# **BMJ Open** Multicentre cross-sectional study on adverse events and good practices in maternity wards in Brazil and Mexico: same problems, different magnitude

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#### ABSTRACT

**Objective** To evaluate the quality of delivery care in maternity wards in Brazil and Mexico based on good practices (GP) and adverse events (AE), in order to identify priorities for improvement.

**Design** A multicentre cross-sectional study with data collection from medical records between 2015 and 2016 to compare indicators of maternal and neonatal GP and EA based on the Safe Childbirth Checklist and standardised obstetric quality indicators. Two Brazilian and five Mexican maternity wards participated in the study. Descriptive statistics and  $\chi^2$  tests were performed to assess performance and significant differences between the hospitals investigated.

**Sampling** We analysed 720 births in Brazil and 2707 in Mexico, which were selected using a systematic random sampling of 30 medical records every fortnight for 12 2week periods in Brazil and 18 2-week periods in Mexico. We included women and their newborns, excluding those with congenital malformations.

**Results** The Mexican hospitals showed greater adherence to GP (58.2%) and a lower incidence of AE (12.9%) than the participating institutions in Brazil (26.8% compliance with GP and 16.0% AE). In spite of these differences, the relative importance of particular quality problems and type of AE are similar in both countries. Tertiary hospitals, caring for women at higher risk, have significantly (p<0.001) higher rates of AE (27.2% in Brazil and 29.6% in Mexico) than institutions attending women at lower risk, where the frequency of AE ranges from 4.7% to 11.2%. Differences were significant (p<0.001) for most indicators of GP and AE. Conclusion Data from outcome and process measures revealed similar types of failures in the quality of childbirth care in both countries and indicate the need of rationalising the use of antibiotics for the mother and episiotomy, encouraging greater adherence to partograph and to the use of magnesium sulfate for the treatment of severe preeclampsia/eclampsia.

#### INTRODUCTION

Childbirth in healthcare facilities is a complex process, with a noticeable potential

### Strengths and limitations of this study

- The multicentre nature of this project made it possible to analyse and compare patient safety in obstetrical services at the facility level in two middle-income countries (Brazil and Mexico), a subject on which little information is available, even though childbirth is one of the main causes of hospital admission in these countries.
- This study measures quality and safety in obstetric services from primary data, as opposed to the more limited information and data published by the official information systems.
- The method and set of indicators used in this study may be useful for obstetric services that want to control their processes and outcomes related to quality and safety in childbirth care.
- The data in this study are not representative of the participating countries but are useful for identifying benchmarks among the institutions evaluated, analysing profiles of participating institutions and prioritising opportunities for improvement.
- The descriptive nature of the study suggests, but does not allow us to establish, causal relationships between compliance with good practices and their repercussions on adverse outcomes. Other studies are necessary to test these hypotheses.

to cause unnecessary harm. It requires strict vigilance of the complications that may arise from the delivery process itself or from the care provided.<sup>1</sup> The high frequency of childbirth in healthcare facilities, the fact that it involves not a single patient but a dyad (mother and newborn (NB)) and the already mentioned complexity of the whole process make maternal and neonatal care a priority for quality of care and patient safety.<sup>2</sup>

Obstetric adverse events (AE) are well delimited by the scientific literature and

include maternal and neonatal deaths, severe maternal morbidity (postpartum haemorrhage, eclampsia and puerperal infections), and minor damage, such as perineal lacerations.<sup>3</sup> Of these, maternal and neonatal deaths constitute the most serious events, being (for the most part) preventable with safe care. For the purpose of this study, AE are the avoidable incidents resulting from healthcare.<sup>4</sup>

International efforts to reduce maternal and child mortality, such as the ones derived from the United Nations Millennium Development Goals, have facilitated some progress in this area. However, many countries have been unable to achieve the expected reduction, despite increased access to institutionalised births, <sup>5 6</sup> suggesting failures in the quality of care provided. In view of this, the 2030 Agenda for Sustainable Development Goals for health and well-being have renewed the global goals related to maternal and child health. However, these goals consider not only the survival of the mother-child dyad but also the provision of quality care, placing women and their babies at the centre.<sup>78</sup>

Research has shown that the majority of maternal and neonatal deaths are preventable, and most of them result from deficient quality of health services.<sup>9 10</sup> To address this problem, the WHO has developed the WHO Safe Childbirth Checklist (SCC), a tool designed to help teams systematically follow critical safety steps. Evidence shows that the implementation of the SCC has a potential effect on improvement of good practices (GP) and patient safety, as it establishes standardised processes for the prevention of mistakes and oversights in the care provided.<sup>11–13</sup> Therefore, it could be a good basis to identify key quality issues around childbirth.

This study aims to describe the frequency of AE and compliance with GP, based on the potential problems addressed by the SCC, identifying priorities for quality improvement in obstetric and neonatal services, and comparing the situation in maternity wards in Brazil and Mexico. These countries are part of a multicentre project with WHO to explore the implementation and usability of the SCC in diverse settings around the world (WHO SCC Collaboration).<sup>14</sup>

# METHODS

## Design

This is a descriptive and analytical study, with repeated fortnightly cross-sectional measurements. Data were taken from medical records of women and their NBs during 2015 and 2016.

#### Context

This multicentre study was conducted in maternity wards in Brazil and Mexico, the largest countries in Latin America, who are partners in collaboration with the WHO to implement the SCC.<sup>14</sup> In Brazil, two facilities in the state of Rio Grande do Norte participated, one of them a specialised tertiary care maternity hospital providing care for women at high risk. In Mexico, five hospitals participated in the study, three of them general hospitals with maternity wards, one second-level maternity hospital and one tertiary care maternity hospital.

