



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

Pennsylvania Patient Safety Authority

February 2010



# Vacuum-Assisted Vaginal Delivery (VAVD) Overview

- Vacuum extractors are used to aid delivery in cases of failure to progress in the second stage of labor
- Their use has increased over the past 10 years, as forceps use has simultaneously decreased
- There are known risks and complications

## ❖❖❖ Quality Measures

- Hospital-level National Patient Safety Indicator developed by the Agency for Healthcare Research and Quality (AHRQ)
  - Obstetrical trauma associated with instrument-assisted vaginal delivery and birth trauma
  - In June 2009, AHRQ released a statistical brief which revealed that in 2006 nearly 157,700 potentially avoidable injuries to mothers and newborns occurred.

## ⋮ Alerts and Warnings

- U.S. Food and Drug Administration (FDA) issued a public health advisory in 1998 highlighting the increased risk of serious fetal intracranial injury or death associated with the use of vacuum devices
- From 1996 through 2004, the Joint Commission received 47 reports of perinatal death or permanent disability
- In 2004, the Joint Commission issued a Sentinel Event Alert titled “Preventing Infant Death and Injury During Delivery”



# Pennsylvania Patient Safety Authority (Authority) Reports

- From July 2004 through April 2009, 367 reports related to VAVD were received
- 77% of these reports (282) included some form of neonatal or maternal injury
- 14% of these reports (51) were Serious Events including four neonatal deaths

## VAVD Injuries

- Of the 282 reports associated with maternal and fetal injury, 51 were Serious Events

**Table 1. Maternal and Neonatal Serious Events by Injury Type**

TYPE AND NUMBER OF <b>MATERNAL INJURY</b>		TYPE AND NUMBER OF <b>NEONATAL INJURY</b>	
Perineal or cervical tears or lacerations resulting in hemorrhage and blood transfusion	8	Fractured clavicle or humerus	11
4 <sup>th</sup> 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)

# Indications

- Termination of a prolonged second stage of labor
- Suspicion of immediate or potential fetal compromise
- Shortening of the second stage of labor for maternal benefit

## ❖❖❖ Contraindications

- Gestational age of less than 34 weeks
- Fetal bleeding disorders or predisposition to fracture
- Cephalopelvic disproportion
- In cases where:
  - infant head not engaged; incomplete cervical dilatation; intact membranes; there is brow, face or breech presentation

# ❖❖❖ Maternal Complications

- Fewer maternal injuries than forceps
- Injuries include
  - Cervical lacerations
  - Vaginal hematomas
  - Hemorrhage
  - Third and fourth degree perineal tears
  - Anal sphincter injury

# ⋮⋮ Neonatal Complications

- VAVD is associated with higher rates of:
  - Cephalhematoma
  - Neonatal jaundice
  - Retinal hemorrhage
  - Subgaleal hematoma

# ⋮⋮⋮ Preoperative Maternal and Fetal Assessment

- Maternal assessment:
  - Full cervical dilatation, ruptured membranes, empty bladder, adequate analgesia
  - Consent and ability to participate in the procedure

