case).

Table 1. Number of cases in the database compared to hospital registers and other official sources of data

	Database	Hospital registers	Source of data for comparison
Maternal indicators			
Total deliveries	7504	7504	Birth register
Maternal deaths	4	4	Maternal deaths reviews
Admission to ICU	239	239	ICU register
PPH	147	147	Birth register
OT after delivery	11	11	OT register
Hysterectomy	22	21	OT register
Newborn indicators [1]			
Stillbirth	82	82	Birth register, monthly reports
Admission to NICU	105	105	NICU register
Admission to SCBU	1121	1121	SCBU register
Neonatal deaths after birth	81	81	Birth register + NICU and SCBU registers + perinatal mortality and morbidity statistics

Notes: [1] Including also the second twin in multiple pregnancies.

Abbreviation: ICU= Intensive care unit; NICU= Neonatal intensive care unit; OT= operating theatre; PPH= post-partum haemorrhage; SCBU= semi-intensive baby unit

The number of missing variables is reported in **Appendix 2**. Missing data were less than 1% for all maternal variables, and less than 2% in all but two newborn variables.

Data accuracy

Random checks by an independent data monitor on 5% of Yellow Forms and 5% of entered cases revealed that mistakes in data collection in the forms occurred in 0.01% of cases, while mistakes in data entry in the database occurred in 0.09% of cases.

Database findings

Tables 2,3 and 4 report the descriptive analysis of key indicators in the database. Overall, during the two years of the study period, 7504 deliveries were recorded (Table 2). In terms of socio-demographic characteristics, most women belonged to the following categories: 4253 (56.7%) were 25 to 34 years old; 6028 (80.3%) had secondary education; 6253 (83.3%) were housewives;

5231 (69.7%) had a normal nutritional status. Overall, in 4182 (55.7%) of deliveries there was either a maternal or foetal medical condition or a risk factor that indicated operative delivery or a negative outcome. The most prevalent among these were: gestational diabetes (13.4%), pre or post-term delivery (12.9%), and previous CS (12.7%). Overall 2870 (38.2%) were primigravidae. Analysing the population according to Robson classification, the most prevalent groups were: group 3 (multiparous, single cephalic, at term in spontaneous labour), (27.1%); group 1 (nulliparous, single cephalic, at term, in spontaneous labour) (23.2%); group 2a (nulliparous, single cephalic, at term, induced), (12.8%); group 5 (previous CS, single cephalic at term), (10.9%).

Table 2. Maternal characteristics

	n (N=7504)	%
Age categories		
< 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
Missing		
Number of pregnancies[1]		
1	2870	38.24
2	2313	30.82
≥3	2285	30.47
Missing	34	0.45
Education		
None	23	0.31
Primary	235	3.13
Secondary	6028	80.33
Higher	1181	15.74
Missing	37	0.49
Work		
Not reported by the mother	77	1.03
Working	1136	15.14
Housewife	6253	83.33
Missing	38	0.51
Marital status		
Married	7350	97.95
Unmarried	96	1.28
Living together	20	0.27
Missing	38	0.51

Nutritional status[2]		
Underweight	670	8.93
Normal	5231	69.71
Overweight	1110	14.79
Obese	440	5.86
Missing	53	0.71
Medical conditions /risk factors (any) [3]	4182	55.73
Gestational diabetes, total	1002	13.36
On medical nutrition therapy	417	5.56
On drug therapy	585	7.80
Gestational age <37 >= 41weeks	966	12.87
Previous CS	956	12.74
Hypertensive disorders of pregnancy, any	506	6.74
Pre-gestational hypertension	168	2.24
Gestational hypertension	179	2.39
Pre-eclampsia not severe	78	1.04
Pre-eclampsia severe	69	0.92
Eclampsia	12	0.16
IUGR at ultrasound	504	6.72
Obesity	440	5.86
Breech/transverse/oblique lie	339	4.52
Pre-gestational diabetes	266	3.54
Maternal cardiac disease	234	3.12
Fetal conditions, other	223	3.10
Maternal hypothyroidism	219	2.92
Maternal age >40	224	2.9
Oligohydramnios	131	1.75
APH	112	1.49
Polyhydramnios	96	1.28
Multiple pregnancies	84	1.12
Severe anaemia	40	0.53
Chorioamnionitis	11	0.15

Notes: [1] Including the ongoing pregnancy. [2] As defined by National Guidelines in Sri Lanka. [3] Any of the medical conditions/risk factors described in the following rows.

Abbreviations: APH= antepartum haemorrhage; CS= cesarean section; IUGR= intrauterine growth restriction.

In terms of process indicators and maternal outcomes (**Table 3**), 1849 (24.6%) of women had their labour induced, and 2251 (30.0%) had a CS. Rate of vaginal birth after CS (VBAC) was 17.1%. Episiotomy was performed in 4213 (56.1%) of women. In terms of health outcomes, there were

four cases of maternal death (0.053%). Overall 254 (3.38%) of cases were identified as maternal near miss. Postpartum haemorrhage (any severity) occurred in 147 (1.9%) women, with 39 (0.52%) women having a severe or massive haemorrhage. Overall there were 22 (0.29%) cases of hysterectomy. During the study period there were no cases of uterine rupture.

