PENNSYLVANIA PATIENT SAFETY ADVISORY

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SUPPLEMENT

1 Medication Errors in Labor and Delivery: Reducing Maternal and Fetal Harm

Practitioners who work in labor and delivery units may administer a variety of medications during the birthing process that, when used in error, may adversely affect both the mother *and* the fetus. In events reported to the Pennsylvania Patient Safety Authority, the predominant medication error types associated with the labor and delivery unit were dose-omission errors and wrong-drug errors.

7 Preventing Maternal and Neonatal Harm during Vacuum-Assisted Vaginal Delivery

While vacuum-assisted vaginal delivery is viewed as a safe alternative to forceps deliveries, there are known maternal and fetal risks associated with vacuum devices, including maternal perineal injury and fetal cranial hemorrhages.

18 Neonatal Complications: Recognition and Prompt Treatment of Shoulder Dystocia

Although it is difficult to accurately predict or prevent shoulder dystocia, delivering healthcare providers can be prepared when this obstetric emergency occurs.

26 Data Snapshot: Maternal Complications

A search of the Pennsylvania Patient Safety Authority's reporting system database results in identification of 256 reports of maternal complications causing harm to mothers.

About the Pennsylvania Patient Safety Advisory

OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes.

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Medication Errors in Labor and Delivery: Reducing Maternal and Fetal Harm

ABSTRACT

Practitioners who work in labor and delivery units may administer an assortment of high-alert medications during the birthing process. These medications, such as oxytocin (used to induce and augment labor) and magnesium sulfate (used to treat preeclampsia and to delay preterm birth), are often administered intravenously. Medications used to manage pain, such as morphine and HYDROmorphone, may also be administered intravenously, while others, such as bupivacaine and fentanyl, may be administered via the epidural route. When high-alert medications are used in error in labor and delivery units, the event can affect both the mother and the fetus. Between June 2004 and April 2009, Pennsylvania healthcare facilities submitted 2,611 event reports involving medication errors in labor and delivery units. Analysis reveals that the most common medication error event type associated with this area is dose omission (22.5%), followed by wrong drug (10.7%). Further analysis showed that 46.4% of wrong-dose/overdosage errors and 55.2% of wrong-rate errors involved high-alert medications. Strategies to prevent medication errors and patient harm in this specialty setting include standardizing the dosing and administration protocols as well as standardizing the concentrations and dosing units of drug infusions and adopting a policy that all infusions be administered with an infusion pump. (Pa Patient Saf Advis 2009 Dec 16;6[Suppl 1]:1-6.)

Practitioners who work in labor and delivery units may administer a variety of medications during the birthing process. These medications, such as oxytocin (used to induce and augment labor) and magnesium sulfate (used to treat preeclampsia and delay preterm birth), are frequently administered intravenously. Medications to manage pain, including morphine and HYDROmorphone, may also be administered intravenously, while others, such as bupivacaine and fentanyl, may be administered via the epidural route. All these medications are high-alert medications and, when used in error, bear a heightened risk of causing significant patient harm. When used in error in labor and delivery units, the medications may adversely affect both the mother *and* the fetus.

Many errors have been reported in the literature involving high-alert medications in labor and delivery; some of these errors have resulted in fatalities. Most of these errors were the result of unfamiliarity with safe dosage ranges and signs of toxicity, inadequate patient monitoring, pump programming errors, and confusion between magnesium sulfate, oxytocin, and intravenous (IV) fluids used for hydration.[1,2] Simpson and Knox accumulated a database of 52 cases involving accidental magnesium overdoses. The authors state that these events were not uncommon, were known to have happened in at least two institutions, and appear to have involved similar themes and causative factors.[3]

Risks are associated with epidural injections and infusions as well. One of the most significant risks is associated with erroneous infusion of epidural medications—particularly epidural infusions containing bupivacaine—intravenously. Intravenous bupivacaine can quickly lead to cardiotoxicity.

A Look at the Numbers

Pennsylvania healthcare facilities submitted 2,611 event reports to the Pennsylvania Patient Safety Authority from June 2004 to April 10, 2009, that described medication errors that took place in labor and delivery units in Pennsylvania. Further breakdown by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention harm index,[4] shows that 68.7% (n = 1,793) of the events reached the patient (harm index = C to I) and 1% (n = 27) of the events were indicated by the facility as resulting in harm to the patient.

The predominant medication error event types associated with the labor and delivery unit (see Table 1) were dose-omission errors (n = 587, 22.5%) followed by wrong-drug errors (n = 280, 10.7%).

Dose-Omission Errors in the Labor and Delivery Unit

Analysis of Authority reports involving dose-omission errors in the labor and delivery unit revealed that 34.8% (n = 204) were associated with antibiotic doses. Antibiotics (e.g., penicillin, ampicillin) are often used during labor and delivery to prevent neonatal Group B *Streptococcus* (GBS) infection. GBS is a type of bacteria that can cause life-threatening infections in neonates, occurring in approximately 1 in every 3,000 infants born in the United States.[5] Infected infants usually contract GBS from their mothers during vaginal birth. Infants with an early-onset infection suffer from one or more of the following conditions: pneumonia, sepsis, and less commonly, meningitis. Infants with a late-onset infection usually have sepsis or meningitis. However, GBS can also cause complications in the mother, unrelated to neonatal infection, including uterine infection before or after delivery. Infection before delivery, or chorioamnionitis, causes fever, uterine tenderness, and increased heart rate in the fetus. This infection is also treated with antibiotics.[6] While only 11 (5.4%) of the 204 dose-omission

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errors involving antibiotics mention GBS as part of the event detail and harm scores do not exceed category D, practitioners should be aware of the importance of antibiotic drug therapy, if warranted, during the labor and delivery phase of the perinatal period.

Wrong-Drug Errors in the Labor and Delivery Unit

Analysis of Authority reports involving wrong-drug errors showed that 180 (64.3%) reached the patient and 11 (3.9%) resulted in patient harm. In addition, 70 events (25%) involved high-alert medications, the majority of which were infusions. In 11 (15.7%) cases involving high-alert medications, oxytocin was administered instead of the prescribed medication, while in 7 (10%) cases, magnesium sulfate was given instead of the intended drug.

Wrong-drug medication errors reported to the Authority include the following:

The patient was in labor, and the anesthesiologist was in the process of inserting an epidural catheter. The patient's blood pressure dropped, and the patient complained of feeling dizzy. The anesthesiologist handed a vial of ephedrine to the RN [registered nurse] and told the nurse to mix it with normal saline and administer 1 mL of the prepared solution to the patient. The RN did so, but then the patient became nauseated and dizzy and began to hyperventilate. It was then realized that the RN had been handed a vial of epinephrine instead of ephedrine. The patient was hydrated, and within a few minutes, all her symptoms had subsided. A vial of epinephrine was in the disposable epidural tray. The anesthesiologist was uncertain if he picked up that vial in error as opposed to the ephedrine vial, which is kept in the epidural cart.

The patient was admitted for induction of labor. Lactated Ringer's fluid was ordered. IV access was obtained, and the IV fluid was connected. The fetal heart monitor started to show deceleration of the heartbeat. The patient was placed on her right side, and the ultrasound showed a fetal bradycardia. The patient was given terbutaline with a return of fetal heart rate to the baseline. Upon repositioning the patient, the IV fluid infusing was noted to contain Pitocin®. The IV fluid was immediately discontinued; lactated Ringer's was started as ordered. Both patient and fetal heart rate remained stable; labor progressed without complications with a successful vaginal delivery of a healthy baby.

Ampicillin was ordered for a laboring patient due to premature ruptured membranes. An IV solution of bupivacaine was pulled by the nurse and hung. The error was discovered by another RN after 125 mL infused. Physicians were notified, and the error was discussed with the patient and family. The patient had transient symptoms. The patient delivered without incident.

This last case is similar to a nationally known case in which, in 2006, a 16-year-old woman in labor died after an epidural analgesic including bupivacaine and fentanyl was inadvertently infused intravenously instead of penicillin. A few minutes after the start of the infusion, the woman experienced seizures, a clenched jaw, and gasping respirations. The woman eventually died despite efforts to resuscitate her.[7,8] In 2008, the UK National Patient Safety Agency and the British media published information involving a similar incident in which a young woman died after receiving IV bupivacaine.[9,10] In this case, the woman in labor should have received normal saline intravenously, but a nurse accidentally selected an identical bag of bupivacaine located in the same unlocked drawer as the saline. The bupivacaine infusion did not contain fentanyl, and therefore, did not require locked storage. Since the nurse thought she was administering a bag of normal saline, she had no reason to require another nurse to double-check the product before giving it. The patient developed seizures and cardiac arrest that could not be reversed.[11]

Table 1. Predominant Medication Error Event Types Associated with the Labor and Delivery Unit (n = 2,442), June 2004 to April 2009

EVENT TYPE	NUMBER	% OF TOTAL REPORTS (N = 2,611)
Dose omission	587	22.5%
Wrong drug	280	10.7%
Medication error—other	272	10.4%
Wrong time	213	8.2%
Wrong patient	177	6.8%
Wrong dose/overdosage	166	6.4%
Prescription/refill delayed	145	5.6%
Unauthorized drug	136	5.2%
Extra dose	120	4.6%
Wrong route	103	3.9%
Wrong dose/underdosage	99	3.8%
Monitoring error—documented allergy	86	3.3%
Wrong rate (intravenous)	58	2.2%

Wrong-Dose/Overdosage Errors in the Labor and Delivery Unit

Authority reports involving wrong-dose errors associated with an overdose of a medication accounted for 6.4% (n = 166) of overall errors in labor and delivery. There were 117 (70.5%) overdoses that reached the patient, eight (4.8%) of which resulted in harm. Seventy-seven (46.4%) of these events involved high-alert medications. See Table 2 for the top 10 medications involved in wrong-dose/overdosage errors in labor and delivery.

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Table 2. Top 10 Medications Involved in Wrong-Dose/Overdosage Errors in the Labor and Delivery Unit (n = 89), June 2004 to April 2009

MEDICATION PRESCRIBED	NUMBER	% OF TOTAL OVERDOSE REPORTS (N = 166)
Oxytocin*	19	11.4%
Misoprostol	13	7.8%
Morphine*	11	6.6%
Magnesium sulfate*	9	5.4%
HYDROmorphone*	8	4.8%
Meperidine*	7	4.2%
Insulin*	7	4.2%
Vitamin K	5	3%
Terbutaline	5	3%
Hydrations	5	3%

* High-alert medications

Qualitative analysis of the top five high-alert medications involved in wrong-dose/overdosage errors (oxytocin, morphine, magnesium sulfate, HYDROmorphone, and meperidine) indicate a strong correlation with failure points related to infusion pump management. Thirty-five (64.8%) of the 54 wrong-dose/overdosage reports with high-alert medications specifically mentioned issues with the use of infusion pumps, including pumps that were not programmed correctly (e.g., wrong-drug concentrations, wrong infusion rates), free-flowing or "wide-open" IVs, and IV pump tubing mix-ups. Important to note is the potential for harm to the fetus with oxytocin wrong-dose/overdosage errors. Nine (47%) of the 19 oxytocin wrong-dose/overdosage errors mentioned the presence of fetal distress, each of which also involved a pump-related contributing factor. The authors of one study noted that errors involving oxytocin administration during labor are predominantly dose-related and often involve a lack of timely recognition and appropriate treatment of excessive uterine activity (tachysystole).[12]

Additional analysis of these reports suggests frequent prescribing errors with misoprostol. Ten (77%) of the 13 misoprostol wrong-dose/overdosage errors involved doses mistakenly ordered in milligrams instead of micrograms. Of note among this error type was the correlation of each of the Vitamin K reports (n = 5) with the wrong-drug concentration (e.g., adult formulation instead of the desired neonatal concentration).

Wrong-dose/overdosage errors reported to the Authority include the following:

The patient was receiving IV fluid (lactated Ringer's) boluses as ordered. The Pitocin (oxytocin) protocol was then initiated. The IV fluid was taken off the pump so that Pitocin could be placed on the pump. Another fluid bolus was ordered for the patient. The RN mistakenly [bolused] the fluid on the pump, which was the Pitocin. The patient received 25 mL of Pitocin. The fetal heart rate dropped; the patient was given terbutaline and was taken for a stat cesarean section.

A new nurse on orientation confused the IV lines, connecting the IV fluids to the pump at the rate of infusion for the Pitocin drip and vice versa. The patient received an increased dose of Pitocin. The electronic fetal monitor showed fetal bradycardia. Reversal of Pitocin was attempted without success. The baby was delivered via a stat cesarean section with reasonable Apgar scores.

The fetal heart tones were low. Pitocin was found to be programmed to run at 72 milliunits/minute. The RN stated she had meant to place Pitocin at 12 milliunits/minute and inadvertently set it at 72. The Pitocin was turned off, and the patient was positioned on her right side. An IV fluid bolus was given.