The clinical staff for obstetric care in the participating facilities included 90 gynaecologists and obstetricians in maternity wards in Brazil and 95 in maternity wards in Mexico, as well as 104 specialised midwifery nurses in Brazil and 578 in Mexico. Regarding NB care, there were 81 paediatricians and neonatologists in the two Brazilian hospitals and 93 in the five Mexican hospitals. The number of nurses specialising in neonatology was 25 in Brazil and 225 in Mexico. The number of beds for maternal and neonatal care, included 129 beds for gynaecology and obstetrics and 62 beds for neonatology in the Brazilian facilities and 298 beds and 195 beds, respectively, in the Mexican facilities. All of them were public hospitals. A convenience sample was used to evaluate the implementation of the SCC in these countries.

The number of births during 2015 in the maternity wards evaluated in Brazil was 6,205, of which 2842 (45.8%) were vaginally delivered and 3363 (54.2%) were by caesarean section. In the participating institutions in Mexico, the total number of vaginal deliveries in the same period was 12524 (63.4%) and 7236 (36.6%) deliveries were by caesarean section.

### **Participants**

We included women who attended the facilities for delivery, and all NBs discharged from July 2015 to January 2016 in Brazil and from July 2015 to March 2016 in Mexico, excluding NBs with congenital anomalies.

A systematic random sampling of 30 medical records every fortnight for 12 2-week periods (6 months) in Brazil and 18 2-week periods (9 months) in Mexico was performed. The sample was selected biweekly so that it was possible to evaluate the temporal variability and statistical stability of the indicators. In addition, random samples with successive measurements of 30 cases were considered workable and useful for quality monitoring and decision-making in health services.<sup>15</sup>

#### Variables

The variables of interest included simple and composite indicators of GP based on the items contained in the SCC, which were converted into indicators and pilot tested in a previous study,<sup>16</sup> and adverse event indicators, which were based on the standardised obstetric quality indicators proposed by Mann *et al.*<sup>17</sup>

A total of 21 indicators were measured, three of which were descriptive of the type of intervention (caesarean delivery, episiotomy and instrumentation), five were complications of the childbirth, 10 were GP (seven simple indicators and three composite indicators) and three were composite indicators of AE. The composite indicators were calculated by aggregating the simple GP and AE indicators. The percentage of deliveries with at least one AE in the mother, NB or both was calculated as the composite indicator of EA, while for GP, the percentage of the sum of the best practices performed within the total recommended practices was calculated. The composite indicator provides a more stable measure of AE, minimising the effects of the low frequencies of some of them; individual cases may be assessed for severity, while the aggregated number for the numerator of the indicator of AE will reflect the frequency of failures in childbirth services.

The description of the indicators and their respective formulas are presented in table 1.

# **Data collection**

The data collection from medical records was performed in a cross-sectional and retrospective manner during 2015 and 2016. Data were collected by health professionals in Mexico and by undergraduate health students in Brazil, who were trained and supervised by a doctoral student in Public Health. An application was developed for data collection on tablets.

In both Brazil and Mexico,<sup>16</sup> a pilot study was performed to analyse the reliability of the instrument, reaching kappa indices with substantial agreement (>0.76) for most of the indicators; alternatively, adjustments were made to the instrument, aiming for greater clarity and reliability. The pilot study cases were not part of the main study.

#### **Data analysis**

Data were analysed in the IBM SPSS Statistics V.22.0 software in the form of descriptive statistics (absolute and relative frequencies) and 95% confidence intervals (95% CIs). Estimates were calculated for total deliveries and for each participating country and institution. The analysis by institutions was carried out because there were facilities with specific characteristics (ie, tertiary care hospitals, maternity hospitals and maternity services in a general hospital) deserving individual analysis. The  $\chi^2$  test was used to assess significant differences (p<0.05) between the countries and the hospitals evaluated.

The composite indicators of GP of AE were analysed graphically, with representations of their point and 95% CI estimates. The countries and institutions were ranked in relation to best performance in obstetric and neonatal care indicators.

There were no missing data for the variables of interest. No recorded actions or events were considered as noncompliance with GP or no occurrence of AE.

#### Patient and public involvement

Patients were not directly involved in this study as data collection was based only on medical records. Each participating institution submitted consent for authorisation and access to medical records, and researchers ensured the confidentiality of data for the institutions and patients involved.

#### RESULTS

#### Characterisation of the sample of women

In the seven hospitals participating in the study, 3427 medical records of women and their NBs were evaluated, of which 720 were in maternity hospitals in Brazil (BR) and 2707 were in Mexico (MX). The mean age of women who attended Brazilian hospitals was 25.7 (SD 7.1) years and, it was 25.0 (SD 6.3) years in Mexican hospitals.

### Good practices in childbirth care

Table 2 presents the results of GP and AE indicators in childbirth care analysed with the objective of knowing the general performance of the institutions of each country participating in the research.

In the general evaluation of these health services in Brazil and Mexico (table 2), there was good adherence in the practice of management of antibiotics in the NB (above 73%) and low adherence to perform justified episiotomy (13.2% in Brazilian facilities vs 6.0% in Mexican facilities). The differences were more significant in terms of management of antibiotics during labour (80.5% in Brazilian facilities vs 6.1% in Mexican facilities), partograph opening and filling (44.9% in Brazil and 88.7% in Mexico) and the composite indicators of compliance with GP for the mother, NB or both, which were performed twice more in Mexican maternity wards as compared with Brazilian ones.

Table 3 shows the GP and AE indicators used to determine the performance of each institution regarding safe practices in childbirth care. The differences were significant (p<0.001) for most of the good practice indicators in the individual analyses of the institutions, with no one institution modelling in relation to the others. However, the general performance of the institutions based on the composite GP indicator for the mother-child dyad was better among Mexican maternity wards, with values around 60%, against figures of 24.5% and 29.1%, respectively, in Brazilian maternity wards. In all institutions, adherence to GP was greater in the care of the mother as compared with that for the NB, except in the Brazilian tertiary care facility. Considering the type of care offered, it was also identified that general maternity wards (secondlevel facilities), which provide care to women at low risk, had higher rates of compliance with GP as compared with those which provide care to women at high risk (thirdlevel facilities).