Table 3. Birth process indicators and maternal outcomes

	n (N=7504)	%
Labour onset		
Spontaneous	4726	62.98
Induction	1849	24.64
Pre-labour CS	893	11.90
Missing	36	0.48
Mode of delivery		
Vaginal spontaneous	4906	65.38
Vaginal operative	310	4.13
Caesarean section	2251	30.00
Missing	37	0.49
Caesarean section		
In spontaneous labour onset	927	19.61
In induction of labour	441	28.85
Episiotomy	4213	56.14
Key maternal outcomes		
Maternal deaths	4	0.05
Admission to ICU	239	3.18
Near-miss cases [2]	254	3.38
PPH	147	1.96
OT after delivery	11	0.15
Hysterectomy	22	0.29
Uterine Rupture	0	0
Sepsis	29	0.39
DVT/PE	2	0.03
Abruptio placentae	21	0.38
Amniotic fluid embolism	0	0
Perineal tears III-IV degree	17	0.23

Notes: [1] As for Robson's classification (17); [2] As for WHO classification (15)

Abbreviations: CS= caesarian section; DVT= Deep vein thrombosis; ICU= Intensive care unit; NICU= Neonatal intensive care unit; OT= operating theatre; PE= pulmonary embolism; PPH= post-partum haemorrhage.

The analysis of the characteristics of the neonates and outcomes (**Table 4**) pointed out the following key indicators: 73 (0.97%) were stillborn; 708 (9.4%) were born preterm (i.e. before 37 weeks of gestational age); 1243 (16.6%) were of low birthweight (i.e. below 2500 grams); 173 (2.3%) were ventilated for more than 10 seconds in the delivery room. Overall 917 (12.2%) newborns had at least one complication during their hospital stay, and among these the most frequent was respiratory distress syndrome (3.7%). Overall, 101 (1.62) newborns had major malformations. Overall 148 (1.98%) were either born dead or died while in hospital; among these cases (death either before or after birth), 55.1% had major malformations.

Table 4. Newborns' characteristics and outcomes

NEWBORN	n (N=7504) [1]	%
Sex		
Female	3644	48.56
Male	3792	50.83
Missing	68	0.91
Gestational age (weeks + days)		
< 33 + 6	223	2.96
34 to 36+ 6	485	6.19
37 to 40+ 6	6491	86.50
> 41	258	3.43
Missing	47	0.62
Weight at birth		
<1499	149	1.99
1500 to 1999	183	2.44
2000 to 2499	911	12.14
2500 to 3499	5365	71.50
3500 to 4000	724	9.65
>4000	104	1.39
Missing	68	0.91
Stillbirth, total	73	0.97
Macerated	42	0.56
Fresh	27	0.36
Missing	4	
Ventilated in delivery room for more than 10 seconds	173	2.34
Asphyxia	62	0.84
Post-delivery		
With mother	6164	82.14
SCBU	1105	14.73

NICU	96	1.28
Referred	9	0.12
Death	75	1
Missing	11	0.07
Neonates with any complication	917	12.22
Complication		
RDS	276	3.73
Infection, other than sepsis	121	1.35
Major malformation	101	1.62
Neurological [2]	38	0.50
Sepsis	28	0.38
Major Birth Trauma	16	0.21
Severe jaundice with ET	15	0.20
Others [3]	232	3.09
Final outcome		
Discharged	7204	96.00
Discharged with disabilities	4	0.05
Death (including stillbirths)	148	1.98
Referred	54	0.72
LAMA	15	0.20

Notes: [1] Data on multiple pregnancies were not included in this primary analysis. [2] Seizures, ventricular haemorrhage and other neurological complications. [3] Most frequent reported conditions in this class were other respiratory problems (e.g. apnoea, meconium aspiration syndrome, pulmonary hypertension), gastrointestinal problems (eg, bleeding), minor jaundice.

Abbreviations: ET= exchange transfusion; LAMA= Left against medical advice; NICU=neonatal intensive care unit; RDS= respiratory distress syndrome; SCBU=semi-intensive care baby unit.

Use of data

Data entered in the database were analysed at intervals of eight months and the results made available to the local coordinator. Findings of the database were presented and discussed in two large workshops with staff from De Soysa Hospital and from other large maternity units in Sri Lanka. Participants to these meetings included: senior obstetricians, neonatologists, postgraduate trainees and other middle level medical personnel, nurses, midwives and other staff. About 50 people participated to each workshop.

During these meetings, key indicators suggesting possible gaps in quality of care were identified, and recommendations for improvement were discussed and agreed upon (**Table 5**). Indicators identified as requiring actions to improve quality of care were: high rate of induction of labour (24.6%), of CS (30.0%) and episiotomy (56.1%); relatively high maternal near-miss cases (3.4%);

relatively high rate of preterm births (9.4%), low-birthweight rate (16.5%), stillbirth (0.97%), and of total deaths in newborns (1.98%). Recommendations developed focused on the key indicators identified and included the use of checklists to standardise case management, training, clinical audits, and more information for patients.