The nurse mistakenly opened the magnesium sulfate infusion wide open instead of lactated Ringer's as ordered. The patient complained of feeling flushed. The error was discovered, and the infusion was discontinued. There was no adverse outcome to the patient.

The physician gave a verbal order for Brethine® (terbutaline) 0.25 mg subcutaneous, but the nurse administered a 2.5 mg dose. Transient fetal tachycardia and maternal hypotension occurred. The patient was monitored, and no further intervention was required.

Wrong-Rate (IV) Errors in the Labor and Delivery Unit

Another medication error event type that often leads to overdoses is wrong-rate errors. A total of 58 (2.2%) medication error reports associated with the labor and delivery unit submitted to the Authority involved wrong-rate errors associated with IV infusions. Of these, 49 (84.5%) events reached the patient, and 2 (3.4%) resulted in patient harm. A total of 32 reports involved high-alert medications, accounting for 55.2% of the errors. The top three drugs involved in wrong-rate (IV) errors were oxytocin (25.9%), hydrations (20.7%), and magnesium sulfate (13.8%).

The following are examples of wrong-rate errors reported to the Authority.

The RN increased the rate [of the oxytocin infusion] to 725 mu instead of 5 mu. The infusion ran for several minutes before being discovered. Brief fetal deceleration was noted. There were no anticipated sequelae to mother or baby. The mother and baby were discharged home in stable condition.

Insulin was ordered for 1.6 units per hour per protocol. The infusion was begun, and 20 minutes later it was noted that the rate was 106 units per hour. The insulin was stopped, the physician was notified, and dextrose was increased.

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Risk Reduction Strategies

Based on the review of reports submitted to the Authority, as well as observations at the Institute for Safe Medication Practices and in the literature, the following strategies may help prevent medication errors in the labor and delivery unit and mitigate patient harm when errors do occur.

Standardization

Establish standardized concentrations and dosing regimens for oxytocin, magnesium sulfate, and other high-alert medication infusions, and if possible, provide commercially available or pharmacy prepared solutions to eliminate the need for nurse preparation at the point of care. Avoid using nonstandard concentrations. Develop specific protocols for the administration of bolus doses. Establish dosing and administration protocols and standard order sets for magnesium sulfate, oxytocin, and other high-alert medication infusions. As part of this work, standardize the unit of measure used to prescribe magnesium sulfate (e.g., g, mEq) and to report lab values (e.g., mg/dL, mEq/L, mmol/L).[1,12]

Infusion Pumps and Administration Sets

Adopt a policy that *all* IV medications be administered via infusion pump, preferably a smart pump with operational dose range alerts. For epidural infusions, use pumps that look different than pumps used for IV infusions. Avoid the use of dual-channel pumps for simultaneous administration of IV *and* epidural drugs. In addition, use yellow-lined tubing without injection ports for epidural infusions in order to set its appearance apart from regular IV tubing, and never use it for anything other than epidural administration. Likewise, when drug infusions are discontinued, require the immediate removal of those drug infusions from the patient's access site, pump, and IV pole to prevent later accidental infusion.[11]

Labeling

Use bold fonts to label IV infusion bags of oxytocin, magnesium sulfate, and other high-alert infusions to differentiate them from each other and from IV hydration infusions. In addition, label infusion pumps with the name of the solution being infused as well as the IV tubing near the IV pump. When infusions are started or the rate is adjusted, trace the tubing by hand from the IV bag, to the pump, and then to the patient for verification. For epidural medications, clearly label infusion bags and syringes that contain epidural medications as well as epidural infusion pumps with the designation "For Epidural Use Only" in large type.[1,2,11]

Storage

Reduce the risk of mix-ups by separating the storage of high-alert IV drug infusions, epidural infusions, and regular fluids, such as lactated Ringer's solution, used for hydration. Create designated areas to place medications needed during different phases of the labor and birth process (e.g., containers or drawers labeled with bold fonts, in which products can be neatly organized). Restrict access to unneeded medications. In addition, never store look-alike products, such as EPINEPHrine and ePHEDrine, side by side in anesthesia or epidural carts.[2,13]

Look- and Sound-Alike Products

Distinguish products with look- and sound-alike names through the use of "tall man" lettering, in which uppercase letters are applied to the parts of the names that are different (e.g., EPINEPHrine, ePHEDrine). This form of differentiating look-alike products should be used on computer screens, pharmacy and nursing unit shelf labels and bins (including automated dispensing cabinets), pharmacy product labels, and medication administration records. In addition, prescribers should use tall man letters when creating electronic order sets as well as in written orders.[13]

Verbal Orders

Reserve verbal orders for true emergency situations or when the prescriber is physically unable to write or electronically transmit orders (e.g., working in a sterile field). If the medication prescribed requires emergency administration (or the nurse is working within a sterile field), repeat back the order, and announce the medication again just before administration (e.g., "I am now giving ePHEDrine 5 mg intravenously.").[14]

Double Checks

Require an independent double check of the drug, concentration, infusion rate, pump settings, line attachments, and patient before administering high-alert medications, such as magnesium sulfate and oxytocin and epidural medications. Point-of-care bar-code systems can also assist in verification of the drug, strength, and the patient. When transferring patients, have the receiving and transferring nurse verify the patient, drug/concentration, line attachment, and pump settings at the bedside against the original order.[1]

Monitoring

Frequently monitor patients' vital signs, oxygen saturation, and level of consciousness, as well as fetal heart tones, maternal uterine activity, and other necessary patient parameters when infusing high-alert medications. When the status of the mother and fetus changes suddenly, include as part of the assessment an immediate check of the infusing solution to ensure that it is the one prescribed. Signs and symptoms of fetal distress often alert the staff that a medication error is in progress. When giving drug boluses, remain at the bedside to monitor the patient continuously. Establish standard rescue procedures in the event of drug overdoses and toxicity, and ensure that required medications are readily accessible to staff on code carts or with other secured emergency supplies.[1,11]

Notes

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Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. All of the following are medications frequently involved in wrong-dose/overdosage medication errors in labor and delivery EXCEPT:
   a. Morphine
   b. Oxytocin
   c. Magnesium sulfate
   d. Cefazolin
   e. Misoprostol
2. The most frequently reported type of medication error occurring in labor and delivery is _____.
   a. extra dose
   b. drug omission
   c. wrong drug
   d. wrong dose/overdosage
   e. prescription/refill delayed
3. All of the following are true about antibiotic use and potential complications from antibiotic omissions in labor and delivery EXCEPT:
   a. Group B streptococcus (GBS) occurs in approximately 1 in every 3,000 infants born in the United States.
   b. Antibiotics (e.g., penicillin, ampicillin) are often used during labor and delivery to prevent neonatal GBS infection.
   c. GBS is a type of bacteria that can cause life-threatening infections in neonates including pneumonia, sepsis, and meningitis.
   d. Infected babies usually contract GBS infection from their mothers during vaginal birth.
   e. GBS bacteria will not contribute to complications in the mother.
4. All of the following are true about wrong-dose/overdosage errors in labor and delivery EXCEPT:
   a. Almost half of the oxytocin wrong-dose/overdosage error reports included the presence of fetal distress.
   b. Among this error type, reports submitted indicated frequent dispensing errors with misoprostol.
   c. More than 60% of wrong-dose/overdosage error reports involving high-alert medications included issues with infusion pumps.
   d. Analysis of Authority reports involving wrong-dose errors associated with an overdose of a medication accounted for less than 10% of all labor and delivery errors.
   e. The Vitamin K wrong-dose/overdosage errors involved the wrong concentration (adult instead of neonatal).

(continued on next page)

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5. Which of following is the most effective strategy to reduce the risk of harm from medication errors in the labor and delivery setting?
   a. Differentiate products with look- and sound-alike names through the use of tall man lettering (e.g., EPINEPHrine, ePHEDrine).
   b. Require an independent double check of the drug, concentration, infusion rate, pump settings, line attachments, and patient before administering high-alert medications.
   c. Separate the storage of high-alert intravenous (IV) drug infusions, epidural infusions, and regular fluids (e.g., lactated Ringer's solution) used for hydration.
   d. Use bold fonts to label IV infusion bags of oxytocin, magnesium sulfate, and other high-alert infusions to differentiate them from each other.
   e. Establish standardized concentrations and dosing regimens for oxytocin, magnesium sulfate, and other high-alert medication infusions.

6. A patient admitted for induction of labor was ordered lactated Ringer's solution. The fetal heart monitor started to show deceleration of the heartbeat. The patient was placed on her left side and given terbutaline with a return of fetal heart rate to the baseline. Upon repositioning the patient, the IV fluid infusing was noted to be Pitocin®.

   Select which of the following strategies would not help prevent this event from reoccurring nor minimize harm.
   a. Label infusion pumps with the name of the solution being infused as well as the IV tubing near the IV pump.
   b. Separate the storage of the lactated Ringer's solution from other high-alert IV drug infusions.
   c. Frequently monitor patients' vital signs, oxygen saturation, and level of consciousness, as well as fetal heart tones, maternal uterine activity, and other necessary patient parameters.
   d. Use individualized concentrations of IV high-alert infusions like Pitocin, magnesium sulfate, and morphine sulfate solutions.
   e. Educate staff about the risk of serious errors in labor and delivery.

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Preventing Maternal and Neonatal Harm during Vacuum-Assisted Vaginal Delivery

ABSTRACT

When women in the second stage of labor fail to progress to a spontaneous delivery, vacuum extractors have been used to successfully aid delivery. Data from the U.S. Department of Health and Human Services' National Center for Health Statistics revealed that vacuum-assisted deliveries accounted for approximately 5% of all deliveries in 2004, based on a seven-state sample of the expanded health data on birth certificates. Additionally, the use of vacuum extraction devices has increased over the last 10 years, while the use of forceps has decreased. Like other operative procedures, vacuum-assisted vaginal delivery has known risk factors and complications. The Pennsylvania Patient Safety Authority received 367 reports of problems involving vacuum-assisted delivery from July 2004 through April 2009. Of these reports, 64 (17%) documented maternal injury and 221 (60%) documented neonatal injury. To maximize the success of vacuum extraction procedures and to minimize complications, clinicians must understand both indications and contraindications for this procedure. Performing a thorough preoperative maternal and fetal assessment, technical proficiency with the vacuum device, setting goals, maintaining situational awareness, and concluding the delivery with a targeted postoperative assessment of both the mother and neonate are all important patient safety concepts associated with vacuum-assisted vaginal delivery procedures. (Pa Patient Saf Advis 2009 Dec 16;6[Suppl 1]:7-17.)

Introduction

Obstetric trauma associated with instrument-assisted vaginal delivery and birth trauma (i.e., injury to the neonate) are hospital-level Patient Safety Indicators developed by the Agency for Healthcare Research and Quality (AHRQ).[1] Vacuum-assisted vaginal delivery (VAVD) is used in specific circumstances during the second stage of labor. An analysis of National Hospital Discharge Survey data in 1992 showed that the vacuum-assisted delivery rate increased from 0.6% in 1980 to 3.3% in 1987.[2] Furthermore, in 2004, vacuum-assisted deliveries accounted for approximately 5% of all deliveries in the United States, based on a seven-state sampling of expanded health data on birth certificates collected by the U.S. Department of Health and Human Services' National Center for Health Statistics.[3] In June 2009, AHRQ released a statistical brief which revealed that in 2006 nearly 157,700 potentially avoidable injuries to mothers and neonates occurred. The highest rates of obstetric trauma for mothers took place during vaginal births with instruments, occurring in 160.5 deliveries per 1,000 instrument-assisted vaginal births.[4]

While VAVD is viewed as a safe alternative to forceps deliveries, there are known maternal and fetal risks associated with vacuum devices, including maternal perineal injury and fetal cranial hemorrhages, some of which can be fatal. These life-threatening complications led the U.S. Food and Drug Administration to issue a public health advisory in 1998. The advisory highlighted the increased risk of serious fetal intracranial injury or death associated with the use of vacuum devices and discussed a five-fold increase in the reports of fetal death or serious injury from 1994 to 1998.[5]

In 2004, the Joint Commission issued a Sentinel Event Alert titled "Preventing Infant Death and Injury during Delivery." From 1996 through 2004, the Joint Commission received 47 reports of perinatal death or permanent disability (i.e., sentinel events). Of the events, 46% were related to vaginal deliveries, of which 21% were vacuum-assisted. Analysis revealed that communication issues topped the list of identified root causes for these events (72%).[6] As of June 2009, 197 cumulative cases of perinatal death or loss of function had been reported to the Joint Commission as sentinel events.[7]

Authority Reports

Analysis of reports submitted to the Pennsylvania Patient Safety Authority from July 2004 through April 2009 identified 367 reports of problems related to VAVD. Of the 367 reports, 282 (77%) included some form of maternal or neonatal injury. Sixty-four of the reports (17%) documented maternal injury, including third- and fourth-degree perineal tears, cervical lacerations, vaginal sulcus tears, hematomas, anal sphincter tears, and postpartum hemorrhage. Two hundred twenty-one reports (60%) documented neonatal injury, including scalp lacerations, cephalhematomas, epidural, subdural and subgaleal hematomas (SGHs), fractures, and respiratory distress. Fifty-one reports (14%) were serious injuries, including four neonatal deaths (1%) (see Table 1). One root-cause analysis was reported, and the reported root cause was "communication among staff members." The top three most frequently cited contributing factors in the Authority reports were "procedures not followed," "communication problems between providers," and "issues related to proficiency."

