



Neonatal Serious Events
Related to Labor and Delivery

April 2024

Background

The number of serious events* reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS) under the *Neonatal complication* subtype of the *Complication of Procedure/Treatment/Test* event type increased by 92% between 2018 and 2022. To better understand the nature of these events, we performed an in-depth review of PA-PSRS reports describing the injury or death of a neonate related to labor and delivery.

Methods

To identify potential neonatal injuries or death related to labor and delivery, we queried the PA-PSRS database for reports of serious events that occurred between January 1 and December 31, 2022, that met one of the following criteria:

- Reports submitted under the *Neonatal complication* subtype of the *Complication of Procedure/Treatment/Test* event type, except those with a location in the Emergency care area group.[†]
- Reports submitted under the *Complication of Procedure/Treatment/Test*, *Error related to Procedure/Treatment/Test*, *Skin Integrity*, or *Other/Miscellaneous* event type with a location in the OB/GYN Unit, Labor and Delivery, or Surgical Services care area group, with a free-text field containing at least one keyword describing a neonate[‡] and at least one keyword describing a potential complication.[§]

The query returned 304 reports, which we manually reviewed to identify relevant events in accordance with the scope of our study. We defined a relevant event as follows: ***An event related to labor and delivery that occurred or became apparent during labor and delivery or within three hours after birth and resulted in an unanticipated injury or the death of a neonate.*** Our manual review identified 169 relevant events.

To supplement the information contained in PA-PSRS reports, we developed a form consisting of 15 questions, four of which were not mandatory (see **Appendix**). One hospital closed before the project began; thus, 168 forms were emailed to 44 facilities on July 13, 2023. Form collection was closed on December 14, 2023.

* A serious event is defined as “[a]n event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.”

[†] Within PA-PSRS, the event reporter chooses among 168 care areas to indicate the location where an event occurred. We sorted each of the care areas into 23 higher-level care area groups.

[‡] The following keywords were used to identify a neonate: newborn, infant, fetus, fetal, neonate, NB, baby

[§] The following keywords and their variations were used to identify a potential complication: cord, NICU, meconium, decel, vacuum, forcep, Apgar, oxygen, O2, FHT, decompensate, tracing, FAVD, VAVD, FHR, instrument, monitor, distress, suction, retract, flaring, intubat, CPAP, Cat II, Cat III, c-section, CS, c/s, cesarean, c section, PPV, resuscitate, floppy, non-reassuring

Variables Coded

We explored two sets of variables. The first set was coded by the event reporter (i.e., facility staff member who submitted the report) and/or form completion personnel (e.g., patient safety officer) and included demographic and clinical information. The second set of variables was coded by the researcher based on a manual review of information contained in the event report and supplemental data form. These variables included labor and delivery events and interventions/outcomes. Labor and delivery events and interventions/outcomes were not mutually exclusive; therefore, multiple events and/or interventions/outcomes were coded for a single event report when appropriate.

Results

After reviewing the information provided in supplemental data forms, we excluded six additional reports that did not meet our definition of a relevant event. This brought the total number of relevant event reports to 162.

Maternal and Neonatal Demographics

Maternal age ranged from 16 to 46 years, with an average age of 29.5 years. More than half of the mothers (54.9%; 89 of 162) had given birth to at least one child previously, and 42.0% (68 of 162) had not given birth to a child previously. The number of prior births was not able to be determined for five mothers.

Nearly two-thirds (62.3%; 101 of 162) of deliveries occurred at full term;** 20.4% (33 of 162) were early term;** 13% (21 of 162) were preterm;** and 4.3% (7 of 162) were late term.** There were no postterm** deliveries in this dataset.

Most neonates (66.0%; 107 of 162) had a normal birthweight,^{††} while one-quarter (25.3%; 41 of 162) had a high birth weight,^{††} and 8.6% (14 of 162) had a low birth weight.^{††}

Labor and Delivery Factors, Events, and Interventions/Outcomes

Following a manual review of the PA-PSRS event reports and supplemental data forms, we analyzed various labor and delivery factors, shown in **Table 1**. We also identified eight labor and delivery event categories and 10 intervention/outcome categories. **Tables 2 and 3** show the totals for each event and intervention/outcome category, respectively. In addition, we explored the relationship between the events and interventions/outcomes, shown in **Table 4**.