Smaller meetings of technical working groups were also organised, to develop and agree on specific tools and procedures to put in practice the recommendations agreed (such as: developing the information pamphlet on VBAC, and the checklists to review obstetric emergencies).

Table 5. Use of data for improving quality of care

Key Indicators identified	Agreed recommendations for quality improvement
Maternal - High rate of induction of labour (24.6%), with many woman in Robson group 2a (nulliparous, single cephalic, at term, induced) - High rate of CS (30.0%), relatively high prevalence of group 5 (multiparous with previous CS) - Low rate of VBAC (17.1%) - High rate of episiotomy (56.1%) - Relatively high rate of near-miss cases - Low reported rate 3rd-4th degree perineal tears	• Checklist to be filled by the doctor in charge for each individual case of induction of labour, specifying indications, methods, timing. Data to be reviewed regularly. Consultant to make decision on IOL • Dedicated workshops on CS, discussing local data and international recommendations (16,17). • Training workshops to help improve the CTG interpretation skills. Stickers to help CTG interpretation. Improved communication regarding CTG interpretation from medical officers to Consultants using "WhatsApp/Viber". • Training workshop to develop a consensus on how to manage foetal distress and poor progress of labour. • Establishment of a nurse-lead VBAC counselling clinic and development of a VBAC leaflet for patients. Education for staff, including community midwives, on methods of counselling. • Implementation of a selective episiotomy policy; training of midwives and medical staff on appropriate indication for episiotomy. • Doctors to identify clearly near-miss cases. Establishment of a system for regular internal review of near-miss cases. • Development of checklists for systematic analysis of obstetric emergencies against international standards of care. • Training of midwifes on checking and reporting the perineum status after delivery.

Newborn - High rate of preterm births (9.4%) - High rate of low birth weight (16.5%) - High rate of stillbirth (0.97%) - High rate of newborns with complications (12.2%) - High rate of total deaths in newborns (1.98%)	• Improve diffusion of national and international guidelines of antenatal care. • Improve prenatal ultrasound diagnosis of SGA and of malformation. • Development of checklist for systematic analysis of newborn care against international standards of care. • Training on newborn resuscitation.

Abbreviations: CTG: cardiotocography; SGA: small for gestational age; VBAC: vaginal birth after cesarean section.

Lessons learned

Results of this study were discussed among partners and lessons learned and future actions were articulated (**Box 2**). Overall the key lesson was that data collection was feasible, that it resulted in a large amount of data with an acceptable quality, and in the development of recommendations for quality improvement; however, use of data could be further improved. Drawing on this experience and on other experiences reported in literature (7,18-23), some concrete actions that may further help improving use of data in the future were discussed (**Box 2**). Although a simplified version of the Yellow Form was discussed, it was difficult to identify what variables to exclude: despite the data collection form including 150 variables, when findings were discussed clinicians tended to request even more additional information.

Box 2. Lessons learned and way forward

Key lessons

1. Data collection was feasible and resulted in a large amount of data with an acceptable quality and in the development of some recommendations for quality Improvement (QI); however, use of data could be further improved.
2. Standard Operating procedures (SOP) and regular data monitoring and evaluation (M&E) was crucial.
3. One data collector was sufficient to collect data in the study setting, but one additional person was needed to ensure regular M&E.
4. Ensuring concrete use of data for QI should not be taken for granted and it requires building a system of coordination to facilitate data diffusion and discussion.
5. In general, clinicians without training or without a particular interest in QI methods, showed low interest in using statistical data for QI purposes, and were more attracted by new technologies. Appropriate involvement of staff (e.g. training, participation to projects, assignment of specific responsibilities), is needed to develop a local team who will act as drivers in QI.
6. It is difficult to find the golden balance between a “simple” data collection form (i.e. collecting few variables) and an “informative” data collection form that satisfies clinicians (i.e. collecting a large

number of variables).

Way forward

1. The "Yellow Form" could be incorporated into the patient file; data collection could be made part of the duties of the hospital staff in charge of each single case. This should facilitate sustainability and may further improve quality of data.
2. All staff involved in data collections should be made aware of the standard case definitions.
3. Regular local M&E should be ensured to avoid drops in data quality.
4. Adding in the database functions of automatic reporting may probably increase local ownership and facilitate use of data.
5. Other forms of diffusing data, rather than workshops, may be explored, such as use of posters or newsletters.
6. With the number of recommendations increasing, the establishment of a technical group for QI within the hospital, with clear roles and responsibilities becomes mandatory to ensure their implementation.
7. To ensure translation into actions of recommendations arising from data discussion, a system for regular follow up should be put in place. This will probably be more effective if embedded in a national system for quality assurance in maternal and child health.

Abbreviations: M&E= monitoring and evaluation; QI= quality improvement; SOP= standard operating procedures.