Indications

Indications for VAVD include termination of a prolonged second stage of labor, suspicion of immediate or potential fetal compromise, and shortening of the second stage of labor for maternal benefit.

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Table 1. Maternal and Neonatal Serious Injuries by Type

TYPE AND NUMBER OF MATERNAL INJURY		TYPE AND NUMBER OF NEONATAL INJURY	
Perineal or cervical tears or lacerations resulting in hemorrhage and blood transfusion	8	Fractured clavicle or humerus	11
Fourth-degree perineal tears requiring operative repair	4	Respiratory distress	9 (2 deaths)
Miscellaneous lacerations requiring operative repair	3	Cephal, subdural, or subgaleal hematoma or skull fracture	8 (1 death)
Vaginal sulcus tears requiring operative repair	2	Miscellaneous injuries	6 (1 death)

A prolonged second stage of labor is defined by the American College of Obstetrics and Gynecology (ACOG) as the lack of continuing progress in a nulliparous woman for three hours with regional anesthesia or two hours without regional anesthesia, and lack of continuing progress in a multiparous woman for two hours with regional anesthesia and one hour without regional anesthesia.[8] A retrospective cohort study of 15,759 nulliparous women demonstrated that maternal morbidity increased significantly after 3 hours of the second stage of labor, and increased further after 4 hours. However, there was no indication of neonatal morbidity where increased fetal surveillance and timely obstetric intervention were used.[9] Therefore, absolute times are not as important as tracking progressive fetal descent during the second stage of labor in conjunction with continuous assessment of both fetal and maternal well-being.

While immediate or suspected fetal compromise is an indication for VAVD, obstetricians must carefully consider whether VAVD, forceps use, or cesarean section is most likely to produce better maternal and fetal outcome. With VAVD, the obstetrician should be prepared to move immediately to an alternative delivery mode if the vacuum-assisted delivery fails.

VAVD is indicated when maternal expulsive effort is medically contraindicated, such as with severe cardiac disease, hypertension, cerebral aneurysm, risk of aortic dissection, proliferative retinopathy, cardiac failure, or in cases of maternal exhaustion.[10]

Contraindications

Gestational age of less than 34 weeks is a contraindication to vacuum extraction due to increased risk of intraventricular hemorrhage.[8,11-14] The procedure is not performed in the presence of fetal bleeding disorders such as alloimmune thrombocytopenia, or with predisposition to fracture such as with osteogenesis imperfecta. Vacuum extraction is also contraindicated if the fetal head is not engaged in the pelvis; with incomplete cervical dilatation; with brow, face, or breech presentations of the fetus; with intact membranes; or when there is suspected cephalopelvic disproportion, which can present as severe or increased molding of the fetal head with a high presenting part failing to descend in the presence of strong uterine contractions. Clinical pelvimetry should be performed to assess the condition of the maternal pelvis before proceeding with any type of operative vaginal delivery.[8] If the clinician cannot determine fetal position, lie, presentation, or degree of engagement or asynclitism, vacuum extraction should be avoided.

Complications

Maternal

VAVDs produce fewer maternal perineal injuries than use of forceps.[15] However, complications from VAVD arise in the form of cervical lacerations, vaginal hematomas, hemorrhage, third- and fourth-degree perineal tears, and anal sphincter injury.

Examples of maternal injuries reported to the Authority include the following:

> *During a VAVD, the patient sustained cervical and vaginal lacerations. She was bleeding heavily . . . the lacerations were repaired but she continued to bleed . . . her hemoglobin dropped to 6. At this point the decision was made to perform a hysterectomy . . .*
>
> *OR [operating room] team called for repair of fourth-degree vaginal laceration . . . [patient was] returned to the OR for heavy rectal bleeding . . . proctoscope, surgical repair of 6 cm rectal laceration, and diversion . . .*
>
> *Patient underwent VAVD . . . episiotomy cut, but patient extended to third-degree laceration with a complete transection of the anal sphincter, resulting in extensive repair . . .*
>
> *[The patient was] admitted at term and underwent VAVD . . . approximately an hour later, [patient was] noted to have large amount of vaginal bleeding. . . . A pelvic exam revealed cervical laceration. . . . [The patient was] taken to OR for repair.*

Maternal postoperative bleeding, hypovolemic shock, unplanned hysterectomy, and severe anal sphincter injury are some of the Serious Events reported to the Authority. Anal sphincter injury can lead to maternal fecal incontinence and has been the subject of clinical review. A retrospective cohort study in 2005 showed that vacuum delivery and occipital posterior (OP) position of the fetus were independent risk factors for anal sphincter injury and that the combination of these two factors incrementally increased that risk.[16] A 2008 systematic review of 451 articles and abstracts related to obstetric sphincter damage revealed several

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factors that increase the risk of anal sphincter injury including vacuum extraction, midline episiotomy, and OP position of the fetus.[17] There is no conclusive evidence that episiotomy was protective of the anal sphincters, and the role of routine episiotomy for operative vaginal delivery is poorly evaluated.[11]

Neonatal

Compared to other modes of delivery, vacuum extraction has been associated with higher rates of cephalhematoma, neonatal jaundice, and retinal hemorrhage, all of which are usually transient and self-resolving.[8,18] Cephalhematomas occur when bridging vessels between the periosteum and bones in the skull are torn and, in up to 5% of the cases, are associated with underlying skull fractures. A Cochrane systematic review comparing vacuum extraction and forceps delivery showed a strong association between vacuum extraction and cephalhematoma, with an average occurrence rate of 10%, compared to a 1% to 2% occurrence with spontaneous vaginal delivery. The accumulation of blood products in the hematoma can lead to secondary jaundice.[18]

SGH is a rare but potentially fatal complication of vacuum extraction, with bleeding between the galea aponeurosis of the scalp and the periosteum. This potential space encompasses the area between the orbital ridges anteriorly, the nape of the neck posteriorly, and the ears laterally. Neonates can lose more than 50% of their total blood volume to this space, leading to hypovolemic and/or hemorrhagic shock (characterized by pallor, tachypnea, tachycardia, and hypotension) and secondary coagulopathy.[19] A prospective observational study of 338 infants delivered by vacuum extraction between 2000 and 2002 identified nulliparity, failed vacuum extraction, and improper cup placement as risk factors for SGH.[20] SGH presents as a firm to fluctuant mass that crosses suture lines. It is frequently noticed within 4 hours of birth and may progress for 12 to 24 hours. Prompt recognition and treatment is critical to successful outcome, with mortality rates ranging between 2.7% and 22.8%.[21]

Neonatal injuries related to VAVD reported to the Authority include the following:

> *. . . term infant attempted to be delivered with vacuum extractor twice and with forceps twice. . . . [Converted to cesarean section]. . . . [The infant] required resuscitation/intubation. The infant was transferred to a tertiary NICU [neonatal intensive care unit] and expired (subdural hematoma/brain death). . . .*
>
> *Infant delivered via vacuum extraction with cephalohematoma and fracture of left clavicle. The infant was transferred to a tertiary facility NICU for further evaluation and was found to have a subdural hematoma. . . .*
>
> *An infant born via VAVD developed seizure one hour after birth. A computed tomography scan [showed] skull fracture and subdural hematomas. . . the infant was transferred to a tertiary facility. . . .*
>
> *Patient [with] term intrauterine pregnancy with arrest of descent, failed vacuum extraction. Infant [was transferred] to NICU [because the infant] sustained subgaleal hemorrhage. . . .*

Preventing Maternal and Neonatal Injury

The first step in preventing maternal and neonatal injury is to be certain that VAVDs are done only when there are clear indications for vacuum extraction, and when there is a high likelihood of success of the procedure, determined by preoperative maternal and fetal assessment.

Limiting vacuum-assisted procedures through facilitation of spontaneous vaginal deliveries can be accomplished via one-on-one maternal support during labor, by adopting an upright or lateral position to facilitate fetal descent, through judicious use of analgesia, and via administration of oxytocin (endogenous hormone; uterine stimulant), if not contraindicated, to strengthen uterine contractions.[11] Delay in pushing for two to three hours during the second stage of labor, or until the urge to push is very strong, may also prevent unnecessary use of the vacuum extraction device. In cases of delayed second stage of labor, cephalopelvic disproportion should be excluded before commencing with the vacuum extraction procedure.

Finally, clinicians sufficiently trained and fully credentialed for VAVD, with the ability to convert the procedure to an immediate cesarean section when indicated, are predictive of successful outcomes.

Once the decision for vacuum extraction has been made, obstetricians can reduce the rate of maternal and neonatal morbidity by performing a thorough preoperative assessment of the mother and fetus, by ensuring technical proficiency with the chosen device, by maintaining vigilant situational awareness during the procedure, and by performing a targeted postoperative assessment of the mother and neonate.

Preoperative Assessment

Maternal Assessment

Consent. Assessment of maternal status includes the mother's willingness and ability to actively participate in the vacuum-assisted delivery; the more effort a mother can contribute during contractions, the less force is required via the vacuum device. Hence, although maternal exhaustion is an indication for VAVD, the mother must be able to participate and facilitate the birth through expulsive effort. Increased traction is not a substitute for absent maternal effort. If the mother is willing and able to participate, informed consent is obtained and documented.[22] Maternal understanding of the vacuum extraction procedure and active consent maximizes cooperation and decreases potential anxiety associated with the impending delivery.

Physical assessment. According to ACOG, the cervix is to be fully dilated before attempting VAVD.[8]

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Guidelines published by the Canadian Society of Obstetricians and Gynaecologists state that vacuum extraction before full cervical dilatation may be considered in rare cases "only when the benefits significantly outweigh the risks and when there is no viable alternative."[23] The Royal College of Obstetricians and Gynaecologists cites cord prolapsed at 9 cm in a multiparous woman or a second twin as exceptions to this rule.[11] Other maternal prerequisites include ruptured membranes, an empty bladder, and adequate analgesia for the procedure.

Fetal Assessment

General fetal condition. Auscultation of the fetal heart rate or analysis of the electronic fetal monitor strip is documented. Although one indication for vacuum-assisted delivery is fetal compromise, vacuum extraction should not be used as a rescue procedure for a severely compromised fetus, because such neonates may benefit from a rapid cesarean section.[11]

Size. The fetal weight is estimated and documented. Pelvimetry should indicate a favorable maternal pelvic space relative to fetal size. The vacuum extraction procedure itself, as well as fetal size equal to or greater than 4,000 gm (8 lb, 14 oz), is associated with greater risk of shoulder dystocia and subsequent obstetric brachial plexus palsy, and the obstetrician must be prepared for this complication.[24] (For more information about shoulder dystocia, see the article "Neonatal Complications: Recognition and Prompt Treatment of Shoulder Dystocia" in this issue.)

Engagement and station. Vacuum extractors should not be applied unless the fetal head is engaged.[8,12] Engagement implies that the biparietal diameter of the fetal head has passed through the maternal pelvic inlet and that the leading point of the fetal head is at least at the level of the ischial spines (0-station). (For more information, see the sidebar "Definition of Engagement.") However, if the head is unusually molded, or if there is a severe caput, as can occur with a prolonged second stage of labor, engagement might not have taken place, even though the head is at 0-station.[12] Severe molding or irreducible overlap of the parietal bones should be taken as a sign of cephalopelvic disproportion, and VAVD should not be attempted.[11] To more accurately assess fetal station, obstetricians can palpate the position of the fetal head abdominally, making certain that no more than one-fifth of the head is above the upper level of the pubic symphysis.[11]

Fetal position. Depending on fetal position, vacuum extraction can be classified as an outlet, low-, or mid-pelvis operation.[8] For outlet operations, the fetal scalp is visible at the introitus without separating the labia; the fetal skull has reached the pelvic floor and the sagittal suture is in the anteroposterior diameter, or right or left occiput anterior or posterior position; the fetal head is at or on the perineum; and rotation does not exceed 45°. For low-pelvis operations, the leading point of the fetal skull is at +2 cm and not on the pelvic floor with two subtypes: (1) a rotation of 45° or less or (2) a rotation greater than 45°. In mid-pelvic operations, the station is above +2 cm, but the fetal head is engaged.

Recent stratification of VAVDs into low- and moderate-risk categories may help obstetricians more accurately assess both clinical indication and risk of the procedure[11] (see Table 2).

Definition of Engagement

The level of the presenting fetal part in the birth canal is described in relation to the maternal ischial spines, which are halfway between the pelvic inlet and pelvic outlet. When the lower-most presenting part of the fetus is at the level of the ischial spines, it is described as being at "0-station." The area above and below the ischial spine is divided into fifths. As the presenting fetal part descends from the inlet toward the ischial spine, the station is described as -5, -4, -3, -2, -1 and 0-station at the ischial spine level, proceeding to station +1,+2,+3, +4, and +5, where the fetal presenting part is then visible at the introitus.