#### Adverse outcomes and events in childbirth care

Comparing the aggregate of the institutions of the two countries (table 2), it was found that, in Mexican facilities, the proportions of deliveries using episiotomies and forceps were higher than in Brazilian facilities, and the percentage of caesarean births was lower (29.0% vs 50.1% in Brazilian facilities). The incidence of neonatal asphyxia, maternal postpartum infection and obstetric haemorrhage was also higher in Mexico. In Brazil, the

Table 1 Descriptio	n and formula of indicators	of good practices, health outc	omes and adverse events in childbirth care
Area	Indicator name	Description	Indicator formula (numerator/denominator)
Indicators of good pra	ctice		
General	Management of antibiotics during labour	Percentage of women with antibiotics prescribed during the childbirth process and it is justified by any cause*	Number of women with antibiotics prescribed during the childbirth process and it is justified by any cause/ Number of women with antibiotics prescribed during the labour process
	Management of magnesium sulfate at delivery for preeclampsia/ eclampsia control	Percentage of women prescribed magnesium sulfate during the childbirth process and it was justified†	Number of women prescribed magnesium sulfate during the childbirth process/Number of women diagnosed with preeclampsia or eclampsia (diagnosis present in the medical record and according to clinical and laboratory criteria)
	Management of antibiotics in the newborn	Percentage of newborns prescribed antibiotics and it was justified by any cause‡	Number of newborns prescribed antibiotics at any time and it was justified by any cause/Number of newborns with prescribed antibiotics
Admission	Partograph open and filled	Percentage of women with open and filled partograph§	Number of women with partograph started and minimally filled with information on temperature, heart rate, blood pressure and cervical dilatation/Number of women attended due to labour
Pre-expulsive phase	Resolution of caesarean delivery justified	Percentage of women with justified caesarean delivery¶	Number of women undergoing caesarean section with a justified indication/Number of women undergoing caesarean section
	Performed justified instrumented childbirth	Percentage of women with justified instrumented delivery**	Number of women with justified indication of instrumented delivery/Number of women with instrumented delivery
	Performed justified episiotomy	Percentage of women with justified episiotomy <sup>††</sup>	Number of women with justified indication of episiotomy/Number of women with episiotomy at delivery
Immediate postpartum phase (1 hour	Good practices in women	Percentage of deliveries with good practices in women‡‡	Sum of all good practices performed on mother's care/Total possible good practices and recommended for the mother
after expulsion) (composite indicators)	Good practices in newborns	Percentage of deliveries with good practices in newborns§§	Sum of all good practices performed on newborn care in the immediate postpartum/Total possible good practices and recommended for the newborn
	Good practices in women and newborns	Percentage of deliveries with good practices in women and newborns	Sum of all good practices performed on mother's care and newborn care/Total possible good practices and recommended for the women and newborn
Health outcomes and	adverse events indicators		
Complications (morbidity)	Incidence of obstetric haemorrhage	Percentage of women with haemorrhage	Number of women who suffered intra- and postpartum haemorrhage/Number of women attended due to labour
	Incidence of pre-, intra- and postpartum blood pressure disorders	Percentage of women with blood pressure disorders¶¶	Number of women with blood pressure disorders in the pre-, intra- and postpartum phases/Number of women attended due to labour
	Incidence of maternal postpartum infection	Percentage of women with postpartum infection	Number of women with perinatal or postpartum infection/Number of women attended due to labour
	Incidence of neonatal infection	Percentage of infants with neonatal infection	Number of infants with neonatal infection/ Live newborns
	Incidence of neonatal asphyxia	Percentage of infants with neonatal asphyxia	Number of infants with neonatal asphyxia event/Live newborns
Results/ Interventions	Percentage of deliveries with caesarean section	Percentage of women with caesarean section	Number of women who underwent caesarean delivery/ Number of women attended due to labour
	Percentage of instrumented deliveries	Percentage of women with instrumental delivery	Number of women undergoing instrumented delivery/ Number of women attended due to labour
	Percentage of deliveries with episiotomy	Percentage of women with episiotomy at childbirth	Number of women with episiotomy at delivery/Number of women attended due to labour

Continued

Table 1       Continued	1		
Area	Indicator name	Description	Indicator formula (numerator/denominator)
Adverse events (composite	Adverse events in women	Percentage of adverse events in women giving birth***	Number of women with at least one adverse event/ Total deliveries
indicators)	Adverse events in newborns	Percentage of deliveries with adverse events in newborns†††	Number of newborns with at least one adverse event/ Total births
	Adverse events in women and newborns	Percentage of deliveries with adverse events in women and newborns	Sum of all adverse events in women and newborn care/Total deliveries

\*Symptoms that may justify antibiotic prescription in the mother: membrane rupture >18 hours; onset of caesarean section; placenta removed manually; labour very manipulated; suspected endometritis; other justifications.

†The use of magnesium sulphate was considered appropriate when the diagnosis of preeclampsia and eclampsia was present or, in the absence of it, when the pregnant woman had at least one of the following clinical or laboratory criteria: systolic blood pressure  $\geq$  160 mmHg; diastolic blood pressure  $\geq$  110 mmHg; cortical blindness; Glasgow coma scale score < 13; stroke; peripheral oxygen saturation < 90%; need for orotracheal intubation; pulmonary oedema; myocardial ischemia; need for positive inotropic agents; need for dialysis; hepatic hematoma or rupture; platelet count below 50,000; creatinine > 1.7 mg/dl; International Normalized Ratio (INR) > 2; abruption with evidence of maternal or foetal compromise; or stillbirth.<sup>48</sup>

\$Symptoms that may justify antibiotic prescription in the newborn: rapid breathing (> 60 breaths/minute) or slow (< 30 breaths/minute); intercostal stretch, breathing noise or seizures; little or no mobility to stimulation; very cold temperature (< 35 °C and not heated) or high temperature (> 38 °C); membrane rupture > 18 hours; other justifications.

