

# Briefly Legal: Extreme Prematurity Complicated by Trauma after Delivery

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## Clinical History

A 29-year-old pregnant woman, G4P3, developed vaginal bleeding and preterm labor and gave birth to an extremely premature male baby. The mother was unsure of her dates, but at 18 weeks gestation, ultrasound dating placed the pregnancy at 24 5/7 weeks gestation at the time of birth.

The mother had become pregnant about six weeks after the prior term delivery.

A fetal ultrasound was performed upon arrival to the hospital and found a biophysical profile of 8/8, representing normal fetal activity (breathing, moving, tone) and normal amniotic fluid volume. The fetus was in breech presentation, and the estimated gestational age (EGA) was 23 3/7 weeks, eight days younger than the EGA assigned by the 2<sup>nd</sup>-trimester ultrasound.

Upon admission, magnesium sulfate for tocolysis, antibiotic prophylaxis against group B streptococcus, and corticosteroids for fetal lung maturation were administered. The fetal tracings were of poor quality. The mother had consented to a vaginal delivery on admission. Still, her deposition stated that she expressed to the obstetrician her desire that everything be done for this baby to optimize its outcome - including cesarean section if needed. No discussion about the prospects of morbidity and mortality in this extremely premature baby or the options for cesarean section were documented in the medical records or in deposition testimony. Severe variable decelerations began about 2 hours prior to birth. The mother was not informed of a change of circumstances in terms of delivery route and was not re-consented despite the deteriorating FHR patterns.

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The patient progressed rapidly in labor with spontaneous rupture of the membranes occurring 2 minutes before the breech delivery. The obstetrician, called to the delivery a few minutes before the birth, attended the birth. The umbilical cord was found between the legs of the delivering breech fetus. At delivery, the baby fell out of the hands of the obstetrician, falling about 3 ½ feet and striking his head on the wheellock of the delivery table before hitting the floor. After the event, the obstetrician wrote that the cord was short and the placenta had abrupted. He charted that the eyes were fused and that the baby did not breathe immediately at birth.

A cord gas was sent, but not until 6 hours after the birth, making it invalid. The baby was intubated in the delivery room and given positive pressure ventilation. Apgar scores were 1<sup>1</sup>, 4<sup>5</sup>, 5<sup>10</sup>. The baby weighed 670 grams on admission, and his head circumfer-

ence was 21 cm. He had a 2-2.5 cm laceration on the left parietal area, which was actively bleeding. His eyes were fused, and he had multiple bruises. A Ballard examination placed the infant at 24 weeks.

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On admission to the NICU, his blood pressure was undetectable and could not be measured even after blood products and several pressors were provided. Initially, he was placed on a conventional ventilator at 100% inspired oxygen but needed high-frequency oscillatory ventilation. His complete blood count (CBC) showed a hematocrit of 30%, a white blood count of  $6.5 \times 10^3$  u/L, and a platelet count of  $116 \times 10^3$  u/L. The first blood gas (venous) at 1.5 hours of life showed a pH of 6.7, a pCO<sub>2</sub> of 45 mmHg, a pO<sub>2</sub> of 26mmHg, and a base excess of -26 – a severe metabolic acidosis. Despite maximum support with pressors and blood products, the baby died at 12 hours, having never achieved a detectable blood pressure

## Discovery

The Coroner's report affirmed that the cause of death was a traumatic brain injury. The findings documented in the Coroner's records included: subgaleal, subdural, and grade 4 IVH (intraventricular hemorrhage, specifically hematoma in the brain parenchyma), multiple bruises, mild chorioamnionitis, absent funisitis, and an umbilical cord length that was normal for 24-week infant (when all of the pieces of cord were accounted for.).

In his deposition, the obstetrician stated that the placenta shot out of the vagina because of the short cord pulling the baby out of his hands onto the floor.

***“Despite maximum support with pressors and blood products, the baby died at 12 hours, having never achieved a detectable blood pressure”***

## Allegations

The case was adjudicated in court. The Plaintiff averred that:

1. There was a failure to obtain proper informed consent. It violated reasonable standards of care by not informing the mother of the change in fetal status about 2 hours before delivery to discuss or recommend a cesarean section. The fail-

ure to properly discuss the risks, benefits, and alternatives to vaginal delivery in the face of the deteriorating fetal condition, meant that the caregivers had NOT obtained proper informed consent from the patient. Despite defense arguments to the contrary, Plaintiff pointed out that the obstetrician was responsible for explaining what is known in terms of morbidity and mortality given the uncertainty of the true EGA ( 23, 24, and 25 weeks). Such conduct by the obstetrician, however, was consistent with the notion that the care providers had decided, without the agreement of the mother, not to intervene for fetal distress in this extremely premature fetus, despite the mother's expressed view that everything be done to enhance the outcome of the baby. Plaintiff explained that such a paternalistic approach was inappropriate and violated reasonable standards of care.