** Preterm:¹ Before 37 weeks gestation; Early term: Between 37 weeks, 0 days and 38 weeks, 6 days gestation; Full term: Between 39 weeks, 0 days and 40 weeks, 6 days gestation; Late term: 41 weeks 0 days gestation to 41 weeks 6 days; Postterm: 42 weeks 0 days and beyond.²

^{††} Low birthweight: Less than 2,500 grams; Normal birthweight: Between 2,500 and 4,000 grams; High birthweight: 4,000 grams or more.³

Table 1. Frequency of Labor and Delivery Factors, N=162

Labor and Delivery Factor	Categorization	Frequency, n (%)
Onset of labor	<i>Spontaneous</i>	78 (48.1%)
	<i>Induced</i>	64 (39.5%)
	<i>Not applicable</i>	14 (8.6%)
	<i>Unknown</i>	6 (3.7%)
Augmentation of labor	<i>Yes</i>	49 (30.2%)
	<i>No</i>	84 (51.9%)
	<i>Not applicable</i>	14 (8.6%)
	<i>Unknown</i>	17 (10.5%)
Rupture of membranes	<i>Spontaneous</i>	62 (38.3%)
	<i>Artificial</i>	79 (48.8%)
	<i>Not applicable</i>	14 (8.6%)
	<i>Unknown</i>	7 (4.3%)
Meconium-stained fluids present	<i>Yes</i>	35 (21.6%)
	<i>No</i>	113 (69.8%)
	<i>Unknown</i>	14 (8.6%)
Mode of delivery	<i>Vaginal</i>	116 (71.6%)
	<i>C-section</i>	46 (28.4%)
TOLAC	<i>Yes</i>	10 (6.2%)
	<i>No</i>	136 (84.0%)
	<i>Not applicable</i>	14 (8.6%)
	<i>Unknown</i>	15 (9.3%)
VBAC	<i>Yes</i>	9 (5.6%)
	<i>No</i>	137 (84.6%)
	<i>Not applicable</i>	14 (8.6%)
	<i>Unknown</i>	15 (9.3%)
Use of instruments	<i>Vacuum</i>	26 (16.0%)
	<i>Forceps</i>	5 (3.1%)
	<i>No instruments used</i>	114 (70.4%)
	<i>Unknown</i>	17 (10.5%)
Duration of labor	<i><12 hours</i>	73 (45.1%)
	<i>>12 hours</i>	62 (38.3%)
	<i>Not applicable</i>	14 (8.6%)
	<i>Unknown</i>	13 (8.0%)

Note: Percentage is calculated using a denominator of 162. Factors labeled as “Not applicable” were scheduled C-sections.

C-section: Cesarean section

TOLAC: Trial of labor after C-section

VBAC: Vaginal birth after C-section

Table 2. Frequency of Labor and Delivery Events, N=162

Event	Frequency, n (%)
Shoulder dystocia	59 (36.4%)
Fetal distress	52 (32.1%)
Meconium-stained fluids	37 (22.8%)
Nuchal cord	28 (17.5%)
Unknown/unable to determine	21 (13.0%)
Other event	9 (5.6%)
Breech presentation	6 (3.7%)
Hypoxic conditions	4 (2.5%)

Note: Percentage is calculated using a denominator of 162. Labor and delivery events were not mutually exclusive; therefore, multiple events were coded for a single event report when appropriate. "Other event" includes a small C-section incision, cord prolapse, hand presentation, precipitous delivery, entrapment of baby's arm behind the back, short clamped umbilical cord, maternal medication administration, rhythm changes after birth, and use of fetal scalp electrodes.

Table 3. Frequency of Interventions/Outcomes, N=162

Intervention/Outcome	Frequency, n (%)
Respiratory distress/support	106 (65.4%)
Fracture	83 (51.2%)
Unanticipated NICU admission	27 (16.7%)
Unanticipated transfer to another hospital	21 (13.0%)
Brachial plexus Injury	17 (10.5%)
Skin injury	17 (10.5%)
Death	12 (7.4%)
Other intervention/outcome	6 (3.7%)
Hypoxic-ischemic injury	5 (3.1%)
Unknown/unable to determine	1 (0.6%)

Note: Percentage is calculated using a denominator of 162. Interventions/outcomes were not mutually exclusive; therefore, multiple interventions/outcomes were coded for a single event report when appropriate. "Other intervention/outcome" includes compartment syndrome, injury to an arm that was not described as a fracture or brachial plexus injury, facial nerve injury, pneumoperitoneum, excessive blood loss due to umbilical cord complication, and gastric perforation.