# ⋮⋮⋮ Preoperative Maternal and Fetal Assessment

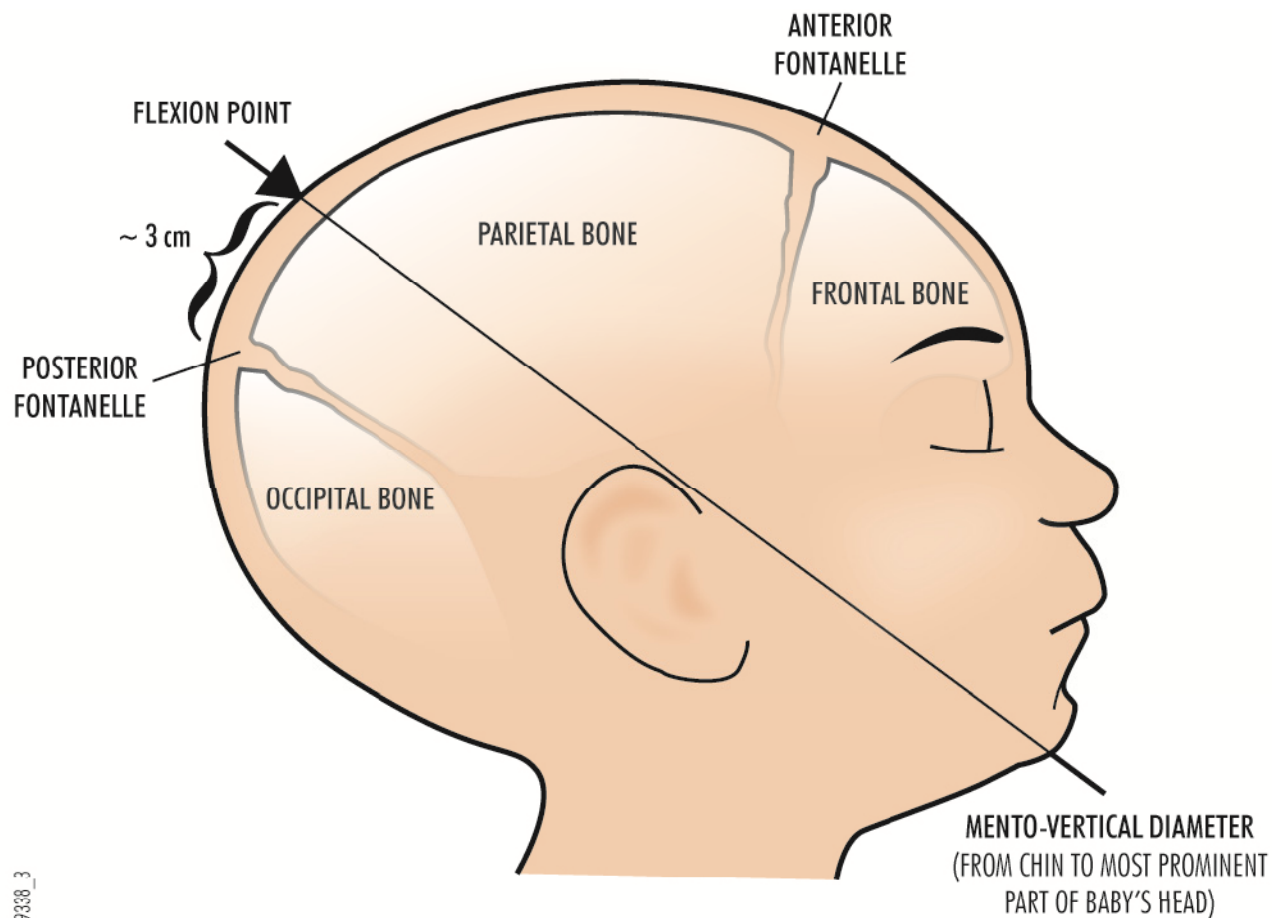
- Fetal Assessment
  - General fetal condition (auscultation of the fetal heart rate)
  - Pelvimetry and EFW (>4000 gm is greater potential for fetal injury)
  - Engagement and station
  - Fetal position

## Technical Expertise

- A prospective case controlled study (2004) showed that operator technical expertise with vacuum extractors was associated with increased safety for both mother and infant
- Familiarity with manufacturer guidelines for the device is also very important

# Technical Expertise

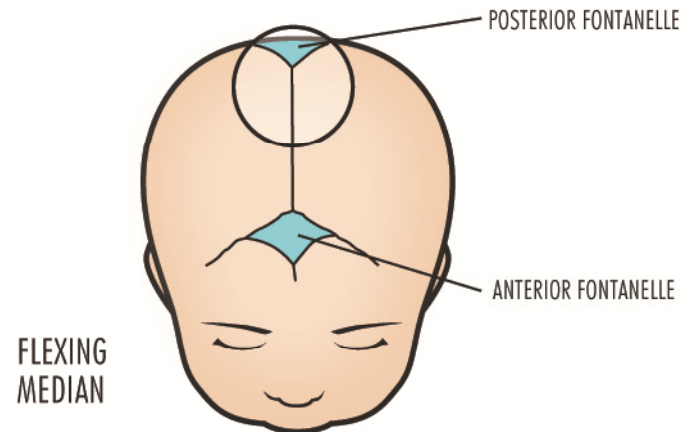
## Cup selection and placement



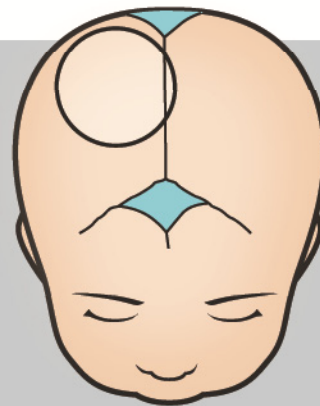
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# Technical Expertise