\$This indicator includes the percentage of partograph opening (presence of mother's name information, date of birth and weeks of gestation) and its completion when at least one of the four criteria of the partograph (temperature, heart rate of the woman and the foetus, blood pressure and cervical dilation) were registered.

¶Justifications for caesarean section: two previous C-sections; transverse situation; twin pregnancy; pelvic presentation; class III and IV heart disease; foetal hydrocephalus; placenta previa; macrosomia; foetal status unstable; foetal malformations; active genital herpes; tumour that obstructs the birth canal; premature placental abruption; HIV; death product > 30 weeks of gestation in patients without labour for more than 24 hours; other justifications.

\*\*Correct and justified indication for instrumented delivery (forceps): suspicion of foetal impairment or foetal instability; prolonged expulsive period; maternal fatigue; previous caesarean section; maternal heart disease; other justifications.

++Justifications of labour with episiotomy: instrumented delivery; short or rigid perineum; shoulder dystocia in the foetus; other justifications. ++Good practices for the mother at admission and in the immediate postpartum period: opening and filling the partograph; disconfirmed presence of a second baby; oxytocin administration in the first minute; control traction of the umbilical cord to extract the placenta; uterine massage after removing the placenta.

§§Good practices for newborns in the immediate postpartum period: drying and keeping warm; administration of vitamin K; administration of ophthalmic prophylaxis; immediate skin to skin contact; late clamping of umbilical cord; breastfeeding right after birth.

¶¶Symptoms considered that qualify for a blood pressure (BP) disorder: systolic BP  $\ge$  90 mmHg and proteinuria; headache and visual changes; diastolic BP  $\ge$  110 mmHg and proteinuria; epigastric pain or pain in the upper right quadrant; laboratory abnormalities.

\*\*\*Adverse events in the mother: blood transfusion; third- or fourth-degree laceration; maternal admission to ICU; postpartum hysterectomy; uterine rupture; return to hospital after discharge; maternal death. All adverse events listed were taken into account, but only one adverse event per woman was considered. Adapted from Mann *et al.* 2006.<sup>17</sup>

†††Adverse events in the newborn: admission to neonatal ICU > 2500 g and for > 24 hours; Apgar < 7 at 5 minutes; birth trauma (e.g., head trauma, fracture, neurological injury, haemorrhage or laceration); hospitalised more than 7 days; foetal or neonatal death. All adverse events listed were considered, but only one adverse event per newborn was considered. Adapted from Mann *et al.* 2006.<sup>17</sup>

incidence of hypertensive disorders and neonatal infection was higher as compared with Mexico.

In the individual analysis of the AE of hospitals in both countries, maternal admission to the intensive care unit (ICU) (4.0% in BR and 0.7% in MX) and hospitalisation of the NB for more than 7 days (5.1% in BR and 5.2% in MX) were the most frequent AE. There were more incidents of third or fourth degree (1.7%) lacerations and foetal or neonatal death (2.5%) in Brazilian hospitals. The most common AE in Mexican maternity wards were blood transfusion (1.0%) and admission to the neonatal ICU >2500 g and for >24 hours (2.2%). Concerning the composite indicators, AE in maternal care were more frequent in Brazil (7.8%) as compared with in Mexico (2.8%), as well as for the composite indicator of AE in the mother and NB (16.0% in Brazil and 12.9% in Mexico). In hospitals in both countries, care for the NB had a higher frequency of AE as compared with the mother.

As shown in table 3, all outcome indicators and AE presented statistically significant differences in the

comparative evaluation of maternity wards (p<0.001). Regarding the type of care offered, the hospitals BR1 and MX2 presented outcome indicators and AEs more frequent than in hospitals caring at women at low risk for 6 of the 11 indicators measured.

Finally, figure 1 illustrates the comparison and institutions regarding adherence to evidence-based GP and the occurrence of AE during childbirth care, with a ranking of those with better performance (ie, greater adherence to GP and lower incidence of AE).

In the comparison between countries, it can be seen that Mexican maternity wards have better performance, with a higher percentage of adherence to GP (58.2%) and a lower incidence of AE (12.9%). Regarding the AE indicator in the mother-child dyad, four of the five institutions in Mexico presented the smallest proportions. The highest incidence of AE occurred in the maternity wards that attend high-risk childbirths in both countries.