Table 4. Frequency of Relationships Between Labor and Delivery Events and Interventions/Outcomes, N=162

Intervention/ Outcome	Event							
	Shoulder dystocia	Fetal distress	Meconium-stained fluids	Nuchal cord	Unknown/unable to determine	Other event	Breech presentation	Hypoxic conditions
Respiratory distress/support	39 (24.1%)	37 (22.8%)	27 (16.7%)	15 (9.3%)	14 (8.6%)	4 (2.5%)	4 (2.5%)	4 (2.5%)
Fracture	36 (22.2%)	17 (10.5%)	15 (9.3%)	14 (8.6%)	14 (8.6%)	3 (1.9%)	3 (1.9%)	1 (0.6%)
Unanticipated NICU admission	8 (4.9%)	14 (8.6%)	8 (4.9%)	6 (3.7%)	3 (1.9%)	1 (0.6%)	-	3 (1.9%)
Unanticipated transfer to another hospital	4 (2.5%)	9 (5.6%)	5 (3.1%)	2 (1.2%)	2 (1.2%)	2 (1.2%)	1 (0.6%)	1 (0.6%)
Brachial plexus injury	14 (8.6%)	5 (3.1%)	5 (3.1%)	4 (2.5%)	1 (0.6%)	-	-	-
Skin injury	1 (0.6%)	8 (4.9%)	3 (1.9%)	2 (1.2%)	1 (0.6%)	1 (0.6%)	-	-
Death	2 (1.2%)	7 (4.3%)	5 (3.1%)	4 (2.5%)	4 (2.5%)	1 (0.6%)	-	-
Other intervention/ outcome	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (1.2%)	2 (1.2%)	2 (1.2%)	1 (0.6%)	-
Hypoxic-ischemic injury	2 (1.2%)	1 (0.6%)	1 (0.6%)	-	-	-	-	4 (2.5%)
Unknown/unable to determine	1 (0.6%)	-	-	-	-	-	-	-

Note: Percentage is calculated using a denominator of 162. Labor and delivery events and interventions/outcomes were not mutually exclusive; therefore, multiple events and/or interventions/outcomes were coded for a single event report when appropriate.

Due to the high frequency of shoulder dystocia events and fracture outcomes, we investigated these further. We did not find any associations between shoulder dystocia and maternal or neonatal demographics, other labor and delivery events, or interventions/outcomes, other than what would be expected based on prior literature⁴ and clinical knowledge.⁵ All 59 shoulder dystocia events involved either normal or high birth weight neonates and occurred more frequently in full and late term deliveries (72.9%; 43 of 59) than in early and preterm births (27.1%; 16 of 59).

Of the 83 fractures, 62.7% (52 of 83) involved the clavicle. Other fracture sites included the humerus (30.1%; 25 of 83), skull (3.6%; 3 of 83), arm (1.2%; 1 of 83), shoulder (1.2%; 1 of 83), and ribs (1.2%; 1 of 83). While some fractures were associated with labor and delivery events, such as shoulder dystocia (22.2%; 36 of 83), a precipitating event could not be determined for nearly one-quarter (24.1%; 20 of 83) of the fractures.

We did not find any meaningful associations between fractures and maternal and neonatal demographics or labor and delivery factors. Fractures were associated with more vaginal (89.2%; 74 of 83) than C-section (10.8%; 9 of 83) deliveries. They were also more frequently associated with normal and high birth weight neonates (95.2%; 79 of 83) and full and late term births (68.7%; 57 of 83). Notably, two-thirds (66.7%, 6 of 9) of the VBAC deliveries involved a fracture; however, we were unable to identify any other associations to offer additional insight as to the relationship between these factors.

We also analyzed all available data associated with the 12 deaths; however, no meaningful patterns were identified.