DISCUSSION

This is the first individual patient database established for comprehensive prospective data collection on births in Sri Lanka. From a review of existing literature, we could identify very few databases that prospectively collected a large number of individual patient variables on hospital births. Of these, most data collection systems were established in high-income countries, or in upper middle-income countries such as Brazil, Peru and South Africa (19-21). We could identify only two systems for prospective collection of individual maternal and newborn variables across the time of birth in low or low-middle income countries (22,23) and both collected data from a single facility (22-24). In respect to the average hospital administrative data, even in high income countries, the dataset implemented in this pilot study contains a large number of variables, such as maternal risk factors, that can be used for evaluating the case mix and for adjusting for confounders (7,21).

Most importantly, routine use of data to improve case management and organization of care is still not a common practice, even in countries with well-established data collection systems (7). Despite there being some good examples of how routine data collection systems are used to shape policies in low and middle-income countries (LMIC), for example in the paediatric field (25), these

are very limited in number. As such, the main value of this study is that it provides an example of how data can be used for discussing and agreeing on recommendations for improving the quality of care.

This study was aimed at reporting the feasibility of implementing an accurate system of data collection and is not at an extensive presentation of the database findings. Additional analyses (such as a detailed analysis of practices and outcomes related to CS according to the Robson Groups (26), and other multivariate and sub-group analyses) will be the object of future publications. Many of the findings of the descriptive analysis reported in this paper such as the rate of maternal deaths, induction of labour and low birth weight babies - are not surprising and are rather in line with other country reports (5,8-13,24,27-31). Results reflect the specificity of the setting: De Soysa Hospital is the largest referral maternity hospital in Sri Lanka, and case mix, as well as local practices, do not necessarily represent the average in the country. For example, the rate of induction of labour, CS and near-miss cases, although being relatively high when compared to other reports in international literature, are below the national reported average (12,13,27,30). Rate of stillbirth and newborn deaths after birth may appear high when compared to national statistics (the most recent national report provides a figure of stillbirth rate of 5.9/1000 (32)). This may be due to the case mix, with 55.7% of pregnancies at the De Soysa Hospital presenting at least one medical condition/risk factor for operative delivery/negative outcome. Additionally, about half of cases of stillbirth had a major malformation. Termination of pregnancy is legally allowed in Sri Lanka only to save the life of the mother, but not for any condition of foetal impairment, not even major malformations (33). The rate of postpartum haemorrhage appeared to be lower than what would be expected for LMIC according to international literature (34), leading us to double check this statistic in the hospital registers and found to be correct (Table 1). The low prevalence of DVT and PE may be due to the fact that these events are less frequent in the Asian population compared to others, or to under-reporting (35,36). It must be acknowledged that for most of the variables collected - such as risk factors, episiotomy, reasons for induction of labour/operative deliveries, newborn complications, etc, there is no other system of official data in the whole country. The main merit of the database was that it provided to hospital staff, for the first time in Sri Lanka, a large number of objective indicators on local practices and outcomes, thus providing an evidence base for discussing the appropriateness of the care delivered at the facility level. Although recommendations developed may not cover all actions needed to improve quality of care, they were agreed locally and as such represent an important step forward in the local culture of quality improvement and in the local ownership of the whole quality improvement process.

In the future, the database will be used to analyse more specific topics, such as the appropriateness of hospital practises related to CS or to induction of labour (these analyses are

already ongoing, and will be reported in future publications). Findings of such analyses may inform the development of additional and mores specific recommendations to improve quality of care. Additionally, the database may provide a way of monitoring trends over time regarding patients' characteristics, hospital practices (i.e., CS rates, and indications for CS) and health outcomes.

Given the paucity of efficient data collection systems in LMIC (6,7), lessons from this study may be of interest to other researchers and policy makers. However, in generalising the findings of this study to other settings, key characteristics of this project must be acknowledged. First, in this study dedicated staff was appointed for data collection and entry. Second, supervision was provided, and data collection was monitored regularly. Data collection that proved accurate under these conditions may fail to have good results if these minimum conditions are not guaranteed, especially if monitoring is not ensured.

The experience accumulated so far in this pilot experience may help scaling up the data collection system in other maternity units in the country. The Sustainable Development Goals (SDG) in countries with low baseline maternal mortality, such as Sri Lanka, include "achieving access to quality essential healthcare services" (37). Target-setting is accompanied by the need for improving measurement approaches and data quality to allow more accurate tracking of country progress as well as causes of death (38). The implementation of a system for individual patient data collection on hospital deliveries in other maternity units in Sri Lanka will allow comparison of several variables (patient characteristics, process outcomes and health outcomes) among different geographical regions, settings, over time. Data generated could be used to improve overall national practices. The data collection form utilised in this project was designed together with professionals from different maternity units in Sri Lanka, therefore, when extending it to other facilities, only minor adaptations may be required. However, scaling up will require a good mechanism for coordination, besides further testing to identify the optimal methods for data collection in other settings (such as smaller maternity units). Furthermore, it will be crucial to establish functional mechanisms (such as regular data audits) to ensure that information generated from the database are actually used in practice to improve quality of health care. As for many other types of data collection, the main problem may be that data are not actually utilised (7).