Source: Cunningham FG, Gant NF, Leveno KJ, et al. *Williams obstetrics*. New York (NY): McGraw-Hill; 2001: 58-60.

Technical Expertise

A prospective case-control study published in 2004 showed that operator technical expertise with vacuum extractors was associated with increased safety for both mother and neonate.[25] Obstetric training programs and appropriate credentialing for VAVD procedures can increase safety on the obstetric unit. Hospital credentialing staff will need to understand the type of training area residents receive regarding VAVD, as vacuum extraction is not always a core component of an obstetric training program. If necessary, hospitals can consider supplemental training with instrumental birthing simulator mannequins to improve outcomes.

Familiarity with manufacturer guidelines regarding use of a particular vacuum device is important, including recommendations for placement, maximum time of procedure, maximum vacuum pressure, maximum traction force, number of "pop-offs," and maximum time on vacuum.

Cup Selection

There are many types of commercial cups available, all of which fall into two main categories: (1) rigid mushroom-shaped cups and (2) soft bell- or trumpet-shaped cups. Generally, soft or rigid anterior cups are used for low or outlet procedures when the fetus is in the occipital anterior (OA) at less than 45° position with little to no asynclitism, and rigid posterior cups are used for rotational (advanced) and mid-pelvic procedures with the fetus at OA greater than 45°, and with OP or occipital transverse (OT) position. Since a number of fetal injuries associated with vacuum

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Table 2. Low- and Moderate-Risk VAVD

LOW-RISK VAVD	**FETAL CAPUT VISIBLE AND STATION LOW OR OUTLET**
	Arrest of descent in second stage of labor
	Nonreassuring fetal status
	Maternal exhaustion but satisfactory uterine contractions and some expulsive effort
	Selective shortening of the second stage of labor
MODERATE-RISK VAVD	**FETAL CAPUT NOT VISIBLE AND STATION LOW OR MID**
	Arrest of descent in second stage of labor
	Nonreassuring fetal status
	Maternal exhaustion, epidural analgesia, and diminished expulsive effort
	Occiput anterior, greater than 45° rotation; occiput posterior/occiput transverse fetal positions

Source: Vacca A. Reducing the risks of vacuum delivery. *Fetal Matern Medi Rev* 2006;17(4):301-15.

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extraction are related to misplacement of the cup,[12,20] the material of the cup may be less important than correct placement. When the fetus is in the OP or OT position, or when there is a significant amount of asynclitism, then the rigid OP cup should be used, as these are the only type of cups that can be maneuvered easily to the flexion point (see Figure 1). A two-center study in the United Kingdom followed 397 vacuum-assisted vaginal deliveries and found that although an OP or OT position was diagnosed in 11% and 14% of the cases, respectively, there was no use of the specifically designed OP cup. Forty-one percent (n = 56) and 52% (n = 25) of the failed VAVDs in this study were those with the fetus in OP or OT position.[26] Special training is required for use of the posterior cup, especially related to maneuvering the cup to achieve correct application, which may explain why obstetricians in the above study failed to utilize this cup even when the fetal position was determined to be OP or OT.

Vacuum Cup Placement

"Flexion point" describes the point on the fetal scalp over which the center of the vacuum should be placed. The flexion point is approximately 3 cm anterior to the posterior fontanelle and centered over the sagittal suture.[27] Placing the vacuum accurately on the fetal scalp helps ensure a good seal and promotes synclitism of the fetal head in relationship to the maternal pelvis. Using a 6 cm cup, the practitioner will center the flexion point beneath the cup when the edge lays approximately two finger-widths (approximately 3 cm) posterior to the anterior fontanelle (see Figure 1).

When the vacuum has been accurately placed, it is called a "flexing median" application. Other applications promote extension of the fetal head and asynclitism and either increase or fail to decrease the diameter of the presenting part, making delivery more difficult. A deflexing (suboptimal) application occurs when the cup is placed closer to the anterior fontanelle, and a paramedian application indicates that the cup was placed more than 1 cm to the right or left of the sagittal suture (see Figure 2).

A prospective study of 1,000 consecutive VAVDs in nulliparous women published in 2008 showed a statistically significant relationship between unfavorable cup placement (deflexing or paramedian placement) and neonatal scalp trauma.[28] Incorrect placement (off of the sagittal suture, or the edge of the cup less than 3 cm from the anterior fontanelle) was also found to contribute to the development of SGH, according to a prospective, observational study conducted from 2000 to 2002.[20] Correct placement of the vacuum cup on the flexion point enhances the natural birthing process and decreases reliance on traction force alone to effect delivery.

Vacuum Pressure

Once the cup has been accurately placed over the flexion point, the operator runs his or her fingers along the edge of the cup to ensure that no maternal tissue is trapped between the cup and the fetal scalp. If tissue is trapped, it will inhibit proper seal of the vacuum device and likely result in maternal tissue tear. Vacuum pressure of 100 to 150 mm Hg is advised, with a reassessment of cup placement and seal. Then, pressure is increased to 500 to 600 mm Hg, according to manufacturer guidelines.

Traction, Pulls, and Duration

Gentle traction force in the axis of the maternal pelvis is introduced in conjunction with uterine contractions. The operator should use both hands: one operating the vacuum device and providing traction force and direction, the other monitoring progress of descent and providing cross pressure to prevent cup detachment (pop-off). The crossbar of the traction device should be held in the fingertips to limit traction force. Steady traction is applied along the axis of the pelvis until the contraction passes or until the mother stops pushing. At this point, traction ceases.

The operator should avoid any intentional rotation of the fetus, or any rocking motion or torque, as this is associated with increased fetal scalp injury.[5] The ventouse is not a rotating instrument. Attempts at cup rotation may encourage cup displacement, loss of station, or scalp injury. It is important to remember that

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Figure 1. Flexion Point

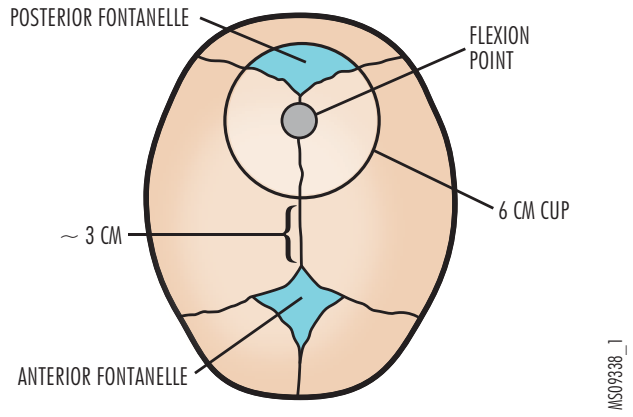
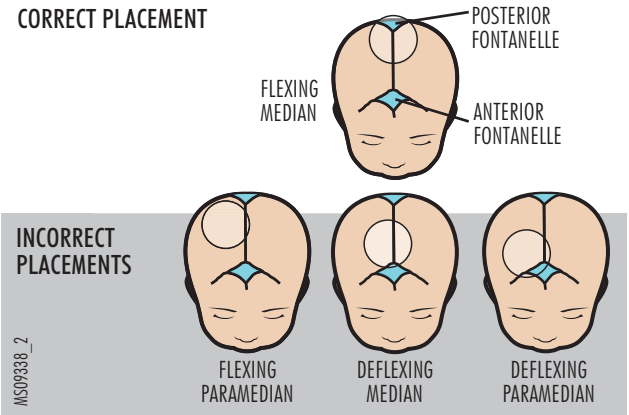


Figure 2. Cup Placement



under traction, the fetal head rotates automatically as descent occurs.

Descent of the fetus should be observed with each traction pull. Recommendations for number of pulls vary by make and model and within the clinical literature. Parameters lie between two and four pulls, with recent recommendations of three pulls during the descent phase and three pulls at the outlet.[29] However, some progress should be observed with each and every pull.

Cup detachments or pop-offs are not a safety feature of the device; they may signify incorrect cup placement, incorrect traction technique (pulling too hard, or in an upward direction as opposed to along the axis of the pelvis), a large caput succedaneum, or faulty equipment.[12] Detachment of the cup is associated with increased incidence of cranial fractures, cephalhematomas, and scalp edema.[30] Most experts advise halting the procedure if more than two to three pop-offs occur,[12] and manufacturers include information regarding maximum number of pop-offs in their device literature. All personnel in the room should be aware of these guidelines and attentive to the number of pop-offs that occur.

A prospective observational study of 119 consecutive attempted vacuum deliveries of nulliparous women in 2001 and 2002 demonstrated that at least 80% of the women could be delivered safely by vacuum extraction when the force did not exceed 11.5 kg, the duration of the procedure was limited to 15 minutes, and the number of pulls was limited to three for the descent phase and three for the perineal phase.[29]

Sequential Device Use

When an obstetrician chooses to perform VAVD and that attempt fails, he or she is left in a precarious situation: continue assisted delivery by attempting to deliver the fetus with forceps or move directly to cesarean section? This decision requires consideration of the details and nuances of each particular delivery. The obstetrician will weigh the potential complications of cesarean section during active labor, especially if performed when the fetus is low in the pelvis, and compare those potential complications to sequential device use. A meta-analysis published in 2000 compared seven studies and showed that sequential device use carried a higher neonatal morbidity than when one instrument was used alone (vacuum or forceps).[18] In the same year, ACOG cautioned against sequential device use.[8] In summary, if an attempted vacuum delivery fails, the fetus is at increased risk no matter which subsequent mode of delivery is chosen. Hence, the importance of the preoperative maternal and fetal assessment becomes clear: obstetricians perform VAVD only when the chance of success outweighs the possibility of failure.

Abandoning the Procedure

VAVD is abandoned if there is difficulty applying the instrument, if there is no appreciable descent with each pull, if there is no significant descent after three pulls of a correctly applied instrument, or if the fetus has not been delivered within 10 to 20 minutes.[11] In a 2005 retrospective population-based study, extended vacuum time of 10 minutes or more was also linked to obstetric brachial plexus palsy injuries in the neonate.[24]

Conditions associated with difficult VAVD include situations in which the fetus is in the OP position, excessive molding of the fetal head has occurred, fetal macrosomia is present, and dysfunctional or prolonged labor with a maternal body mass index greater than 30 is present.[11,31] In these cases, a trial of VAVD may be considered, preferably in a room equipped for immediate cesarean section.[13]

Human Factors

Situational awareness is important to prevent maternal and neonatal harm during delivery. In the delivery room, obstetricians can lose track of important information such as the number of pulls, the number of pop-offs, and the total time on vacuum and total

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time of procedure when attempting to effect delivery. Some examples of possible loss of situational awareness reported to the Authority include the following:

> *. . . physician failed to follow proper procedure during vacuum-assisted delivery . . . attempted nine pulls with four pop-offs. . . . The nurse advised physician of number of pulls without physician stopping. . . . Policy states that the number of attempts and pop-offs is to be limited to three. . . .*
>
> *. . . vacuum extractor applied many times; [nurse] informed physician of limit of applications. . . .*
>
> *. . . vacuum extractor applied 6 to 7 times by obstetrician; infant born with a large amount of caput. . .*

Strategies to improve and maintain situational awareness include using an obstetric partogram[11] and using a checklist or third party to track the important parameters in VAVDs: time on vacuum, total time on procedure, traction, pressure, number of pulls, and number of pop-offs. Teamwork helps the obstetrician provide the best care to the patient. Empowering team members to speak up, acknowledging their feedback when limits are exceeded, and ensuring team agreement of an endpoint to the procedure may all help maintain situational awareness.

Postoperative Maternal and Neonatal Assessment

Maternal

The postpartum maternal patient is assessed for injury to the birth canal; specifically, bleeding due to cervical, perineal tears, lacerations, or injury to the anal sphincter. Lacerations are repaired. Severe tears or lacerations may necessitate repair in the OR. Hemorrhage may necessitate administration of blood products and monitoring in an intensive care unit. There may be risk for deep vein thrombosis in cases of prolonged labor. The extended maternal assessment should include an assessment for urinary, stress and bowel incontinence, especially subsequent to perineal tissue injury, or anal sphincter disruption.

Neonatal

Clinically diagnosed scalp injuries occur largely because of the physics of vacuum extraction. As the vacuum force is applied, the extractor draws the fetal scalp into the body of the cup. This produces the characteristic mound of scalp tissue and edema, the chignon or caput succedaneum, which may be identified after an extraction. While most superficial scalp injuries resolve spontaneously or with minimal treatment, the SGH can be a life-threatening complication of vacuum extraction. Because of the small but significant risk of SGH, the attending personnel should be informed whenever a VAVD has occurred, regardless of the immediate condition of the neonate. SGHs are dangerous because the signs and symptoms may not be clinically apparent until some hours postpartum. Vigilant serial assessment is necessary for 48 hours postvacuum procedure to assess for signs of intra- or extracranial bleeding. Nurses working in neonatal nurseries fully assess the neonatal scalp by removing the nursery cap and physically inspecting the cranium.