Limitations

While reporting to the PA-PSRS database is mandated by Pennsylvania law, it is possible that some events go unreported. It is also important to note that instances of labor and delivery complications and neonatal-related outcomes in high-risk patients may not have been reportable if the increased risk was communicated to the patient prior to delivery. In addition, this study was limited to reports of events that occurred over a one-year period; therefore, they may not be generalizable or representative of all neonatal serious events related to labor and delivery.

While the supplemental data form included non-mandatory questions regarding the primary cause and contributing factors to the event, we received an insufficient number and detail of responses to these questions to perform a meaningful analysis of the data. As a result, we were unable to establish any causation between maternal and neonatal demographics, events, and/or interventions/outcomes.

Conclusion

Results from this study highlight neonatal serious events related to labor and that may benefit from further research. Facilities must seek to identify causes and contributing factors to these events and report their findings to PA-PSRS. The more comprehensive data that is reported, the better equipped the Patient Safety Authority will be to identify trends and future opportunities to prevent neonatal complications and death across the Commonwealth.

Note

This analysis was exempted from review by the Advarra Institutional Review Board.

References

1. American College of Obstetricians and Gynecologists. Preterm Labor and Birth. 2023.
2. The American College of Obstetricians and Gynecologists Committee on Obstetric Practice Society for Maternal-Fetal Medicine. Definition of Term Pregnancy. 2013.
3. Osterman MJK, Hamilton BE, Martin JA, Driscoll AK, Valenzuela CP. Births: Final Data for 2021. National Vital Statistics Reports Centers for Disease Control. 2023;72(1).
4. Youssefzadeh AC, Tavakoli A, Panchal VR, Mandelbaum RS, Ouzounian JG, Matsuo K. Incidence trends of shoulder dystocia and associated risk factors: A nationwide analysis in the United States. *Int J Gynaecol Obstet.* 2023;162(2):578-89. Epub 2023/01/28. doi: 10.1002/ijgo.14699. PubMed PMID: 36707062.
5. Davis DD, Roshan A, Varacallo M. Shoulder Dystocia. StatPearls [Internet]. Treasure Island, FL: StatPearls Publishing; 2023.

Appendix

PA-PSRS Supplemental Data Form Neonatal Complications

PA-PSRS Report Number: _____

Mandatory questions are marked with an asterisk ()*

1. Primary cause of the event as identified during the investigation (or causal statement)

2. Other contributing factors identified during the investigation

3. Actions taken or planned in response to the investigation

4. Description of investigation method(s) used*

5. Additional details discovered during the investigation but not included in the PA-PSRS report

Labor and Delivery

6. Labor and delivery details (see below for specific types of information to provide in response to this question)*
 - Induction of labor or spontaneous labor
 - If induced, reason(s) for induction, agents used
 - Was labor augmented? If so, reason(s) for augmentation, agents used
 - AROM or SROM
 - Was fluid meconium stained or malodorous?
 - Monitoring details (internal or external monitor)
 - VBAC or TOLAC
 - Mode of pain relief, if any
 - Mode (vaginal, C-section)
 - If C-section, reason(s) it was performed
 - Use of forceps or vacuum
 - If vacuum, how many pulls, pop-offs
 - Fetal position
 - Duration of labor

Neonatal Information

7. Gestation (weeks and days) at time of delivery*

8. Neonate weight at birth*

9. APGAR scores at 1 and 5 minutes (and additional scores, if applicable)*

10. Were any resuscitative measures performed on the neonate at delivery (e.g., PPV, supplemental oxygen, chest compressions, intubation)?*

11. Congenital abnormalities, if any*

Maternal Information

12. Mother's age*

13. Gravity and parity (GTPAL: gravidity, term births, preterm births, abortions/miscarriages, living children)*

14. Previous complicated pregnancies or deliveries*

Additional Event-Related Information

15. Maternal and/or neonatal factors leading to the reportable event (see below for specific types of information to provide in response to this question)*

- Fetal heart tracings (category I, II, III)
- Nuchal cord
- Pregnancy complications (gestational diabetes, placenta Previa, preeclampsia, IUGR, GBS+)
- Placental abruption, uterine rupture, maternal cardiac arrest, maternal seizure