Limitations of this study include that, 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 assess changes in key indicators over time. Although the study was carried out in a single-centre, it has the merit of reporting both technical feasibility related to the database implementation, quality of data (completeness and accuracy), lessons learned, and, actual use of data – the latter three being often neglected issues.

CONCLUSIONS

This pilot study on the implementation of an individual patient database on hospital deliveries in Sri Lanka proved that in this setting a large quantity of data could be collected accurately. The study is an example on how data can be used to discuss hospital practices, identify gaps in quality of care, and agree recommendations for improving the quality of hospital case management. More implementation research is needed to identify the best model for scaling up data collection to other maternity units in Sri Lanka and in other low-middle income countries. More research in general should report on the actual use of data, and should aim at identifying effective ways of translating recommendations generated from data into practice.

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Data sharing statement

All key data are provided in the paper. Additional details can be provided by the contact author upon request.

Author contributions

ML, HS and MP conceived the study and procured funds

ML, HS, RM, NS, NG, MJ, RVG, and MP developed the data collections tools

AK, RF, AS and FRI collected data

BC, HW, CB 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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Supplementary files

Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care

List of files

Appendix 1. YELLOW FORM

Complete this chart AT DELIVERY (white part) and AT DISCHARGE (dotted part) □**Soysa** □**Other**
If other hosp, add name:_____

Adm (dd/mm/yy) ☐☐☐☐☐☐ **Deliv** ☐☐☐☐☐☐ **Disch** ☐☐☐☐☐☐ **BHT 15-** ☐☐☐☐☐

Age (years) ☐☐ **Education** ☐No schooling ☐Primary (Grades 1-6) ☐Secondary (Grades 6-10) ☐Higher
Working status □ No data □ Working □ Housewife **Marital status** □ Married □ Unmarried □ Unmarried living together

GA at delivery (wks/days) ☐☐/☐ **GA estimated with US** ☐N ☐Y ☐Missing

Gravida (pregnancies)[1] ☐☐ **Para**[1] ☐☐ **Born alive**[1] ☐☐ ([1] For para / born alive – exclude current pregnancy)

BMI at booking □ Underweight (< 18.4) □ Normal (18.5 - 22.9) □ Overweight (23 - 27.4) □ Obese (> 27.5)

(Risk factors at time of delivery-check all) [2]

Multiple pregn	□N □Y	**PreGes Hyperten**[3]	□N □Y	**Ges Hyperten**[3] **no proteinur**	□N □Y
Pre-ecl NOT SEV	□N □Y	**Pre-ecl SEV**	□N □Y	**Eclampsia**	□N □Y
Chorioamnionitis	□N □Y	**Major fetal malformation/s**	□N □Y	**IUGR/SGA**[4]	□N □Y
Pregeste Diab	□N □Y	**GDM in diet**	□N □Y	**GDM, in drug therapy**	□N □Y
Maternal-cardiac disease[2]	□N □Y	**Maternal hypothiroidism**	□N □Y	**Polihydramnios**	□N □Y
Olidramnion	□N □Y	**APH/major plac previa/accret**	□N □Y	**Severe Anaemia (Hb<7)**	□N □Y
Other	□N □Y				

If Other maternal conditions, specify_____
If Other fetal conditions, specify_____
If Other, specify_____

One tick only

Steroids[5]	□ N	□ complete	□ incomplete	□ dose unclear
Previous CS	□ N	□ Y	□ Missing	Number_____
If prev CS, trial of labour	□ No previous CS	□ N	□ Y	
Presentation	□ Cephalic	□ Breech	□ Other	□ Missing
Labour onset	□ Spont	□ Induc (even if failed)[6]	□ PreLabCS[6]	□ Missing
Delivery mode	□ Vag spont	□ Vag forcep/ventuse	□ CS	□ Missing
If CS, type	□ No CS	□ Emerg	□ Elect	□ Missing

If IOL, main indication given (one tick only)

□ 1 No IOL	□ 2 Post-term	□ 3 Prelab rupture membs	□ 4 Diabetes on diet
□ 5 Diabet on insulin/metform	□ 6 Macrosomy at US[7]	□ 7 IUGR/SGA [4]	□ 8 Multiple pregnancies
□ 9 Maternal Age > 40 y	□ 10 Hypert/Preecl/Eclam	□ 11 Cardiac disease	□ 12 Oligoidramn
□ 13 Other add_____	□ 14 Prolonged latent phase/ painful contractions not in labour		□ 0 Missing

If IOL, mode of induction (one tick only) [8]

□ 1 No IOL	□ 2 PGE	□ 3 Oxytocin	□ 4 Foley
□ 5 ARM	□ 6 PGE+ oxytocin ± ARM	□ 7 Foley+ARM/oxytocin	□ 8 Foley + PGE
□ 9 ARM + oxytocin	□ 10 Other add: _____		□ 0 Missing

If operative delivery, main indication (one tick only)