experts pointed out that the obstetrician's description of the events leading to the dropped baby was not credible, that they were self-serving and not validated in the medical chart. Placentas, especially those that are separated, are not delivered with force, and the cord was not short for 24 weeks gestation (per the Coroner's report)

Notwithstanding the change in the Coroner's assessment of the cause of death, as shown in his initial assessment, the baby died of hypovolemic shock secondary to blood loss in his subgaleal and subdural spaces and the grade 4 IVH – all documented on postmortem examination. The combination of birth trauma (the fall) superimposed on fetal distress was responsible for the extra- / intracranial bleeding, his hypovolemia and anemia, and the cause of death. There was obvious hypovolemic shock from the acute blood loss in the subgaleal and subdural spaces, IVH, and multiple bruises. Subgaleal and subdural hemorrhages were pathognomonic of head trauma in a newborn delivered from a breech presentation when the head is significantly larger, proportionally than the torso.

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Indeed, the statistics from the NICHD (National Institute Child Health and Development) and VON (Vermont Oxford Network) relevant to the year of birth for this baby (male, singleton, exposure to antenatal steroids, birth weight of 670 grams, 24 weeks) should have been discussed with the mother. Those statistics showed a survival to be 63% (NICHD) and 70% by VON for the year the baby was born. The NICHD outcome for profound neurodevelopment impairment was 3-5%, for moderate-severe neurodevelopment impairment to be 32-37%, for blindness <15%, for deafness 1-2%, for moderate-severe cerebral palsy 6-9%, and cognitive developmental delay 31-35%. Ultimately, all predictive tools (National Institute of Child Health and Development and Vermont Oxford Network) and published papers, including babies for the 2016 birth year, far exceed >50% survival, being 63%-70% survival for 24 weeks gestation and >>50% have good outcomes.

2. Plaintiff alleged that the care providers were obliged to operate based on the gestational age of at least 24 5/7 weeks from an 18-week ultrasound. This was required by the standard of care, notwithstanding that 2nd-trimester ultrasounds, while superior for dating compared to later ultrasounds, are still associated with a range of errors. Also, the biparietal diameter and femur length, which tend to be the most reliable of the various parameters for estimating gestational age, are consistent with 26-27 weeks if used alone. The Ballard exam, where EGA measurements are rounded to weeks, excluding days, estimated the gestational age at 24 weeks. The Coroner placed the baby at 24 5/7 weeks. Brain gyral patterns are very accurate concerning dating.
3. The newborn died from suffering severe trauma at delivery due to the physician's negligent conduct during the delivery that permitted the baby to fall to the floor. The plaintiff

4. While there was no evidence of abruption in the Coroner's report, that diagnosis is clinical, not pathological, and one of the most common discernible causes of preterm labor and delivery. It was below the standard of care to fail to include abruption in the differential diagnosis of preterm labor with frequent contractions and deteriorating fetal condition.
5. In response to the assertion of the Defense, plaintiff experts pointed out that the Ballard examination does not account for fractions of the week: it rounds off gestational age to weeks. Additionally, the birth weight was higher than 670 grams since some blood was on the floor and wheellock. Similarly, when delivered a few hours after this ultrasound, a direct examination of the newborn assessed him as more mature than 23 weeks gestation, as stated by the Defense.
6. In response to the assertions of the Defense, plaintiff experts averred that the clinical presentation of GBS could not reasonably explain the trauma or other clinical features given the brief time of ruptured membranes, the treatment of the mother with antibiotics three hours prior to birth, the absence of clinical signs of maternal or neonatal infection, and the negative blood cultures on the baby. As for the allegation that the negative culture in the baby resulted from the mother having received antibiotics, Plaintiff pointed out that the laboratory accounts for the prior antibiotic administration in the culture media.
7. In response to the Defense expert's assertion that respiratory distress syndrome was a significant contributing cause

of the morbidity, Plaintiff explained that the baby had shock lung.