Risk Reduction Strategies

The operative risks of VAVD are a combination of several factors, some of which are modifiable. The following are risk reduction strategies to enhance the success of VAVD.

Facility Strategies

- Become familiar with the training received by residents regarding VAVD. Supplement resident training with formal mentoring programs on-site. Ensure proper credentialing of providers. Consider simulated birthing mannequins as adjuncts to resident and physician training.
- Implement policies that specify parameters such as indications and contraindications for VAVD, total time of procedure, maximum time on vacuum, maximum number of pop-offs, and maximum pressure use. Practice teamwork drills to refine effective communication of the parameters.
- Consider classifying VAVDs into lower and higher risk groups; according to station of outlet, low or mid; and according to rotation of OA less than 45°, OA greater than 45°, OT, or OP.
- Consider bundling VAVD into a set of criteria, all of which must be met in order to proceed with the VAVD. (Visit the Authority's Web site at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx to view or download accompanying patient safety tools, including a sample VAVD bundle tool and an educational poster.)
- Standardize documentation of vacuum-assisted vaginal deliveries.[11] Consider including the indication for the procedure; documentation of the informed consent process, position, and station of the fetal head and how it was assessed (vaginally or abdominally); amount of molding and caput present; assessment of maternal pelvis; assessment of fetal heart rate and contractions; ease of application of vacuum and placement position; duration of traction and force used; and description of any maternal or neonatal injuries.[23]
- Implement unit-level auditing of all operative deliveries. Know the rates of VAVD, VAVD failure, sequential device use, neonatal morbidity to composite trauma, APGAR of less than 7 at five minutes, and cord arterial pH of less than 7.1 (or facility-specific parameters). Audit the unit as a whole, and audit individual obstetricians.[11]

Preoperative Strategies

- Consider alternative delivery strategies, especially those that facilitate normal spontaneous vaginal delivery. These strategies may include labor coaches, maternal upright or lateral positioning, judicious use of epidural analgesia, oxytocin

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administration if not contraindicated, and delay of maternal pushing until two hours into the second stage of labor or until the urge to push is very strong.[11,23]

- Discuss the risks and benefits of VAVD with the mother, preferably in the office setting before the need to proceed with operative delivery occurs. Document informed consent.
- Rule out contraindications to the VAVD, including gestational age less than 34 weeks, fetal osteogenesis imperfecta, fetal alloimmune thrombocytopenia, an unengaged fetal head, or unknown fetal position.[8]
- Have an exit strategy before proceeding with VAVD; be prepared to move to immediate cesarean section if the extraction is unsuccessful, and if sequential device use (forceps) is contraindicated. Remember, the incidence of intracranial hemorrhage is highest in neonates delivered by cesarean section following a failed vacuum or forceps delivery.[8]
- Use vacuum extractors cautiously in cases of neonatal macrosomia or prolonged labor; the risk of shoulder dystocia increases with these conditions.[8]

Operative Strategies

- Use vacuum extractors only when a specific obstetric indication is present. Be sure that the operator is experienced in its use and familiar with indications, contraindications, and manufacturer guidelines regarding use.[5]
- Apply steady traction in the line of the birth canal, which is the supported use for all vacuum devices; avoid rocking or torque type movements, which can lead to cranial injury.[5]
- Minimize the duration of vacuum application, because cephalhematoma is more likely to occur as duration increases.[8]
- Have a designated team member available to track important parameters for VAVD such as time at procedure, total time on vacuum, number of pop-offs, and vacuum pressure. Verbal confirmation of parameters can help team members maintain situational awareness, and avoid the temptation to try "just one more pull" to effect delivery. Empower team members to express concerns, and acknowledge concerns when they are expressed.

Postoperative Strategies

- Notify all members of the maternal and neonatal care team that a VAVD occurred so that they can monitor the neonate for signs of complications.[5]
- Document the procedure carefully, including the indications for procedure, maternal and fetal condition, informed consent process, device use, cup placement, pressure in mm Hg, number of pulls, any pop-offs, and success or failure of the attempt.
- Perform a thorough postoperative maternal assessment to identify any trauma to the perineal tissue, birth canal, or anal sphincters. Repair any injury carefully. Observe for postpartum bleeding and/or hemorrhage.
- Perform a thorough neonatal assessment focused on the scalp. Assess for signs of cephalhematoma, bruising, bleeding, or lacerations. Perform serial assessments to document signs of intracranial bleeding or SGH.
- If neonatal cranial complications arise, be prepared to intervene quickly and treat aggressively. Neonates may require transfer to a tertiary facility for aggressive management of SGH.

Conclusion

The literature reveals that vacuum extraction devices have an overall low complication rate and can be safely used during the second stage of labor. However, 367 reports of problems with vacuum extractions have been submitted to the Authority since 2004, 282 of which documented either maternal or fetal harm. To maximize both maternal and fetal safety during these procedures, practitioners in obstetrics are encouraged to consider all available delivery modes, and tailor each delivery to their specific patient. If vacuum-assisted delivery is chosen, patient safety can be maximized through comprehensive preoperative assessment of both the mother and fetus; through informed consent; via correctly applied technical expertise related to the chosen device; by maintaining situational awareness; and by performing targeted postoperative maternal and neonatal assessments.

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(See Self-Assessment Questions on next page.)

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Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. All of the following are indications for vacuum-assisted vaginal delivery (VAVD) EXCEPT:
   a. A multiparous woman with a prolonged second stage of labor, as evidenced by lack of continual progress for more than one hour with regional anesthesia
   b. Immediate fetal compromise, as indicated by decelerations in fetal heart rate
   c. Maternal medical conditions that prohibit effective pushing during labor, such as severe cardiac disease, hypertension, or risk of aortic dissection
   d. Lack of progressive fetal descent during the second stage of labor
2. Which of the following conditions contraindicates VAVD?
   a. A nulliparous woman with a prolonged second stage of labor, as evidenced by lack of continual progress for three hours with regional anesthesia
   b. Gestational age of 40 weeks
   c. Fully dilated cervix and engaged fetal head with occipital anterior (OA) presentation
   d. A multiparous woman with a prolonged second stage of labor, as evidenced by lack of continual progress for two hours without regional anesthesia with undetermined fetal position and presentation

Case Scenario

A 32-year-old gravid female, G2P1, delivered a 39-week-old male neonate by means of VAVD. The indication for the procedure was a lack of continual progress over a five-hour period, with use of regional anesthesia. Maternal pelvic examination revealed an engaged fetus with OA presentation at less than 45° rotation. The cervix was fully dilated. The fetal size was estimated at 3,800 gm. There were no imminent signs of fetal distress, but the mother displayed signs of exhaustion.

After notifying appropriate team members and ensuring an operating room (OR) for a potential conversion to cesarean section, the obstetrician obtained informed consent from the patient. He chose a 6 cm Kiwi soft-cup vacuum cap for the procedure. The obstetrician applied vacuum three times for approximately 20 seconds each time (force of approximately 450 mm Hg, in conjunction with maternal contractions, and in-line with the pelvic cavity). Between the three pulls, there were two "pop-offs." One team member stated that in the event of a third pop-off, the obstetrician should move to another mode of delivery. However, during the third pull, with a bit of right rotation of the vacuum, the delivery was successful.

The neonate appeared healthy with pink skin, a robust cry, and full movement of all extremities. There was a chignon on the scalp, just left of the sagittal suture, near the anterior fontanelle. APGAR scores were 7, 7, and 9. The neonate was transferred to the nursery, where nursing staff were unaware of the vacuum extraction. Within two hours after delivery, the neonate was quiet, listless, and pale.

3. Assess the case study above and choose which of the following statements is true.
   a. The obstetrician performed VAVD without proper indication for the procedure.
   b. The obstetrician performed VAVD with proper indication for the procedure.
4. Situational awareness during VAVD is most appropriately illustrated by which of the following case facts?
   a. The obstetrician applied the vacuum three times for about 20 seconds each time.
   b. The obstetrician used 450 mm Hg force during the VAVD procedure.
   c. A team member stated that an alternative delivery mode should be employed if a third pop-off occurred.
   d. The obstetrician delivered the infant after a bit of right rotation during the third pull.
5. Which of the following statements best illustrates the obstetrician's lack of technical expertise?
   a. The obstetrician chose a 6 cm Kiwi soft-cup for the vacuum extraction.
   b. The neonate developed a chignon just left of the sagittal suture, near the anterior fontanelle.
   c. The obstetrician used a force of approximately 450 mm Hg in conjunction with maternal contractions.
   d. There were two pop-offs during the procedure.

Continued Scenario

The nursery staff did not recognize the neonate complication for an additional two hours. By this time, the neonate was gravely ill. When the nurse removed the neonate's cap, she noticed an enlarged chignon near the anterior fontanelle, as well as diffuse swelling over the entire scalp extending from the brow to the nape of the neck posteriorly. She notified the physician of these findings immediately. The neonate was diagnosed with a subgaleal hemorrhage and transferred to a tertiary facility for continued care.

6. Which technical failures likely contributed to the neonate's injury?
   a. The obstetrician's choice of procedure, choice of cup, and placement of the vacuum cap on the infant's scalp
   b. The obstetrician's inadequate assessment of maternal pelvis and fetal position
   c. The obstetrician's placement of cup on the scalp and use of torque during the procedure
   d. The obstetrician's failure to notify subsequent caregivers of the vacuum extraction and incorrect APGAR rating

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7. Which factors potentially contributed to the delay in the neonate diagnosis of subgaleal hemorrhage?
   a. Choice of vacuum cup and inaccurate APGAR scores
   b. Failure to inform subsequent caregivers of the vacuum extraction procedure and lack of serial assessment of the neonate head
   c. Incorrect APGAR scores and lack of comprehensive documentation of the procedure
   d. Two pop-offs and use of torque during delivery

8. Which steps, if taken by the obstetrician, have the greatest chance of eliminating or minimizing neonatal injury?
   a. Use a 5 cm cup instead of a 6 cm cup during the vacuum extraction procedure; use no more than 400 mm Hg of force; apply force during maternal contractions.
   b. Ensure correct placement of the vacuum cap using well-known fetal scalp landmarks; avoid the use of torque; pull in-line with the vaginal canal during contractions.
   c. Use the APGAR neonate assessment tool to categorize neonates with high probability of injury.
   d. Proceed to an alternative mode of delivery after one failed attempt with the vacuum extractor.

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Neonatal Complications: Recognition and Prompt Treatment of Shoulder Dystocia

ABSTRACT

The most common injuries associated with shoulder dystocia include fractures, brachial plexus nerve damage, and birth asphyxia. Between June 2004 and October 2008, the Pennsylvania Patient Safety Authority received 316 reports involving shoulder dystocia. Neonatal injuries were identified in 124 (39%) of these reports and included fractures, brachial plexus injuries, and death. There are several antepartum and intrapartum risk factors that contribute to shoulder dystocia, such as maternal gestational diabetes, fetal macrosomia, documented anencephaly, the use of forceps or vacuum extraction, and precipitous or prolonged second stage of labor. Shoulder dystocia risk management involves identification and communication of patients at risk for shoulder dystocia before delivery, the management of shoulder dystocia when it occurs to minimize potential injury to fetus and mother, thorough documentation and treatment upon discovery of the problem, and ongoing interdisciplinary simulation drills for all obstetric personnel that include the application of external and/or internal maneuvers. (Pa Patient Saf Advis 2009 Dec 16;6[Suppl 1]:18-25.)

The Problem

The American College of Obstetricians and Gynecologists (ACOG) practice guidelines describe shoulder dystocia as a delivery that requires additional obstetric maneuvers following the failure of the shoulders to deliver spontaneously with gentle downward traction on the fetal head.[1] The occurrence of shoulder dystocia is difficult to predict, although risk factors have been documented as gestational diabetes, fetal macrosomia, and previous occurrence of shoulder dystocia during birth, according to ACOG.[1] These complicated deliveries require prompt and systematic responses.[2] The competing major concern during shoulder dystocia is fetal hypoxia, which can result from compression of the neck and central venous congestion, compression of the umbilical cord, or reduction of the placental intervillous flow from prolonged increased intrauterine pressure, combined with secondary fetal bradycardia. While it is reasonable that prolonged head-to-shoulder interval thresholds may be associated with permanent central neurologic dysfunction, there is no clear consensus in the clinical literature on the amount of time allowed for the safe resolution of shoulder dystocia.[3]

The causes of shoulder dystocia are mechanical and are associated with impaction of the anterior fetal shoulder behind the maternal pubis symphysis or impaction of the posterior fetal shoulder on the sacral promontory, or impaction of both, which results in the fetal head being delivered while the shoulders are impacted.[1,2] Shoulder dystocia may result from the failure to deliver the fetal shoulder without using external or internal maneuvers. There is a subjective component of this diagnosis that requires internal and/or external maneuver determination by the delivery provider.[1] Shoulder dystocia is the fourth most common cause of medical litigation involving delivering providers and accounts for 11% of all obstetrics-related lawsuits.[2,4-7] The number of shoulder dystocia reports varies and ranges from 0.2% to 3% of all vaginal deliveries in the United States.[1,8] Between June 2004 and October 2008, the Pennsylvania Patient Safety Authority received 316 reports involving shoulder dystocia. In 124 (39%) of these reports, neonatal injuries, including fractures and brachial plexus injuries were identified, as well as deaths.