□ 1 No operative del	□ 2 CTG anom/suspected fetal distress	□ 3 Failed induction
□ 4 Distocya 1st	□ 5 Distocya 2nd stage[10]	□ 6 Past CS
□ 7 Breech/abnormal lie	□ 8 History of subfertility	□ 9 APH/major placenta previa
□ 10 Cardiac disease	□ 11 Prelab diagn CPD/short mother	□ 12 Multiple pregnancies
□ 13 IUGR	□ 14 Pre term	□ 15 Diab
□ 16 Hypert/Precl/Eclam	□ 17 Maternal request	□ 18 Other
□ 0 Missing		

If other fetal cause specify _____
If other maternal specify_____
If other cause_____

Episiotomy	□ N	□ Y	□ Missing			
Analges in labour[9]	□ N	□ Petidine	□ Epid	□ Spin	□ Mix	□ Other
If CS, anaestesia	□ No CS	□ Spinal/epid	□ General			
3rd Stage manag	□ Active	□ No active	□ Missing			
Removal placenta	□ Spont	□ Manual	□ ERPC	□ Missing		
Operator del	□ Nurse	□ MW	□ HO	□ SHO	□ Reg	□ Con □ Missing

PTO

Complications (one tick)

Perineal tears	□ N/I-II d	□ III d	□ IV d	□ Missing	
PPH [11]	□ N	□ Minor	□ Severe	□ Massive	
Blood transfusion	□ N	□ Y	**Units (#)**	_____	
Cord prolapse	□ N	□ Y	**Abruptio placentae**	□ N	□ Y
Uterine rupture	□ N	□ Y	**Amn fluid embol**	□ N	□ Y
Admission to ICU/HDO	□ N	□ Y	**Major organ dys** [12]	□ N	□ Y
OT after deliv	□ N	□ Y	**Hysterectomy**	□ N	□ Y
Sepsis/sev infect	□ N	□ Y	**DVT/PE**	□ N	□ Y
Other Complications	□ N	□ Y	**Other infections**	□ N	□ Y

Final outcome (one tick)

□ Discharged □ Disc with disab due to preg complic [13] □ Death □ Referred □ LAMA

Near Miss [14] □ N □ Y

If NM or death, cause (select main; if more than one, write in Notes)

□ 1 Pre-exist cardiac dis	□ 2 Other pre-existing medic con	□ 3 Suicide
□ 4 Hypertension	□ 5 Preeclampsia/Eclampsia	□ 6 PPH
□ 7 Amniotic fluid embolism	□ 8 Sepsis/infection	□ 9 DVT/PE
□ 10 Complic anaesthesia	□ 11 Other	□ 0 Missing

If Others specify_____

Notes_____

Post delivery duration stay (days) [15] ☐☐

If stay >24 h, reason ☐ maternal ☐ newborn ☐ both ☐ hospital regulations ☐ Missing

----------**NEWBORN (N1)**----------

Born □ Alive [1] □ Dead [2] **If stillbirth**[3] □ noSB □ Macerated □ Fresh □ Intrapartum □ Missing

Sex □ Female □ Male □ Missing **BW** (gr) [4] ☐☐☐☐ **Apgar1/5 /10** ☐☐/☐☐/☐☐

Ventilated in delivery room [5] □ N □ Y □ Missing **Asphyxia** [6] □ N □ Y □ Missing

Postdelivery □With mother □ SCBU □ NICU □ Referred □ Obitorio □ Missing

Reason for referral □ medical complication □ surgical complication □No beds □ Other □ Missing

If baby in NICU /SCBU, add here BHT code ☐☐☐☐☐

COMPLICATIONS

RDS [7] □N □Y **Jaundice with ET** □N □Y **Sepsis** □N □Y

Other Infect(incl NEC) □N □Y **Major birth trauma** [8] □N □Y **Major malformation**[9] □N □Y

Neurol (seizure,IVH,HIE) □N □Y **Phototherapy > 24 h** □N □Y **Other** □N □Y

If other, add_____

Final □ Discharged □Disc with disabilities □ Death □ Referred □ LAMA

----------**NEWBORN (N2 if twins)**----------

Born □ Alive [1] □ Dead [2] **If stillbirth**[3] □ noSB □ Macerated □ Fresh □ Intrapartum □ Missing

Sex □ Female □ Male □ Missing **BW** (gr) [4] ☐☐☐☐ **Apgar1/5 /10** ☐☐/☐☐/☐☐

Ventilated in delivery room [5] □ N □ Y □ Missing **Asphyxia** [6] □ N □ Y □ Missing

Postdelivery □With mother □ SCBU □ NICU □ Referred □ Obitorio □ Missing

Reason for referral □ medical complication □ surgical complication □No beds □ Other □ Missing

If baby in NICU /SCBU, add here BHT code ☐☐☐☐☐

COMPLICATIONS

RDS [7] □N □Y **Jaundice with ET** □N □Y **Sepsis** □N □Y

Other Infect(incl NEC) □N □Y **Major birth trauma** [8] □N □Y **Major malformation**[9] □N □Y