Indicator	Brazil % (n/N) (Cl 95%)	Mexico % (n/N) (Cl 95%)	P value
Good practice indicators			
Good practices general			
Management of antibiotics during labour	80.5 (318/395) (77.6 to 83.4)	6.1 (130/2136) (5.2 to 7.0)	0.000*
Management of magnesium sulfate at delivery for preeclampsia/ eclampsia control	7.4 (25/339) (5.5 to 9.3)	14.0 (27/193) (12.7 to 15.3)	0.014†
Management of antibiotics in the newborn	90.7 (39/43) (88.6 to 92.8)	73.2 (90/123) (71.5 to 74.9)	0.017†
Good practices in admission			
Partograph opening and filling	44.9 (323/720) (41.3 to 48.5)	88.7 (2400/2707) (87.5 to 89.9)	0.000*
Good practices in the pre-expulsive phase of labour			
Resolution of justified caesarean delivery	91.7 (331/361) (89.7 to 93.7)	61.3 (476/777) (59.5 to 63.1)	0.000*
Performed justified instrumented childbirth	50.0 (1/2) (46.3 to 53.7)	72.5 (29/40) (70.8 to 74.2)	0.513
Performed justified episiotomy	13.2 (7/53) (10.7 to 15.7)	6.0 (49/823) (5.1 to 6.9)	0.036†
Good practices in the immediate postpartum (Composite indicators)			
Good practices in women	28.0 (1009/3600) (24.7 to 31.3)	65.8 (8903/13535) (64.0 to 67.6)	-
Good practices in newborns	25.7 (1112/4320) (22.5 to 28.9)	51.9 (8432/16242) (50.0 to 53.8)	-
Good practices in women and newborns	26.8 (2121/7920) (23.6 to 30.0)	58.2 (17335/29777) (56.3 to 60.1)	-
Health outcomes and adverse events indicators			
Complications/Morbidity			
Incidence of obstetric haemorrhage	1.1 (8/720) (0.3 to 1.9)	3.4 (91/2707) (2.7 to 4.1)	0.00†
Incidence of pre-, intra- and postpartum blood pressure disorders	47.1 (339/720) (43.5 to 50.7)	7.1 (193/2707) (6.1 to 8.1)	0.000*
Incidence of maternal postpartum infection	2.5 (18/720) (1.4 to 3.6)	3.9 (106/2707) (3.2 to 4.6)	0.071
Incidence of neonatal infection	4.0 (29/720) (2.6 to 5.4)	3.1 (84/2707) (2.4 to 3.8)	0.217
Incidence of neonatal asphyxia	1.9 (14/720) (0.9 to 2.9)	7.7 (208/2707) (6.7 to 8.7)	0.000*
Interventions			
Percentage of deliveries with caesarean section	50.1 (361/720) (46.4 to 53.8)	29.0 (777/2681) (27.3 to 30.7)	0.000*
Percentage of instrumented deliveries	0.6 (2/359) (0.3 to 1.2)	2.1 (40/1904) (0.3 to 2.6)	0.023†
Percentage of deliveries with episiotomy	14.8 (53/359) (12.2 to 17.4)	43.2 (823/1904) (41.3 to 45.1)	0.000*
Adverse events in the women (Composite indicator)	7.8 (56/720) (5.8 to 9.8)	2.8 (75/2707) (2.2 to 3.4)	0.000*
Blood transfusion	1.4 (10/720) (0.5 to 2.3)	1.0 (28/2707) (0.6 to 1.4)	0.419

Continued

Table 2 Continued			
Indicator	Brazil % (n/N) (Cl 95%)	Mexico % (n/N) (Cl 95%)	P value
Third- or fourth-degree laceration	1.7 (6/359) (0.4 to 3.0)	0.1 (3/1904) (0.0 to 0.2)	0.000*
Maternal admission to ICU	4.0 (29/720) (2.6 to 5.4)	0.7 (19/2707) (0.4 to 1.0)	0.000*
Postpartum hysterectomy	1.4 (10/720) (0.5 to 2.3)	0.3 (7/2707) (0.1 to 0.5)	0.001†
Uterine rupture	0.4 (3/720) (-0.1 to 0.9)	0.1 (3/2707) (0.0 to 0.2)	0.116
Return to hospital after discharge	0.6 (4/720) (0.0 to 1.2)	0.6 (17/2707) (0.3 to 0.9)	0.823
Maternal death	0.1 (1/720) (-0.1 to 0.3)	0.1 (2/2707) (0.0 to 0.2)	0.621
Adverse events in newborns (Composite indicator)	10.0 (72/720) (7.8 to 12.2)	11.1 (300/2707) (9.9 to 12.3)	0.407
Admission to neonatal ICU >2500 g and for >24 hours	1.5 (11/720) (0.6 to 2.4)	2.2 (60/2707) (1.6 to 2.8)	0.249
Apgar<7 at 5 min	1.9 (14/720) (0.9 to 2.9)	0.7 (18/2707) (0.4 to 1.0)	0.002†
Birth trauma (eg, head trauma, fracture, neurological injury, haemorrhage or laceration)	0.1 (1/720) (-0.1 to 0.3)	0.3 (9/2707) (0.1 to 0.5)	0.352
Newborn hospitalised for more than 7 days	5.1 (37/720) (3.5 to 6.7)	5.2 (140/2707) (4.4 to 6.0)	0.972
Foetal or neonatal death	2.5 (18/720) (1.4 to 3.6)	0.9 (25/2707) (0.5 to 1.3)	0.001†
Adverse events in women and newborns (Composite indicator)	16 (115/720) (13.3 to 18.7)	12.9 (350/2707) (11.6 to 14.2)	0.034†

The case numbers of the composite indicators of good practice are higher than the total number of deliveries evaluated because, in each medical record, up to five good practices are performed for the mother and up to six good practices for the newborn (total of 11 good practices for the mother-child binomial).

The composite indicators were calculated by aggregating the simple good practices and adverse events indicators, which are described in table 1.

\*Variable with p<0.001 †Variable with p<0.05. n, numerator; N, denominator.

### DISCUSSION Main findings

It is known that the problem of high maternal and neonatal morbidity and mortality is intrinsically related to the quality of care provided,<sup>28–10</sup> but there have been a lack of studies with primary data to monitor childbirth care indicators in relation to the impact of AE and the use of evidence-based practices. In addition, there is already considerable literature describing estimates of AE or GP using medical records, but many studies have omitted obstetrical services and focused instead on general medical and surgical wards.

The main results of this study were the apparent difficulty of adhering to evidence-based practices in childbirth care and the high frequency of avoidable AE that affect mothers and their NBs. NB care has relatively worse indicators than maternal care, and the problems are similar, although significantly different in magnitude, in the facilities of both countries. Thus, this research contributes to the identification and prioritisation of quality problems in childbirth care and can guide interventions to increase adherence to GP and reduce AE.