Risk Factors

Maternal Risk Factors

Maternal risk factors for shoulder dystocia include gestational diabetes, obesity, postterm pregnancy, advanced age, abnormal pelvic anatomy, and short stature. Intrapartum risk factors for shoulder dystocia include instrument-assisted vaginal delivery (forceps or vacuum), precipitous or protracted second-stage labor (one to three hours depending on parity and anesthesia), and delayed head-to-body delivery time. ACOG considers prolonged second stage of labor as the lack of continuing progress in a nulliparous woman for three hours with regional anesthesia or two hours without regional anesthesia, and the lack of continuing progress in a woman for two hours with regional anesthesia and one hour without regional anesthesia.[9]

Fetal Risk Factors

Fetal anthropometric variations and documented anencephaly are associated with increased risk of shoulder dystocia. Specific factors include fetal macrosomia, large chest or biparietal diameter, the absence of truncal rotation, and the fetal shoulders remaining in the anterior-posterior plane.[8] Most macrosomic neonates do not experience shoulder dystocia, but shoulder dystocia incidence increases from 5% to 9% among fetuses with nondiabetic mothers when weights increase from 4,000 to 4,500 g. Shoulder dystocia is a risk with fetal weight of 5,000 g or more but may also occur with fetuses of average weight.

Clinically Applied Forces

Fetal manipulation can be reasonably used during shoulder dystocia deliveries, but it is important for birthing providers to be aware of the natural tendency to increase applied traction when faced with a difficult delivery. Increasing clinically applied traction to the head during the birth process may produce

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stretch injuries of the fetal brachial plexus.[7,10,11] Applying overly vigorous traction on the head or neck or excessively rotating the body may cause more serious damage to the neonate and severely stretch the brachial plexus nerve roots from the spinal column, potentially causing permanent loss of arm function.[5] Future function of affected fingers, hands, and arms will depend on which nerves are damaged.[5] The use of internal fetal maneuvers is associated with less clinically applied traction and less brachial plexus stretching, which are two critical determinants of mechanical birth injury in cases of shoulder dystocia.[12]

The extent of nerve injury depends on the magnitude and direction of the delivery force, as well as the rate at which it is applied.[7] Clinically applied forces may typically reach up to 10 lb of force traction during routine deliveries.[7] Obstetric brachial plexus injury is caused by the stretching of the nerves. If there is no mechanical disruption to the nerve or axons, the stretching results in temporary dysfunction known as neurapraxia. Ninety percent of obstetric brachial plexus palsy consists of neurapraxia, and complete recovery is expected.[7] Stretching beyond the brachial plexus elastic limit that results in the cutting or crushing of a nerve fiber, and in which part of the axon separates from the cell nucleus, results in Wallerian degeneration. There may be partial recovery in these cases, which often results in scarring and granuloma formation, known as neuroma. If the brachial plexus stretch is more severe, mechanical disruption produces a rupture in the nerve tract and sprouting neurons are typically unable to bridge the defect. These lesions can be grafted, which may result in restoring limited conduction. The most severe stretch injury is an avulsion in which the nerve roots become detached from the spinal cord.[7]

The direction of the clinically applied forces also determines the extent of the injury. If forces are applied axially with the cervical and thoracic vertebrae aligned, the brachial plexus is least stretched.[7] The greatest concentration of tension at Erb's point (formed by the union of the C5 and C6 nerve roots) occurs with lateral flexion of the neck, even with small amounts of traction.[7] Externally applied forces to the fetal head and neck increase the extent and degree of tension, which can misalign the head further from the opposite shoulder, producing a predictable and consistent injury.[7]

The rate at which forces are applied also affects the likelihood of injury. Rapidly applied forces are less tolerated by the brachial plexus than those applied in a smooth and slow manner. Allen et al. found two cases of fetal shoulder dystocia in neonates with similar birth weights and delivered with similar magnitude of force.[13] One neonate was delivered with clinically applied forces that were applied three times more rapidly than those experienced by the other neonate. While shoulder dystocia occurred in both cases, the neonate that was subjected to rapidly applied forces also sustained temporary brachial plexus injury.[13]

A randomized study by Crofts et al. found that 75 of 113 birthing providers applied much greater forces (two-thirds more) during simulated cases of shoulder dystocia than during simulated normal deliveries when the practitioners determined the level and applied the patterns of forces.[11]

Prolonged labor and the use of forceps or vacuum extraction are associated with increased risk for shoulder dystocia, although the risk is significantly greater with vacuum extraction. (For more information, see the article "Preventing Maternal and Neonatal Harm during Vacuum-Assisted Vaginal Delivery" in this issue.)

Uterine Forces

Sandmire and Demott indicate that one cause of brachial plexus injuries is the maternal uterine forces that occur during the mechanisms of labor.[14] The maximum uterine forces exerted in childbirth is around 35 lb.[7,10] This force occurs with the combination of McRoberts positioning (mother's thighs are abducted and hyperflexed onto the abdomen) and the valsalva maneuver. Although 35 lb may appear to be sufficient to cause injury, the forces are transmitted axially and do not typically cause lateral deviation of the head from the shoulders, which is needed to stretch the brachial plexus beyond its limit. The stretching of the brachial plexus to deviation is more likely to be caused by uterine malformation. Still, it is important, particularly in the case of shoulder dystocia, to note that the birthing clinician apply the least amount of traction to the fetal head.[7]

Pennsylvania Patient Safety Authority Reports

In the 316 shoulder dystocia Incidents and Serious Events reported to the Pennsylvania Patient Safety Authority from June 2004 to October 2008, 124 (39%) of the neonates experienced injuries associated with shoulder dystocia. (See Table 1.) Forty-one percent of these patients experienced skeletal fractures, 25% developed decreased limb movement, 12% resulted in Erb's palsy and brachial plexus injury, and 2% died. (See Table 2.) Examples follow of shoulder dystocia events that were reported through the Authority's reporting system.

Table 1. Shoulder Dystocia Events Reported to the Pennsylvania Patient Safety Authority, June 2004 through October 2008

INJURIES ASSOCIATED WITH SHOULDER DYSTOCIA	NUMBER OF REPORTS	PERCENTAGE
No reported injuries associated with shoulder dystocia	192	61%
Reported injuries associated with shoulder dystocia	124	39%
Total	316	100%

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Table 2. Neonatal Injuries Associated with Shoulder Dystocia Reported to the Pennsylvania Patient Safety Authority, June 2004 through October 2008

NEONATAL INJURIES	NUMBER OF REPORTS	PERCENTAGE OF NEONATAL INJURIES (N = 124)	PERCENTAGE OF ALL SHOULDER DYSTOCIA REPORTS (N = 316)
Skeletal injuries (clavicular fracture, humeral fracture)	51	41%	16%
Decreased limb movement	31	25%	10%
Erb's palsy and brachial plexus injury	15	12%	5%
Crepitus	7	6%	2%
Cephalohematoma/subdural hemorrhage	4	3%	1%
Death	3	2%	1%
Other (audible pop or click, bruising, laceration)	63	51%	20%
Total (may have multiple, overlapping injuries)	174		

Fracture and Brachial Plexus Injury

A macrosomic infant was born to a diabetic mother. Shoulder dystocia [was identified and] resulted in an undisplaced clavicle fracture and brachial plexus injury. The need for full CPR [cardiopulmonary resuscitation] in the delivery room [occurred upon delivery of the infant]. The infant [was resuscitated].

Decreased Limb Movement

During a spontaneous [full-term] vaginal delivery of a viable [fetus], a shoulder dystocia occurred. The McRoberts maneuver was performed along with [the application of] suprapubic pressure. After the delivery, it was noted that the baby had decreased movement of the right arm. The diagnosis of brachial plexus palsy [was made].

Erb's Palsy

A forceps-assisted delivery for maternal exhaustion [was conducted]. Shoulder dystocia [was identified and] reduced with the McRoberts maneuver. Approximately 24 seconds elapsed from the delivery of [the baby's] head to delivery of the shoulders. On initial assessment, the baby was noted to have a flaccid arm and was diagnosed with shoulder dystocia and Erb's palsy. [The baby's] arm remained flaccid throughout the [hospital] stay.

Death

A [multiparous] mother with diabetes was admitted in active labor. [Fetal heart rate] began to show some decelerations with minimal variability. [Several hours later, the mother] was fully dilated and pushing when a shoulder dystocia was noted. [The application of] suprapubic pressure and McRoberts [maneuver] were unsuccessful. An emergency cesarean section was done. A [full-term neonate] was [delivered] with Apgars of 0/0/0.

Several of the facilities that reported shoulder dystocia events through the Authority's reporting system identified contributing risk factors that led to the injuries sustained during antepartum care, intrapartum care, and at delivery. Maternal gestational diabetes, fetal macrosomia, and documented anencephaly were listed as antepartum contributing risk factors. Use of vaginal instrumentation by the delivering practitioner and delayed second stage of labor were among the intrapartum contributing risk factors. Injuries that were reported at delivery as the result of shoulder dystocia included fetal skeletal injuries, decreased limb movement, brachial plexus injuries, fetal lacerations, and fetal subdural hemorrhage. Fetal death was also reported.

A number of reports contained recommendations in response to the shoulder dystocia events. One hundred eighteen of the recommendations were identified as system improvements that facilities planned to implement to prevent recurrence of shoulder dystocia. Thirty-one percent of the reports that listed recommendations included peer review of the event through mortality and morbidity meetings, department meetings, or patient safety and quality assurance committees. (See Table 3.) Seven (6%) of the recommendations listed use of alternative maneuvers during the birthing process, including limiting the use of forceps, using the McRoberts maneuver, and considering earlier conversion to a cesarean section. In seventy-one (60%) of the recommendations, no system issues were reported and shoulder dystocia was listed as an unavoidable complication of childbirth. Two (2%) of the recommendations were for earlier documentation of shoulder dystocia diagnosis. In five (1.6%) of the events, facilities reported conducting a root-cause analysis (RCA) and listed staffing levels, physical assessment, use of alternative maternal or fetal maneuvers, the care planning process, and communication with patient and family as factors that contributed to these events. One hundred eighty (57%) of the reports stated that the facility did not conduct an RCA, and 131 (41%) of the reports did not indicate whether an RCA would be conducted.

Complications

Maternal Complications

Literature indicates maternal complications associated with shoulder dystocia include postpartum blood loss; hemorrhage; uterine atony; rectovaginal fistula; symphyseal separation or diathesis, with or without

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transient femoral neuropathy; third- or fourth-degree episiotomy or tearing; and uterine rupture.[1,3,5]

Fetal Complications

Fetal complications resulting from shoulder dystocia include brachial plexus and palsy injuries (Erb's, Klumpke, and Erb-Duchenne-Klumpke palsy), fractures (clavicle or humerus), hypoxia (with or without neurologic damage), and death.[1,3,5] The most common fetal complication is brachial plexus injury, which occurs in 4% to 15% of neonates with shoulder dystocia.[3,5,15] (See Figure 1.) According to Gross et al., the external application of fundal pressure resulted in a 77% complication rate and is strongly associated with fetal orthopedic and neurologic damage.[4]

The examples below represent events reported to the Authority about shoulder dystocia complications that indicated use of external fundal pressure.

> *[The mother] continued [to] push with no progress. [The decision was] made to use a vacuum. An episiotomy was performed and the vacuum was applied [several] times. The fetal head was delivered and mild shoulder dystocia [was discovered and] resolved after one minute with the McRoberts maneuver and fundal pressure. [A maternal] laceration was discovered after the baby was delivered.*

> *Infant was born by vaginal delivery and a shoulder dystocia occurred. At time of shoulder dystocia, the mother was placed in McRoberts position and fundal pressure was applied. Upon delivery, the infant was bagged and stimulated prior to spontaneous respirations. Apgar scores were 3 and 6. It was observed at that time that the infant had decreased movement of the right arm.*

While most incidents of brachial plexus injuries are associated with shoulder dystocia, there is clinical literature indicating that permanent brachial plexus injuries have occurred that are not associated with shoulder dystocia or delivering provider traction. It is likely that there may be significant biological variability in the predisposition of brachial plexus injury in individual neonates.[6,15] This variation depends on the delivery difficulty and requires the subjective application of secondary maneuvers by the delivering provider.