Neurol (seizure,IVH,HIE) □N □Y **Phototherapy > 24 h** □N □Y **Other** □N □Y

If other, add_____

Final □ Discharged □ Disc with disabilities □ Death □ Referred □ LAMA

***DEFINITIONS (WOMAN)**

[1] **Gravida /Para/ Born alive:** fill this excluding current pregnancy/delivery (example: 3 pregnancies, 2 children, 1 stillbirth will be gravida 3, para 2, born alive 1)

[2] **Risk factors at time of delivery:** consider here the risk factors present at time of delivery and that can affect the delivery outcome. Examples:

- If the mother had severe anaemia but this was corrected before delivery, do not tick the severe anaemia box).
- If the mother had hypertension, pre-eclampsia, eclampsia, or hypothyroidism during current pregnancy , still tick the box even if the situation is under control
- If relevant cardiac problems present or even in the past, still tick the box.

[3] **Hypertension:** this is defined with a BP > 140/90

[4] **IUGR/SGA:** defined as weight < 10 centile of estimated weight-for-GA or < 10 centile for abdominal circumference (Bangladesh growth chart). IUGR/SGA is based on US estimate (if there was an indication for US, such as clinical signs suggesting IUGR, but US was not performed or uncertain, collect this information under “other or uncertain”.

[5] **Steroids:** Complete dose is Dexametason 8 mg /12 hrs for 3 doses –can you double if this is you national standard ? (last GL 6mg/ 12 h 48 h)

[6] **Induction**: as labour onset should be selected even in the case of **failed IOL** and subsequent CS, not "prelabour caesarean section" (note that this is accordingly to Robson classification)

[7] **Macrosomy at US:** defined as weight > 3500 grams or 90 Centile weight-for-GA

[8] **If IOL, mode of induction:** record here only procedures for IOL,i.e. until 4 cm dilatation

[9] **Analg:** record only drugs actually given (not just prescribed). Record paracetamol under “other”

[10] **Distocya 2nd stage**: CS at full dilatation

[11] **PPH** Minor (not severe not massive) Severe PPH (≥ 1000 ml *or* any bleeding with hypotension or tachycardia *or* blood transfusion) Massive (lost of ≥40% of blood volume, blood volume= body weight(kg)/12)

[12] **Major organ dysfunction:** as for Near miss definition **-**do not consider diabetes as major organ dysfunction (see following ANNEX 1)

[13] **Disabilities from pregnancy complications:** include here stroke, anaemia, post partum depression or other psychiatric disorders and other disabilities (not include preexisting problems such as GDM, hypertension, or hysterectomy)

[14] **Near Miss=** A maternal near-miss case is defined as “a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy” (*WHO 2011*). This implies either severe disease (severe PPH, severe pre-eclampsia, Eclampsia, sepsis, uterine rupture, severe complications of abortion), or critical interventions (admission UTI, intervention radiology, laparotomy, blood transfusion) or organ dysfunction (see ANNEX 1)

[15] **Post delivery duration stay:** count this in days. If admitted on 2 April and out day 3 April count this as 1 day if it is less than 24 h. If more than 24h , count this as 2 days

DEFINITIONS (NEWBORN)

[1] **Born alive**= fetus/baby of any GA and any birth weight showing any sign of vital activity (breath, cardiac, movements)

[2] **Born dead**= when not born alive; it includes stillbirth

[3] **Stillbirth** = macerated are fresh are based on clinical evaluation; intrapartum is a fetus where heart rate was perceived before delivery (and than lost after delivery)

[4] **Birth weight**=avoid approximation (use weight in grams)

[5] **Ventilated in delivery room=** not just stimulated, but ventilated (with bag or CPAP) for more than *10 seconds*

[6] **Asphyxia**= no spontaneous start of breathing, ventilation for at least *30 sec* and/or thoracic compressions as in international guidelines or any drug

[7] **RDS (Respiratory Distress Syndrome)**= tick this box for a baby with respiratory distress lasting more than 24 hours

[8] **Major birth trauma**= include here brachial plexus injury/arm palsy, fractures at any site, sub-aponeurotic (subgaleal) hemorrhage. Do NOT include here cephaloaematoma and caput succedaneum

[9] **Major Malformation**= do not include here minor malformation such as skin tags and pits, syndactyly, polydactyly, additional finger, PDA even if persistent.