The organisation of a multicentre collaborative study, despite the operational and financial difficulties, allowed a detailed study of the performance of institutions from two countries with similar socioeconomic characteristics, Brazil and Mexico. The results of the institutions are not representative of the entire national scenario, but provide a good source of data for critical analysis of the quality of maternal and NB care. Other generalisations are possible for obstetrical services with the same financial and structural profiles.

Indicator	BR1 % (n/N) (CI 95%)	BR2 % (n/N) (CI 95%)	MX1 % (n/N) (CI 95%)	MX2 % (n/N) (CI 95%)	MX3 % (n/N) (CI 95%)	MX4 % (n/N) (CI 95%)	MX5 % (n/N) (CI 95%)	
Hospital level	Third level	Second level	Second level	Third level	Second level	Second level	Second level	P value
Good practice indicators								
Management of antibiotics during labour	83.3 (189/227) (79.4 to 87.2)	76.8 (129/168) (72.4 to 81.2)	6.0 (25/417) (4.0 to 8.0)	9.9 (13/131) (7.4 to 12.4)	6.3 (33/524) (4.3 to 8.3)	6.2 (33/531) (4.2 to 8.2)	4.9 (26/533) (3.1 to 6.7)	0.000*
Management of magnesium sulfate at delivery for preeclampsia/ eclampsia control	11.7 (23/197) (8.4 to 15.0)	1.4 (2/142) (0.2 to 2.6)	0.0	12.5 (10/80) (9.7 to 15.3)	15.2 (7/46) (12.2 to 18.2)	25.9 (7/27) (22.2 to 29.6)	12.0 (3/25) (9.3 to 14.7)	0.000*
Management of antibiotics in the newborn	90.2 (37/41) (87.1 to 93.3)	100 (2/2) -	80.0 (8/10) (76.6 to 83.4)	68.2 (30/44) (64.3 to 72.1)	88.5 (23/26) (86.1 to 91.5)	67.9 (19/28) (64.0 to 71.8)	66.7 (10/15) (62.7 to 70.7)	0.062
Partograph opening and filling	4.2 (15/360) (2.1 to 6.3)	85.6 (308/360) (82.0 to 90.2)	94.1 (506/538) (92.1 to 96.1)	78.4 (424/541) (74.9 to 81.9)	95.4 (517/542) (93.6 to 97.2)	83.7 (457/546) (80.6 to 86.8)	91.9 (496/540) (89.6 to 94.2)	0.000*
Resolution of justified caesarean delivery	90.7 (205/226) (87.7 to 93.7)	93.3 (126/135) (90.7 to 95.9)	68.3 (84/123) (64.4 to 72.2)	47.9 (128/267) (42.7 to 52.1)	92.4 (171/185) (90.2 to 94.6)	42.0 (42/100) (37.9 to 46.1)	50.0 (51/102) (45.8 to 54.2)	0.000*
Performed justified instrumented childbirth	100.0 (1/1) -	0.0	0.0	78.8 (26/33) (75.4 to 82.2)	42.9 (3/7) (38.7 to 47.1)	0.0	0.0	0.086
Performed justified episiotomy	22.7 (5/22) (18.4 to 27.0)	6.5 (2/31) (3.9 to 9.1)	2.0 (6/297) (0.8 to 3.2)	30.0 (30/100) (26.1 to 33.9)	14.8 (4/27) (11.8 to 17.8)	0.0	5.7 (9/158) (3.7 to 7.7)	0.000*
Good practices in the women (composite indicator)	22.1 (398/1800) (17.8 to 26.4)	33.9 (611/1800) (29.0 to 38.8)	65.2 (1754/2690) (61.2 to 69.2)	57.5 (1556/2705) (53.3 to 61.7)	69.7 (1888/2710) (65.8 to 73.6)	69.3 (1892/2730) (65.4 to 73.2)	69.7 (1883/2700) (65.8 to 73.6)	1
Good practices in newborns (composite indicator)	26.4 (571/2160) (21.8 to 31.0)	25.0 (541/2160) (20.5 to 29.5)	63.8 (2060/3228) (59.7 to 67.9)	46.5 (1509/3246) (42.3 to 50.7)	57.7 (1875/3252) (53.5 to 61.9)	45.8 (1499/3276) (41.6 to 50.0)	46.0 (1489/3240) (41.8 to 50.2)	I
Good practices in women and newborns (composite indicator)	24.5 (969/3960) (20.1 to 28.9)	29.1 (1152/3960) (24.4 to 33.8)	64.4 (3814/5918) (60.4 to 68.4)	51.5 (3065/5951) (47.3 to 55.7)	63.1 (3763/5962) (59.0 to 67.2)	56.5 (3391/6006) (52.3 to 60.7)	56.8 (3372/5940) (52.6 to 61.0)	1
Health outcomes and adverse	events indicators							
Incidence of obstetric haemorrhage	1.9 (7/360) (0.5 to 3.3)	0.3 (1/360) (0.3 to 0.9)	4.3 (23/538) (2.6 to 6.0)	5.2 (28/541) (3.3 to 7.1)	2.0 (11/542) (0.8 to 3.2)	2.6 (14/546) (1.3 to 3.9)	2.8 (15/540) (1.4 to 4.2)	0.000*
Incidence of pre-, intra- and postpartum blood pressure disorders	54.7 (197/360) (49.6 to 59.8)	39.4 (142/360) (34.4 to 44.4)	2.8 (15/538) (1.4 to 4.2)	14.8 (80/541) (11.8 to 17.8)	8.5 (46/542) (6.2 to 10.8)	4.9 (27/546) (3.1 to 6.7)	4.6 (25/540) (2.8 to 6.4)	0,000*
Incidence of maternal postpartum infection	5.0 (18/360) (2.7 to 7.8)	0.0	3.5 (19/538) (1.9 to 5.1)	10.4 (56/541) (7.8 to 13.0)	1.3 (7/542) (0.3 to 2.3)	2.0 (11/546) (0.8 to 3.2)	2.4 (13/540) (1.1 to 3.7)	0.000*
Incidence of neonatal infection	7.5 (27/360) (4.8 to 10.2)	0.6 (2/360) (0.2 to 1.4)	1.3 (7/538) (0.3 to 2.3)	6.1 (33/541) (4.1 to 8.1)	3.7 (20/542) (2.1 to 5.3)	2.2 (12/546) (1.0 to 3.4)	2.2 (12/540) (1.0 to 3.4)	0.000*
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Case numbers and the 95% confidence intervals are shown in parentheses. The case numbers of the composite indicators of good practice are higher than the total number of deliveries evaluated because, in each medical record, up to five good practices are performed for the