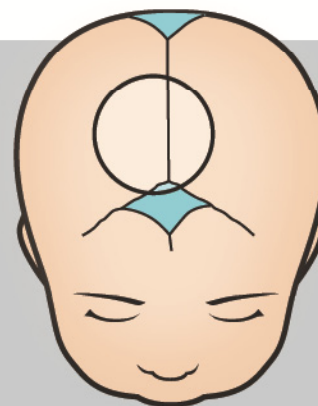
## CORRECT PLACEMENT



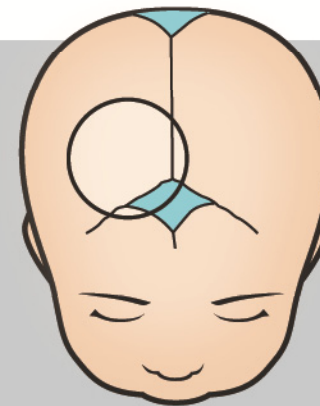
## INCORRECT PLACEMENTS



FLEXING  
PARAMEDIAN



DEFLEXING  
MEDIAN



DEFLEXING  
PARAMEDIAN

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# Technical Expertise

- Per manufacturer's guidelines:
  - Vacuum pressure
  - Duration
  - Pop-offs
- Traction
- Pulls

# ❖❖❖ Human Factors

- Sequential device use
- Maintaining situational awareness
- Abandoning the procedure



# Postoperative Maternal and Neonatal Assessment

- Maternal
  - Injury to the birth canal
    - Bleeding due to cervical tears, perineal tears or lacerations, injury to the anal sphincter
  - Deep vein thrombosis in cases of prolonged labor
  - Urinary, stress and bowel incontinence



# Postoperative Maternal and Neonatal Assessment

- Scalp injuries
  - Fractures, hematomas, lacerations
- Retinal hemorrhage
- Subgaleal hematoma

## Authority Reports

- 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. Postoperatively, the patient became hypotensive and tachycardic and developed hypovolemic shock/DIC [sic] .*

## ❖❖❖ Authority Reports

- *Physician failed to follow proper procedure during vacuum-assisted delivery. Attempted 9 pulls with 4 pop-offs. Nurse advised physician of number of pulls without physician stopping. Policy states number of attempts and pop-offs to be limited to 3.*
- *Infant delivered via vacuum extraction with cephalohematoma and fracture of right clavicle. The infant was transferred to a tertiary facility NICU for further evaluation and was found to have a subdural hematoma. . . .*

## ⋮ Authority Reports

- *Term infant attempted to be delivered with vacuum extractor twice and with forceps twice. . . The vacuum extractor was applied the second time, and then [converted to cesarean section]. The baby was born with APGARS1-1-3; required resuscitation/intubation. The baby was transferred to tertiary neonatal intensive care unit and expired there (subdural hematoma/brain death).*

# ⋮⋮⋮ Risk Reduction Strategies

- Facility
  - Resident training and credentialing
  - Policy review
  - Implement a VAVD “bundle”
  - Retrospective chart review

# ⋮⋮⋮ Risk Reduction Strategies

- Preoperative strategies
  - Alternative delivery strategies
  - Informed consent
  - Rule out contraindications
  - Have an exit strategy

# ⋮⋮⋮ Risk Reduction Strategies

- Operative strategies
  - Use vacuum extractors only when a specific obstetrical indication is present
  - Use steady traction in line with the birth canal; avoid rocking motions or torque
  - Minimize duration of vacuum application
  - Maintain situational awareness

# ❖❖❖ Risk Reduction Strategies

- Postoperative strategies
  - Notify all members of the maternal and neonatal care teams of use of vacuum
  - Document the procedure carefully
  - Perform thorough maternal and neonatal assessments
  - If neonatal cranial complications occur, intervene quickly and treat aggressively



# Making Vacuum-Assisted Vaginal Delivery Safer

- Performing a thorough preoperative maternal and fetal assessment
- Technical proficiency with the vacuum device
- Setting goals and maintaining situational awareness
- Concluding the delivery with a targeted postoperative assessment of both the mother and neonate are all important patient safety concepts