[10] **Day of death**= for still birth use day zero

[12] **ANNEX 1 DEFINITIONS ORGAN DISFUNCTION (SOURCE: WHO MANUAL)**

Organ dysfunction / life-threatening conditions

☐ C0 **Cardiovascular dysfunction**
[shock, use of continuous vasoactive drugs, cardiac arrest, cardio-pulmonary resuscitation, severe hypoperfusion (lactate >5 mmol/L or >45mg/dL) or severe acidosis (pH<7.1)]

☐ C1 **Respiratory dysfunction**
[acute cyanosis, gasping, severe tachypnea (respiratory rate>40 bpm), severe bradypnea (respiratory rate<6 bpm), severe hypoxemia (PAO2/FiO2<200 O2 saturation <90% for ≥60min) or intubation and ventilation not related to anaesthesia]

☐ C2 **Renal dysfunction**
[oliguria non responsive to fluids or diuretics, dialysis for acute renal failure or severe acute azotemia (creatinine ≥300umol/ml or ≥3.5mg/dL)]

☐ C3 **Coagulation/hematologic dysfunction**
[failure to form clots, massive transfusion of blood or red cells (≥ 5 units) or severe acute thrombocytopenia (<50,000 platelets/ml)]

☐ C4 **Hepatic dysfunction**
[jaundice in the presence of pre-eclampsia, severe acute hyperbilirubinemia (bilirubin>100umol/L or >6.0mg/dL)]

☐ C5 **Neurologic dysfunction**
[prolonged unconsciousness / coma (lasting >12 hours), stroke, status epilepticus / uncontrollable fits, total paralysis]

☐ C6 **Uterine dysfunction / Hysterectomy**
[haemorrhage or infection leading to hysterectomy]

Appendix 2. Missing variables

	Total	Missing	% Missing
Maternal variables			
Age	7504	34	0.4
Work	7504	38	0.5
Education	7504	37	0.4
Para (number of children)	7504	34	0.4
Marital status	7504	38	0.5
Gravidas (pregnancies, including the ongoing)	7504	34	0.4
Born alive	7504	34	0.4
Gestational age at delivery	7504	47	0.6
Gestational age estimated with ultrasounds	7504	53	0.7
BMI	7504	53	0.7
Discharge	7504	35	0.4
Delivery	7504	32	0.4
Multiple pregnancies	7504	34	0.4
Pregestetional hypertension	7504	33	0.4
Gestetional 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
Chorionamnionitis	7504	36	0.4
Major fetal malformation	7504	36	0.4
IUGR/SGA	7504	36	0.4
Pregestetional diabetes	7504	35	0.4
Gestetional diabetes mellitus in diet	7504	35	0.4
Gestetional diabetes mellitus in drug therapy	7504	36	0.4
Maternal cardiac disease	7504	34	0.4
Maternal hypothiroidism	7504	37	0.4
Polihydramnios	7504	36	0.4
Oligohydramnios	7504	38	0.4
APH/major placentia previa	7504	37	0.4
Severe anaemia	7504	38	0.5
Other (risk factors)	7504	63	0.8
Steroids	7504	37	0.4

Previous CS	7504	38	0.5
If previous CS, trial of labour	7504	39	0.4
Presentation	7504	37	0.4
Labour onset	7504	36	0.4
Delivery mode	7504	37	0.4
If CS, type	7504	37	0.4
Indication of labour	7504	36	0.4
Mode of induction	7504	42	0.5
If operative delivery, indication	7504	38	0.5
Episiotomy	7504	43	0.5
Analgesia in labour	7504	43	0.5
3rd stage management	7504	39	0.5
Removal of placenta	7504	39	0.5
Operator delivery	7504	41	0.5
Perineal tears	7504	36	0.4
PPH	7504	38	0.5
Blood transfusion	7504	36	0.4
Cord collapse	7504	42	0.5
Uterine rupture	7504	42	0.5
Admission to ICU	7504	22	0.2
OT after delivery	7504	43	0.5
Sepsis/several infections	7504	44	0.5
Other complications	7504	45	0.6
Abruption placentae	7504	42	0.5
Amniotic fluid embolism	7504	42	0.5
Major organ dysfunction	7504	37	0.4
Hysterectomy	7504	36	0.4
DVT	7504	46	0.6
Final outcome	7504	42	0.5
Near miss	7504	20	0.2
Newborn variables ¶			
Born	7504	43	0.5
If stillbirth, fresh or macerated	7504	75	1.0

Sex	7504	51	0.6
Birth weight	7504	68	0.9
Apgar at 1’	7504	168	2.2
Apgar at 5’	7504	168	2.2
Apgar at 10’	7504	166	2.2
Ventilated in delivery room	7504	119	1.5
Asphyxia	7504	124	1.6
Post-delivery	7504	44	0.5
Respiratory distress syndrome	7504	114	1.5
Other infections	7504	110	1.4
Neurological complications (seizure, IVH, HIE)	7504	114	1.5
Jaundice with ET	7504	112	1.4
Major birth trauma	7504	120	1.6
Phototherapy for over 24 hours	7504	121	1.6
Sepsis	7504	113	1.5
Major malformation	7504	120	1.6
Other complications	7504	172	2.3
Final	7504	108	1.4

Abbreviations: APH= ante-partum haemorrhage; BMI= body Mass index; CS= caesarian section; DVT= deep vein thrombosis; ET= exchange transfusion; HIE= Hypoxic Ischemic Encephalopathy; ICU= Intensive care unit; IUGR=Intra-uterine growth restriction; IVH= intra-ventricular haemorrhage; OT=operating theatre; PPH= post-partum haemorrhage; SGA= small for gestational age.

¶ For multiple pregnancies, only data on the first newborn provided