mother and up to six good practices for the newborn (total of 11 good practices for the mother-child binomial). The composite indicators were calculated by aggregating the simple good practices and adverse events indicators, which are described in table 1. \* Variable with p<0.001 n, numerator; N, denominator.

Continued

Table 3

Indicator	BR1 % (n/N) (CI 95%)	BR2 % (n/N) (CI 95%)	MX1 % (n/N) (CI 95%)	MX2 % (n/N) (CI 95%)	MX3 % (n/N) (CI 95%)	MX4 % (n/N) (CI 95%)	MX5 % (n/N) (CI 95%)	
Hospital level	Third level	Second level	Second level	Third level	Second level	Second level	Second level	P value
Incidence of neonatal asphyxia	3.6 (13/360) (2.1 to 6.1)	0.3 (1/360) (0.3 to 0.9)	7.8 (42/538) (5.5 to 10.1)	17.4 (94/541) (14.2 to 20.6)	4.2 (23/542) (2.5 to 5.9)	6.0 (33/546) (4.0 to 8.0)	3.0 (16/540) (1.6 to 4.4)	0.000*
Percentage of deliveries with caesarean section	62.8 (226/360) (57.7 to 67.6)	37.5 (135/360) (32.5 to 42.5)	23.2 (123/530) (19.6 to 26.8)	49.4 (267/540) (45.2 to 53.6)	34.2 (185/541) (30.2 to 38.2)	18.7 (100/536) (15.4 to 22.0)	19.1 (102/534) (15.8 to 22.4)	•000.0
Percentage of instrumented deliveries	0.7 (1/134) (0.3 to 1.6)	0.4 (1/225) (0.3 to 1.1)	0.0	12.1 (33/273) (9.4 to 14.8)	2.0 (7/356) (0.3 to 3.2)	0.0	0.0	0.000*
Percentage of deliveries with episiotomy	16.4 (22/134) (12.6 to 20.2)	13.8 (31/224) (10.2 to 17.4)	73.0 (297/407) (69.2 to 76.8)	36.6 (100/273) (32.5 to 40.7)	7.6 (27/356) (5.4 to 9.8)	55.3 (241/436) (51.1 to 59.5)	36.6 (158/432) (32.5 to 40.7)	0.000*
Adverse events in women (composite indicator)	13.3 (48/360) (9.8 to 16.8)	2.2 (8/360) (0.7 to 3.7)	3.0 (16/538) (1.6 to 4.4)	6.3 (34/541) (4.3 to 8.3)	0.7 (4/542) (0.0 to 1.4)	1.8 (10/546) (0.7 to 2.9)	2.0 (11/540) (0.8 to 3.2)	0.000*
Adverse events in newborns (composite indicator)	17.2 (62/360) (13.3 to 21.1)	2.8 (10/360) (1.1 to 4.5)	8.7 (47/538) (6.3 to 11.1)	26.1 (141/541) (22.4 to 29.8)	7.0 (38/542) (4.9 to 9.1)	8.8 (48/546) (6.4 to 11.2)	4.8 (26/540) (3.0 to 6.6)	*000.0
Adverse events in women and newborns (composite indicator)	27.2 (98/360) (22.6 to 31.8)	4.7 (17/360) (2.5 to 6.9)	11.2 (60/538) (8.5 to 13.9)	29.6 (160/541) (25.8 to 33.4)	7.6 (41/542) (5.4 to 9.8)	9.7 (53/546) (7.2 to 12.2)	6.7 (36/540) (4.6 to 8.8)	*000.0
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Figure 1 Comparison of the percentage of good practices and adverse events by country (Brazil and Mexico) and per institution, 2015 and 2016. Legends: the graph shows the estimate of the indicator next to the red circle and above and below it, its upper and lower Cl 95% limits.

# **Comparison with other studies**

# Difficulties in adhering to good practices in childbirth care

Adherence to GP in mother and NB care presented several opportunities for improvement, especially in the

Brazilian setting. Studies related to the SCC initiative have shown positive effects on increasing adherence to GP,<sup>11–13</sup> but there have been no studies to date showing its impact on the reduction of AE.

