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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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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 8 months, and the results made available to local staff. Outcomes of the study included: technical problems; data completeness; data accuracy; key database findings; and 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 with 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 birthweight rate (16.5%); stillbirth (0.97%); and of total deaths in newborn (1.98%). Based on key indicators identified, a list of recommendations was developed, including the use checklists to standardise case management, training, clinical audits and more information for patients. A list of lessons learnt with the implementation of the data collection system was also 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.

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-income and middle-income countries. Although this is a single-centre 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.

BACKGROUND

The availability of an actionable health information system is one of the key components of the WHO framework for improving the quality of maternal and newborn healthcare[1 2] and one of the recommended cross-cutting actions in the WHO Strategy for Ending Preventable Maternal Mortality.[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-income 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 MMR has shown that 50% of maternal deaths are from direct causes, with preventable causes, such as postpartum haemorrhage and sepsis, being among the top five causes of death.[9] Almost 80% of all women died in hospitals,[9] where specialised 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 towards 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 (online supplementary appendix 1) and recorded 150 variables for each delivery. These included demographic and socioeconomic 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); and 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 (online supplementary 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; and if there was any technical problem. Data collectors were young medical doctors who were trained on the standard operating procedures 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 (ie, 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 4-month intervals.

Data analysis and use

Data were analysed at intervals of 8 months using a standardised plan for analysis, predefined 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: (1) birth register; (2) intensive care unit admissions register; (3) operating theatre (OT) register; (4) neonatal intensive care unit admissions register; (5) special care baby unit admissions register; (6) maternal death reviews; (7) perinatal mortality and morbidity statistics; and (8) 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 with the original medical files. Accuracy in data entry was measured by the number of variables correctly recorded in the database compared with 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

Technical problems:
- Any type of technical problem in implementing and using the database.

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.

Data accuracy:
- Number of correct variables in the yellow form versus the original medical files.
- Number of correct variables in the database compared with the yellow forms.

Database findings:
- Descriptive analysis of the key variables as agreed among partners.

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

Ethical considerations

Confidentiality was maintained by deidentifying 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 with other official hospital data sources.

Table 1 Number of cases in the database compared with 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*			
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

*Including also the second twin in multiple pregnancies.
ICU, intensive care unit; NICU, neonatal intensive care unit; OT, operating theatre; PPH, postpartum haemorrhage; SCBU, semi-intensive baby unit.

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).

The number of missing variables is reported in online supplementary 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 2–4 report the descriptive analysis of key indicators in the database. Overall, during the 2 years of the study period, 7504 deliveries were recorded (table 2). In terms of sociodemographic characteristics, most women belonged to the following categories: 4253 (56.7%) were 25–34 years old; 6028 (80.3%) had secondary education; 6253 (83.3%) were housewives; and 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%), preterm 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%); and group 5 (previous CS, single cephalic at term) (10.9%).

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.

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 (ie, before 37 weeks of gestational age); 1243 (16.6%) were of low birth weight (ie, below 2500 g); and 173 (2.3%) were ventilated for more than 10 s 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.

Use of data

Data entered in the database were analysed at intervals of 8 months, and the results were made available to the local coordinator. Findings of the database were presented and

Table 2 Maternal characteristics

	n (n=7504)	%
Age categories (years)		
<18	95	1.2
18–24	1862	24.8
25–34	4253	56.6
35–39	1036	13.8
>40	224	2.9
Missing		
*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†		
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)‡	4182	55.73
Gestational diabetes, total	1002	13.36
On medical nutrition therapy	417	5.56
On drug therapy	585	7.8
Gestational age <37 ≥41 weeks	966	12.87
Previous CS	956	12.74
Hypertensive disorders of pregnancy, any	506	6.74
Pregestational 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
Pregestational diabetes	266	3.54
Maternal cardiac disease	234	3.12
Fetal conditions, other	223	3.1
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

*Including the ongoing pregnancy.
†As defined by National Guidelines in Sri Lanka.
‡Any of the medical conditions/risk factors described in the following rows.
APH, antepartum haemorrhage; CS, caesarean section; IUGR, intrauterine growth restriction.

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 on (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%); and 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).

Lessons learnt

Results of this study were discussed among partners, and lessons learnt and future actions were articulated

Table 3 Birth process indicators and maternal outcomes

	n (n=7504)	%
Labour onset		
Spontaneous	4726	62.98
Induction	1849	24.64
Prelabour CS	893	11.9
Missing	36	0.48
Mode of delivery		
Vaginal spontaneous	4906	65.38
Vaginal operative	310	4.13
Caesarean section	2251	30
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*	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

*As for WHO classification.[15]
CS, caesarian section; DVT, deep vein thrombosis; ICU, intensive care unit; OT, operating theatre; PE, pulmonary embolism; PPH, postpartum haemorrhage.

Table 4 Newborns' characteristics and outcomes

Newborn	n (n=7504)*	%
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	86.5
>41	258	3.43
Missing	47	0.62
Weight at birth		
<1499	149	1.99
1500–1999	183	2.44
2000–2499	911	12.14
2500–3499	5365	71.5
3500–4000	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 s	173	2.34
Asphyxia	62	0.84
Postdelivery course		
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†	38	0.5
Sepsis	28	0.38
Major birth trauma	16	0.21
Severe jaundice with ET	15	0.2
Others‡	232	3.09
Final outcome		
Discharged	7204	96

Continued

(box 2). Overall, the key lessons were that data collection was feasible, 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.

Table 4 Continued

Newborn	n (n=7504)*	%
Discharged with disabilities	4	0.05
Death (including stillbirths)	148	1.98
Referred	54	0.72
LAMA	15	0.2

*Data on multiple pregnancies were not included in this primary analysis.
†Seizures, ventricular haemorrhage and other neurological complications.
‡Most frequent reported conditions in this class were other respiratory problems (eg, apnoea, meconium aspiration syndrome and pulmonary hypertension), gastrointestinal problems (eg, bleeding) and minor jaundice.
ET, exchange transfusion; LAMA, left against medical advice; NICU, neonatal intensive care unit; RDS, respiratory distress syndrome; SCBU, semi-intensive care baby unit.

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-income countries or LMICs[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 organisation of care is still not a

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 of third to fourth degree perineal tears.	► Checklist to be filled by the doctor in charge for each individual case of induction of labour, specifying indications, methods and timing. Data to be reviewed regularly. Consultant to make decision on induction of labour (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-led 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.

CS, caesarian section; CTG, cardiotocography; IOL, Induction Of Labour; SGA, small for gestational age; VBAC, vaginal birth after caesarean section.

Box 2 Lessons learnt 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 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 (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 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 be put in place. This will probably be more effective if embedded in a national system for quality assurance in maternal and child health.

common practice, even in countries with well-established data collection systems.[7] Despite there are some good examples of how routine data collection systems are used to shape policies in low-income and middle-income countries (LMICs), 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 subgroup 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 with 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 with 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 deep vein thrombosis and pulmonary embolism may be due to the fact that these events are less frequent in the Asian population compared with 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 and so on, 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 more 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 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 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 and settings over time. Data generated could be used to improve overall national practices. The data collection form used 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 to ensure that information generated from the database are actually used in practice to improve quality of healthcare. Indeed, for many data collection systems, the main problem is that data are not actually used for improving practices.[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 learnt 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 LMICs. 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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