Guidelines

There are no evidence-based guidelines for the prediction, prevention, or management of shoulder dystocia. The current practice guidelines are based on limited scientific evidence and the consensus opinions of experts.[2] ACOG developed these practice guidelines to aid obstetric practitioners in making decisions about appropriate obstetric care.[1] Most cases of shoulder dystocia cannot be predicted or prevented because there is no accurate method to identify fetuses that will develop this complication.[1] Ultrasound measurements to estimate macrosomia have limited accuracy. Planned cesarean delivery based on *suspected* macrosomia is not a reasonable strategy, but a planned cesarean delivery may be reasonable for the nondiabetic mother with an estimated fetal weight exceeding 5,000 g or for the diabetic mother whose fetus is estimated to weigh more than 4,500 g.[1] Macrosomic neonates of diabetic mothers are characterized by larger shoulder and extremity circumferences, decreased head-to-shoulder ratio, higher body fat, and thicker upper-extremity skin folds compared with neonates of nondiabetic mothers of similar birth weight.[1] The intensive treatment of maternal diabetes during pregnancy may reduce the risk of neonatal macrosomia and fetal shoulder dystocia.[1]

Table 3. Recommendations Listed by Facilities Associated with Shoulder Dystocia Reported to the Pennsylvania Patient Safety Authority, June 2004 through October 2008

RECOMMENDATIONS	REPORTS
No system recommendations identified	71 (60%)
Peer review, department meeting, morbidity and mortality	37 (31%)
Consider cesarean section conversion earlier	4 (3%)
Limit forceps use and application of external maneuvers	3 (3%)
Better documentation	2 (2%)
Other	1 (1%)
Total (may have multiple, overlapping recommendations)	118 (100%)

Shoulder Dystocia Management

The appropriate management of shoulder dystocia is based on the recognition of risk factors. As part of antenatal care, a thorough patient history would include maternal age, parity, week of gestation, and birth history. Noting the birth weight of the mother's other infants in the case of multiparity is extremely important because subsequent births may result in shoulder dystocia.[2,5] Other important patient information to obtain includes whether forceps and/or vacuum extraction were used in previous deliveries. Any delivery in which the neonate experiences a fracture may suggest shoulder dystocia.[5] Prenatal laboratory and diagnostic studies including glucose screening or any history of maternal diabetes may also indicate propensity for shoulder dystocia. If available, fetal ultrasound reports may help rule out macrosomia and can be used to estimate fetal weight, although their accuracy may be limited.[3,5] Measurement of fundal height can assist in determining whether the uterine size is consistent with gestational age. Documentation of estimated fetal weight is very important, despite the controversy and margin of error because the failure to assess and document fetal weight during pregnancy or labor may constitute a deviation from the standards of practice.[8] Reporting any suspicion of fetal macrosomia to the delivering provider will help the team collaborate and

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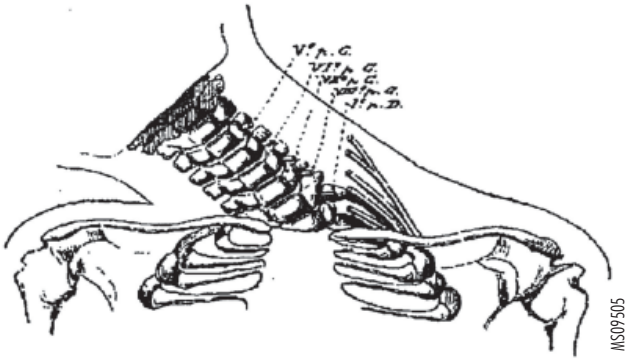
Figure 1. Brachial Plexus Injury



Source: Allen RH. On the mechanical aspects of shoulder dystocia and birth injury. *Clin Obstet Gynecol* 2007 Sep; 50(3):607-23.

implement an interdisciplinary plan for the management of a shoulder dystocia emergency.[2]

Maneuvers for Relieving Shoulder Dystocia

The objective for the relief of shoulder dystocia is to compensate for the incompatible fetal shoulder and maternal pelvic dimensions by changing the relative positions of the maternal pelvis and the fetal shoulders. This may be accomplished by shrinking the fetal shoulder width, and/or manually performing a forward-progressing rotational movement of the fetal shoulders within the birth canal.[10] The use of internal, rotational maneuvers takes better advantage of the maternal pelvic geometry.[10] The successful resolution of shoulder dystocia requires at least one of the following four components:[3]

1. Flatten the maternal sacrum and fetal cephalad rotation of the symphysis using the external McRoberts maneuver to reorient the maternal pelvis.
2. Collapse the fetal shoulder width by the external application of suprapubic pressure—*not* fundal pressure, which may impact the shoulder further.
3. Alter the orientation of the longitudinal axis of the fetus plane through internal rotation maneuvers.
4. Replace the bisacromial shoulder with the axiallary-sacromial width by delivering the posterior arm.

The order of these maneuvers is not as important as their effective and appropriate use. The persistent use of one ineffective maneuver may interfere with safe maternal and fetal outcomes.

- The McRoberts maneuver is the sharp flexion of the maternal thighs against the abdomen to achieve pelvic tilt and straightening of the lumbosacral joint. This maneuver is generally simple to perform.[12] The combination of the external McRoberts maneuver with suprapubic pressure relieves about 50% of shoulder dystocia cases. The mechanical effect of the McRoberts positioning—cephalad rotation of approximately 15°—lifts the pubis symphysis up approximately 1 cm and may be sufficient to clear the obstructed anterior shoulder.[10] This action causes cephalad rotation of the pubis symphysis, reducing the inclination of the pelvic inlet and offering a greater anteroposterior diameter for the fetal shoulders. This also increases net expulsive forces by converting voluntary maternal pushing efforts into enhanced intrauterine pressure independently of contractions.[7,16] Typically, the use of suprapubic pressure results in downward force on the anterior fetal shoulder, facilitating its disimpaction above the pubis symphysis. (See Figure 2.) Failure of these maneuvers may indicate a more severe degree of shoulder dystocia and the need to use internal maneuvers.[16]
- The Rubin's maneuver is an internal rotation maneuver that adducts the fetus's shoulder girdle, thus reducing its diameter.[3] It consists of inserting the fingers of one hand into the vagina to the area behind the posterior aspect of the fetus's anterior or posterior shoulder and rotating the shoulder toward the fetal chest. Some healthcare providers perform this in concert with the external McRoberts maneuver to facilitate its success.[3] Lowering the bed may facilitate these maneuvers.[16]
- The Woods' corkscrew maneuver may be attempted if the Rubin's maneuver is unsuccessful. In this internal maneuver, the delivering provider places at least two fingers on the anterior aspect of the fetal posterior shoulder and applies gentle upward pressure around the circumference of the arc in the same direction as the Rubin's maneuver, creating a more effective rotation. These two maneuvers may be used together to increase torque forces by using two fingers behind the fetal anterior shoulder and two fingers in front of the fetal posterior shoulder. This may be difficult for the delivering provider due to limited space for the hand of the provider. The downward traction should be continued during these maneuvers, similar to the rotation of a screw being removed. It is important to note that the episiotomy has no direct effect in releasing shoulder dystocia, which is a primary issue of bony impaction. Episiotomy is a soft tissue procedure and will provide additional room for the healthcare providers' hand to perform internal maneuvers, if necessary.[3,16]
- The Reverse Woods' corkscrew maneuver may be necessary to adduct the fetal posterior shoulder out of the impacted position and into an oblique plane for delivery if the Woods' corkscrew maneuver is not successful.[3] The 30° rotation of the shoulders from their pathologic orientation of the Rubin's maneuver provides 2 cm more room for the passage of the fetal shoulders.[10] The delivery of the posterior arm before the shoulders reduces the bisacromial diameter, leaving only the axilloacromial diameter. The delivering provider locates the posterior shoulder and nudges it anteriorly. The fetal elbow is flexed and the forearm is delivered in a sweeping motion over the anterior fetal chest

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wall. The posterior hand is followed by the arm and shoulder, thus facilitating the neonate's delivery. The fetus will likely spontaneously rotate in a corkscrew manner as the arm is removed, followed by the anterior shoulder falling under the symphysis, then delivery.[3,16] It is important to note that the delivery of the posterior arm maneuver has an increased rate of humeral fractures.[16]

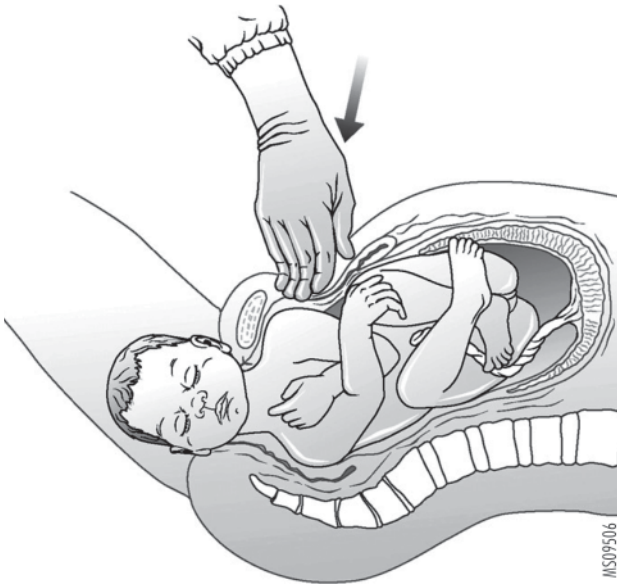
- Delivery of the posterior arm combined with the Rubin's or McRoberts maneuver affords the potential for 4 cm of additional space.[10] Internal maneuvers also offer kinematic advantages over external maneuvers in resolving shoulder dystocia and take better advantage of maternal pelvic geometry. These maneuvers may be performed as early as possible in the management algorithm or in conjunction with the McRoberts maneuver.[10,12] These maneuvers are associated with reduced clinically applied traction and less brachial plexus stretching—two critical determinants of mechanical birth injury associated with shoulder dystocia.[12]
- The all-fours maneuver may also be used to facilitate delivery. For this maneuver, the mother is positioned on her hands and knees, and the effects of gravity and increased space in the hollow of the maternal sacrum facilitate delivery of the posterior shoulder and the arm.[3] Rapid delivery ensues within approximately two to three minutes in more than 80% of the deliveries when the all-fours maneuver is used, as described in one study.[16]

Several maneuvers of last resort for shoulder dystocia can be considered only in dire emergencies when external and internal maneuvers fail to achieve delivery. These procedures are associated with the highest rates of fetal injury and maternal trauma. These maneuvers include the deliberate fetal clavicle fracture, the cephalic replacement maneuver, hysterotomy (upper-segment uterine incision), and symphysiotomy.[3,16]

Maneuver Sequence

While there are no specific guidelines on the sequential use of shoulder dystocia maneuvers, facilities and birthing centers may consider using a set pattern of steps that providers can follow during births and interdisciplinary drills. When shoulder dystocia is diagnosed and the delivering provider encounters inadequate progression of dilatation and descent in labor, it is important to communicate signs and summon the obstetric rapid response team. The availability of emergency resuscitation equipment is also essential, in order to provide the safest and most effective care for the mother and fetus during the delivery. Having a set plan means that all involved birthing personnel will be familiar with the delineation of care and responsibilities. The delivering provider directs the obstetric team (obstetric assistants, anesthesia providers, neonatal support personnel), but each member has specific responsibilities. Facilities may consider developing protocols to designate

Figure. 2 Shoulder Dystocia and the Application of Suprapubic Pressure



Reprinted from Gottlieb AG, Galan HL. Shoulder dystocia: an update. Obstet Gynecol Clin North Am *2007 Sep;34(3):501-31, with permission from Elsevier (http://www.sciencedirect.com/science/journal/08898545).*

these responsibilities and regular shoulder dystocia drills may be helpful to rehearse such an emergency. Documentation is very important to provide a record of the timing of each maneuver so that if one is not successful after a reasonable amount of time, another can be attempted. The reasonable amount of time is determined by each facility.[3,16]

Interdisciplinary drills include a set of maneuvers performed sequentially by delivering providers as needed to complete vaginal deliveries. Conducting simulation drills may better prepare delivering providers and other obstetric personnel to perform an organized emergency management when an impacted fetal shoulder occurs.[15] Drills may provide the obstetric team with the skill set to respond adequately to these crisis scenarios. Consider the use of a mnemonics inventory that lists all possible external and internal maneuvers that may be used for the systematic resolution of shoulder dystocia. Refer to the two mnemonics (see "BE CALM" and "HELPERR") that document possible external and internal maneuvers, designed for the resolution of shoulder dystocia.

Documentation

It is also important to document in the postpartum record any physical abnormalities of the neonate such as bruising or lack of arm muscle tone. Provide factual information and consistently document any episode of shoulder dystocia encountered by all birthing personnel.[5]

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BE CALM

The BE CALM mnemonic outlines the external and internal maneuvers that may be used when shoulder dystocia occurs.

*B*reathe; do not push

*E*levate legs to McRoberts position

*C*all for help

*A*pply suprapubic pressure (*not* fundal pressure)

En*L*arge vaginal opening

*M*aneuvers

Source: Camune B, Brucker MC. An overview of shoulder dystocia: the nurse's role. *Nurs Womens Health* 2007 Oct;11(5):488-97.