We observed a satisfactory adherence (greater than 75%) in the opening and filling of the partograph for most of the hospitals evaluated, but it was significantly lower (4.2%) in the Brazilian maternity ward BR1. The partograph is considered an important tool for monitoring the progress of labour. It helps healthcare professionals detect situations of risk to the mother and fetus, and its correct use can reduce infections, hypoxia and trauma to the NB and even maternal and infant mortality.<sup>18 19</sup> Our study confirms that, in spite of all that, this practice, which is considered among the most useful and stimulating practices,<sup>19</sup> is subtilised in facilities of middle-income countries.<sup>20</sup>

Another worrying finding is the low percentage of clinical justifications for the use of antibiotics in Mexican hospitals (6.1%). The routine use of antibiotics in obstetric care is common,<sup>21 22</sup> mainly for prophylactic purposes, but a previous study identified low adequacy in its use (62.2%).<sup>22</sup> Irrational antibiotic use may facilitate microbial resistance and make the manifestations of infection more severe.<sup>21 22</sup> It may also have an effect on neonatal outcomes,<sup>23</sup> resulting in changes in the baby's microbial activity that may cause immediate and longterm AE.<sup>24 25</sup>

Magnesium sulfate is the drug of choice for the treatment of severe hypertensive disorders, such as severe preeclampsia/eclampsia,<sup>26–29</sup> a relatively frequent condition in participating hospitals. Its prescription is advised because it reduces the risk of eclampsia by  $58\%^{28}$  and has superior efficacy to other medicines when eclampsia is reported.<sup>26–29</sup> We identified low adequacy in the use of this medication (7.4% in Brazil and 14.0% in Mexico) in cases of women with severe hypertensive problems. This is a worrying result considering the causal relationship between gestational hypertensive syndromes and maternal morbidity and mortality.<sup>30 31</sup>

In addition to these practices, we found low compliance with other GP recommended by the WHO, especially in Brazil, with figures less than 30%. Given that the practices considered in our study are effective, efficient and safe,<sup>1</sup> it is expected that, as in other studies,<sup>11–13</sup> adherence will increase with quality improvement initiatives.

# Preventable adverse outcomes and events reaching mothers and newborns

The growth of caesarean section internationally is evident.<sup>32-34</sup> According to the latest data from 150 countries, the average global rate of caesarean section is 18.6%.<sup>34</sup> Systematic reviews from the WHO indicate that, at the population level, caesarean section rates higher than 10% are not associated with reductions in maternal and neonatal mortality.<sup>33</sup> The Robson Classification is recommended as a global standard for comparing these rates at the hospital level.<sup>33</sup> Our study showed high caesarean section rates for all analysed institutions, being especially high in the tertiary care hospitals. In addition, we feel the rate of caesarean section in Brazilian maternity wards is extremely high (50.1%). This is consistent

with the national scenario, as the C-section rates in Brazil are one of the highest worldwide.<sup>32</sup> It also raises the possibility that some of the AEs would have been preventable if related to C-sections, simply because many of the C-sections are likely to be unnecessary.

Episiotomy is another intervention whose almost routine use, without justifying criteria, makes it an ineffective and unnecessarily harmful practice. In some cases, episiotomy can lead to third and fourth degree perineal lacerations and damage to the anal sphincter.<sup>35</sup> We found significant differences in the adoption of this practice by facility, but the justification of its use was very low in all hospitals.

These indicators should be subject to systematic monitoring and quality improvement projects, because the unrestricted use of caesarean section and episiotomy may result in unnecessary interventions and AE for the mother-child dyad.<sup>34,35</sup>

The analysis of the simple AE indicators, highlights neonatal death and admission of the mother and NB (weight 2500g and for >24 hours) in ICUs. These results confirm the evidence that AE prolong hospital stays, add unnecessary hospital expenses and result in suffering, disability and death.<sup>36-40</sup> The composite indicators of AE presented similar results to other studies<sup>38-42</sup> involving general hospitals that include the obstetric clinic. Research on obstetric and neonatal AE is still relatively scarce. Reported figures vary between 2.5% and 24.3%.<sup>37 43-45</sup> We also highlight the higher incidence of AEs in obstetric hospitals providing care for women at high risk as compared with general hospitals. We have not found studies describing these events by type of facility in relation to complexity or level of care.

The results in relation to AE may be a consequence of poor adherence to GP in these services and express the importance of monitoring and interventions to reduce AE, not only to prevent maternal and neonatal deaths but also to improve care and prevent childbirth complications. The WHO suggests the implementation of checklists as an important barrier to AE,<sup>46</sup> as they assist care teams in systematically following critical safety steps.<sup>47</sup> In addition, it is suggested to integrate this with other quality care strategies, such as interdisciplinary team training, standardisation of evidence-based care and feedback on team performance.<sup>45</sup>

#### Strengths and weaknesses of the study

The strengths of this study are that it describes the profile of AE and GP in obstetric services of different levels of complexity and may be useful in identifying opportunities for improvements in the quality of delivery care, as well as to propose a method for monitoring and analysing the quality of obstetric care based on standardised indicators. Comparative results between facilities and countries highlight the importance of the context for prioritising quality problems, while stressing similarities in the type of problems to address. This study may have limitations related to registration bias, since the collection of data from medical records depends on the quality and regularity of the information recorded. This bias may have occurred because it involves routine events in which they simply do not register their realisation or because they relate to the accountability of professionals. In order to minimise this limitation and guarantee the comparability of data, a previous pilot study was carried out, and the criteria for data gathering for each indicator were established.

Another limitation may be related to the descriptive nature of the study, which does not allow us to establish causal relationships between the conformity with GP and the occurrence of AEs. However, these data allow us to generate hypotheses that GP can influence AE, and future studies are necessary to investigate and test these hypotheses in order to know the effectiveness and clinical safety of childbirth care practices.

#### **CONCLUSION**

The evaluation of the care processes developed in this research allows the identification and contextual prioritisation of interventions to improve the quality of health services and can contribute to a review of care processes, making the practices safer and more effective.

Considering the results obtained, the following opportunities for improvement are highlighted: rationalising the use of antibiotics for the mother; encouraging greater adherence to the partograph; improve the use of C-sections based on valid clinical criteria; reducing the use of episiotomy; and reducing maternal and neonatal AE. Interventions adapted to the context in which these services are provided is fundamental to improve the quality of care and reduce AE in childbirth and the postpartum period. Future research in other contexts may be needed to further generalise our results, but the indicators we have used may be utilised to monitor maternal and NB care in similar settings.

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