HELPERR

The HELPERR mnemonic outlines the external and internal maneuvers that may be used when shoulder dystocia occurs.

Call for *H*elp

*E*valuate for episiotomy

*L*egs (use the McRoberts maneuver)

Suprapubic *P*ressure

*E*nter maneuvers (internal rotation)

*R*emove the posterior arm

*R*oll the patient

Sources: Camune B, Brucker MC. An overview of shoulder dystocia: the nurse's role. *Nurs Womens Health* 2007 Oct;11(5):488-97; Baxley EG, Gobbo RW. Shoulder dystocia. *Am Fam Physician* 2004 Apr 1;69(7):1707-14.

During postpartum care and following all complicated deliveries, a discussion with the mother and family is conducted. It is important that the delivery events be documented. If shoulder dystocia has been diagnosed or a brachial plexus injury has been identified, speculation about its cause or incomplete documentation may be difficult to defend in a legal case. The following information is useful to document when encountering a delivery complicated by shoulder dystocia for retrospective review.[14]

- When and how the shoulder dystocia was diagnosed[14]
- Progress of labor (active phase and second stage)[14]
- Presence of the "turtle sign" (the tight retraction of the delivered fetal head against the maternal perineum)[1,2,4,5]
- Position and rotation of the fetus's head[14]
- Presence of an episiotomy[14]
- Whether anesthesia was required[14]
- Estimation of force and duration of traction applied[14]
- Order, duration, and results of maneuvers used[14]
- Duration of shoulder dystocia[14]
- Documentation of adequate pelvimetry before initiating labor induction or augmentation[14]
- Neonatal and obstetric providers impressions of the neonate after delivery[14]
- Information given to the mother that shoulder dystocia has occurred[14]
- Personnel involved in delivery[14]

Conclusion

While it is difficult to accurately predict or prevent shoulder dystocia, delivering healthcare providers can be prepared when this obstetric emergency occurs. Antepartum care includes the consideration of maternal and fetal risk factors. Intrapartum care includes the prompt identification, quick diagnosis, and management of shoulder dystocia. The delivering provider obtains assistance from the obstetric team, which provides emergency care for the mother and fetus throughout the delivery. Prompt application of various external and/or internal maneuvers as specified by each organization may provide quick resolution of the shoulder dystocia. Facilities may consider providing mandatory and ongoing interdisciplinary drills for all obstetric personnel that include the application of external and/or internal maneuvers. Above all, complete documentation will provide all healthcare personnel, patients, and their families with a clear understanding of the events that led to the discovery and resolution of the shoulder dystocia, brachial plexus injury, or any other obstetric emergency.

Notes

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Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. All of the following clinical manifestations are useful when determining fetal risk factors for shoulder dystocia EXCEPT:
   a. Documented anencephaly
   b. Fetal anthropometric variations
   c. Fetal shoulders remaining in the anterior-posterior plane
   d. Ultrasound measurements for macrosomia
2. The strategies for the successful resolution of shoulder dystocia include all of the following EXCEPT:
   a. Collapse the fetal shoulder width by the external application of fundal pressure.
   b. Alter the orientation of the longitudinal axis of the fetus plane through internal rotation maneuvers.
   c. Replace the bisacromial shoulder with the axiallary-sacromial width by delivering the posterior arm.
   d. Flatten the maternal sacrum and fetal cephalad rotation of the symphysis using external maneuvers.
3. Which of the following interventions should not be implemented when shoulder dystocia is encountered?
   a. Apply McRoberts maneuver with suprapubic pressure.
   b. Increase traction on the fetal head and rotate the body.
   c. Position the mother in the all-fours maneuver.
   d. Perform Rubin's rotation maneuver with McRoberts maneuver.
4. A birthing provider encounters fetal shoulder dystocia during a delivery. The provider performs external maneuvers and applies suprapubic pressure without success. Internal rotation maneuvers are successful in releasing the fetal shoulder, but the neonate is noted to have a flaccid arm at delivery. Erb's palsy is diagnosed and communicated to the mother.

   The components for accurate and detailed documentation when encountering shoulder dystocia include all of the following EXCEPT:
   a. Order, duration, and results of all maneuvers used
   b. Position and rotation of the fetus's head
   c. Prediction for future shoulder dystocia births
   d. Lack of arm muscle tone of the neonate
   e. Information given to the mother that shoulder dystocia has occurred
5. All of the following labor and delivery factors increase risk for shoulder dystocia EXCEPT:
   a. Increased maternal anteroposterior pelvic diameter
   b. Instrument-assisted vaginal delivery (forceps or vacuum)
   c. Delayed head-to-body delivery time
   d. Prolonged second-stage labor

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Data Snapshot: Maternal Complications

Analysts for the Pennsylvania Patient Safety Authority queried the Authority's reporting system database for maternal complications of pregnancy and childbirth. Search criteria included either (1) the event types for maternal complications or (2) events in obstetric, labor and delivery, and operating room venues with mention of "mother" or "maternal" in the narratives. The analysts limited the search to Serious Events (reporting patient harm) among female patients 15 years old and older from the beginning of event reporting (officially June 28, 2004) through August 31, 2009. Neonatal complications were excluded.

The search resulted in the identification of 256 reports of maternal complications causing harm to the mother. The ages of the mothers ranged from 16 to 47. For the 203 reports in which the method of delivery was mentioned, 99 deliveries were vaginal and 104 were ultimately by cesarean section.

Table 1 lists the reports by event type. Some events have been reclassified by the analysts for consistency in reporting aggregate figures.

Table 1. Maternal Complications Reported by Event Type, June 2004 through August 2009*

EVENT TYPE	TOTAL	PERCENTAGE
Maternal Complication		
Death	20	7.8%
Unplanned transfer to intensive care unit	15	5.9%
Uterine rupture	17	6.6%
Unanticipated blood transfusion (adding 97 other significant complications needing treatment for bleeding)	118	46.1%
Pulmonary embolism	2	0.8%
Seizure (adding 2 other central nervous system complications)	8	3.1%
Infection	17	6.6%
Laceration of the birth canal	22	8.6%
Neuropathy	6	2.3%
Laceration of adjacent organ during cesarean section	5	2%
Wound dehiscence	5	2%
Retained placenta	4	1.6%
Retained object	3	1.2%
Skeletal injury	2	0.8%
Spinal headache	2	0.8%
Unattended delivery	2	0.8%
Inadequate postoperative pain management	1	0.4%
Inversion of the uterus	1	0.4%
Reaction from known latex allergy	1	0.4%
Spontaneous rupture of the liver	1	0.4%
Unplanned cesarean section in mid-delivery of twins	1	0.4%
Anesthesia Event		
Ascending epidural	3	1.2%
	256	100%

* All reported as "complications of procedures/treatments/tests."

Deaths

Twenty mothers died, including three with intra-uterine fetal demise. Four of the deaths were due to amniotic fluid emboli. Others were associated with Group A streptococcus infection, postpartum bleeding, pulmonary embolus, uterine rupture, cerebrovascular thrombosis, and seizure; two of the patients had hysterectomies for postpartum bleeding (one died of a pulmonary embolus). Half of all the deaths were attributed to cardiac and/or pulmonary failure not otherwise specified.

Unplanned Transfers to Intensive Care Units (or Other Higher Levels of Care)

Five patients had cardiac and/or respiratory arrests, not due to blood loss or emboli, and survived; one was thought secondary to an adverse drug reaction to Pitocin®. Another seven patients had other cardiac and/or pulmonary complications not due to blood loss or emboli. Two patients had HELLP syndrome, a complication of pre-eclampsia characterized by hemolytic anemia, elevated liver enzymes, and low platelet counts, without further complications. One patient was transferred to the intensive care unit postoperatively, without any reasons given.

Uterine Ruptures

Fifteen patients ruptured their uteri during labor or delivery and survived. Six patients were attempting vaginal births after cesarean sections (VBAC); two (33%) were reported to have needed hysterectomies. Four of the other nine patients surviving uterine ruptures during labor and delivery were also reported to have needed hysterectomies (40% including the death). One other patient ruptured in midpregnancy because of a uterine abnormality. One more ruptured during a dilation and curettage procedure for a miscarriage.

Unanticipated Blood Transfusions, Plus Other Complications Causing Significant Bleeding

Postpartum bleeding was, by far, the most commonly reported maternal complication (46% of all the reports), with 118 patients having significant bleeding requiring treatment, for reasons other than uterine rupture, and surviving. The causes of bleeding included uterine atony, placental complications, lacerations, hematomas, postoperative bleeding, and coagulopathies. One report involved bleeding from

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perforation of the uterine wall during insertion of a Foley catheter. Hysterectomies were reported to be needed to control the bleeding in 36 of these survivors, plus the 2 patients who died (discussed above), and 1 survivor whose most significant problem was a subdural hematoma secondary to her diffuse intravascular coagulation (DIC) (discussed below).

Pulmonary Emboli

Two patients survived pulmonary emboli. One had a vaginal delivery and the other had a cesarean section.

Seizures, Plus Other Central Nervous System Complications

Six patients were reported to have seizures and survived. None of the seizures were a pre-existing comorbidity. Two other patients were added to this group by the analysts. Both had subdural hematomas; one was secondary to disseminated intravascular coagulation severe enough to necessitate a hysterectomy.

Primary Infections

One patient developed septic shock. Three patients had chorioamnionitis. Four patients developed necrotizing fasciitis of their wounds; three developed an intra-abdominal abscess; and five patients developed wound infections after cesarean sections. One other patient developed an infection of her episiotomy.

Other Complications

- Twenty-two patients had lacerations of the birth canal that did not present primarily as bleeding problems. All were related to vaginal deliveries. The lacerations were predominantly third- and fourth-degree perineal lacerations, one of which required a diverting colostomy. Other sites described were the vagina, the peri-urethral area, and the cervix.
- Six patients had neuropathies of their lower extremities.
- Five patients had lacerations of adjacent organs during cesarean sections that were reported as unanticipated complications; three were of the bowel and two were of the bladder. Another two bladder lacerations were reported as complications of cesarean sections done for the uterine ruptures mentioned above. Another bladder laceration, with concomitant ureteral obstruction, was reported as a complication of a cesarean section done for one of the patients with bleeding discussed above.
- Five patients had wound dehiscences after cesarean sections.
- Four patients had retained placentas, apparently uncomplicated by bleeding or infection.
- Three patients had retained objects. Two patients had vaginal sponges left after vaginal deliveries and repairs of vaginal lacerations. One patient had a needle fragment that needed finding at the end of a cesarean section.
- Two patients had skeletal injuries. One had a fractured rib and the other had a symptomatic pubic separation.
- Two patients had spinal headaches. Three ascending epidurals were also reported as anesthesia events.
- Two patients were delivered by the labor and delivery nurse; their primary providers were not present.
- Other complications included inadequate postpartum analgesia, inversion of the uterus, an allergic reaction to latex in a patient with a known allergy, a spontaneous rupture of the liver in a patient with HELLP syndrome, and conversion to an unplanned cesarean section after the successful vaginal delivery of a first twin.

Hysterectomies

Forty-five patients were reported to have needed hysterectomies: 2 who died following postpartum bleeding as noted above, 6 who survived uterine ruptures, 36 who survived postpartum bleeding, and 1 survivor whose DIC was complicated by a subdural hematoma. One of the patients, less than 30 years old, had a bilateral salpingo-oophorectomy as well.

The mortality rate for the hysterectomies reported in response to maternal complications was 4%. Hysterectomies were done for 6 of the 16 patients (38%) who ruptured their uteri during labor and delivery (15 who survived and 1 who died). Hysterectomies were done for 39 of the 121 patients (32%) with bleeding complications (including the 2 who died, as noted above, and the 1 whose most significant problem was a subdural hematoma secondary to DIC). The mortality rate was 5% for the hysterectomies done as a potentially lifesaving procedure for postpartum hemorrhage.

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Online Resources Associated with Patient Safety Advisories

Patient Safety Officers have expressed their interest in distributing educational resources within their healthcare facilities. The Pennsylvania Patient Safety Authority provides a growing collection of resources related to *Pennsylvania Patient Safety Advisory* articles to help increase situational awareness and patient safety within healthcare facilities. Examples include sample policies, educational videos and posters, brochures, interactive learning graphics, and reference materials.

This collection of resources is available online at http://www.patientsafetyauthority.org. Topics addressed include the following:

- Preventing wrong-site surgery
- Aspiration screening
- Diagnostic radiation and pregnancy
- ASF patient screening and assessment
- Hospital bed safety
- Airway fires during surgery
- Color-coded wristbands
- Common hazards in the behavioral health patient room

More improvement comes from improving a system than improving the performance of individuals within an existing system.

PATIENT SAFETY AUTHORITY

An Independent Agency of the Commonwealth of Pennsylvania

Whether you would like to learn more about the topics described above, or you need tools to help you meet other challenges, these educational resources can help.

If you would like additional information, please contact us at (866) 316-1070, or e-mail support_papsrs@state.pa.us.

PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

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The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a nonpunitive approach and systems-based solutions.