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#### Defense arguments

1. The Defense argued that even though ultrasounds during the 2<sup>nd</sup> trimester are accurate for dating, a standard deviation of 10 days would put the baby at 23 weeks at birth – they failed to point out that adding ten days on the upper end of the estimate meant that it was 27 weeks at birth.
2. The Defense contended that the short intervals between conceptions were a significant comorbidity that decreased the chances of survival for this baby. Plaintiff experts disagreed.
3. The Defense further asserted that the baby had a <50% chance of survival and >50% chance of poor outcome regardless of delivery mode and head trauma from being dropped. Plaintiff experts disagreed.
4. They attributed the cause of death to GBS sepsis and other comorbidities impacting the baby’s survival, including RDS, histologic chorioamnionitis, abruption of the placenta, short cord, prolapsed cord, GBS sepsis, and pregnancies that were too close together. Further, IVH grade 4 is very common at this gestation. Had the baby survived, he would have been very disabled. Plaintiff experts disagreed.
5. The Defense also maintained that IVHs were very common in premature babies of this gestation but neglected to point out that that risk increased with increasing evidence of decelerations during labor. Further, contemporary statistics showed that severe IVH was present in <6% at < 32 weeks’ gestation. Plaintiff experts disagreed.

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***“The case went to court. On the stand during his testimony to the jury, the Coroner recanted his original opinion, now stating that the baby died because of extreme prematurity. After some deliberation, the jury decided for the Defense, explaining later that they felt sorry for the obstetrician.”***

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#### Disposition

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jury, the Coroner recanted his original opinion, now stating that the baby died because of extreme prematurity. After some deliberation, the jury decided for the Defense, explaining later that they felt sorry for the obstetrician.

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#### Discussion

The Neonatal Research Network (NRN) was established in 1986 to address the critical need for rigorous research in babies admitted to the Neonatal Intensive Care Units (NICUs), so that solid evidence generated by such research could be used to improve the treatment and enhance the options for health outcomes of critically ill newborn babies. The National Institutes of Child Health and Human Development (NICHD) funded the NRN.

The debate in the case calls attention to the 2008 article by Jon Tyson et al. in the *New England Journal of Medicine*, “*Intensive care for extreme prematurity—moving beyond gestational age.*” This study of 4,446 infants born at 22-25 weeks’ gestation between January 1, 1998 and December 31, 2003, reported survival and neurodevelopmental outcome statistics at 18-22 months according to gestational age, birthweight, and gender of the infant. They also considered whether the birth was a singleton or multiple, whether steroids had been administered, as well as the hospital’s approach to active treatment of these babies in the delivery room. The findings of this study challenged the widespread use of using gestational-age thresholds alone in deciding whether to administer intensive care to extremely premature infants. This study showed that each 100-gram increase in birth weight reduced the risk of death or disability for infants, similar to the risk reduction from a one-week increase in gestational age. Other factors enhancing outcome included: female gender, singleton birth, exposure to antenatal steroids, and active intervention in the delivery room. Based on the paper’s findings, an “NICHD calculator” was devised to provide estimates of possible outcomes based on patient and hospital characteristics. In many respects, the more aggressive the approach, the better the outcome.

This original predictive tool of 2008 was updated and validated by cohorts of patients from the NICHD-NRN in 2012 (enrollment 2006-2012) and by cohorts of patients from the VON in 2006-2012 and 2013-2016. As one might expect, the survival rates and favorable outcomes were improved compared to the original publication. The VON 2013-2016 survival for 24 weeks gestation was 70%. The latest NICHD-NRN tool (2012) is now ten years old and is available: <https://www.nichd.nih.gov/research/supported/EPBO/use>

In the VON cohort for 24 weeks gestation, the survival in 2006-2012 was 66% (slightly better than the NICHD of 63%), and in VON, the 2013-2016 survival for 24 weeks gestation was 70%.

The baby, in this case, was born in 2016. The neurodevelopmental outcomes were very similar. Another predictive study published in Pediatrics in 2012 entitled: “Outcome Trajectories in Extremely Preterm Infants” evaluated infants with birth weight <1.0 kg admitted to 18 large academic tertiary NICUs during 1998-2005. The authors found that the prediction of death or neurodevelopmental impairment improved using information available during the clinical course, specifically delivery room treatment, at 7-days, 28-days, and 36 weeks postmenstrual age. This study confirmed that:

1. The predictive ability was improved by adding gender and birthweight, as Tyson et al. had shown.
2. The 5-minute Apgar score was an additional predictor of mortality, which reflects not only the condition at birth but also whether and how effectively resuscitation was provided.
3. The importance of birth weight declines, whereas that of respiratory illness severity increases with advancing postnatal age. Surprisingly, the ability to predict death and impairment did not improve with increasing postnatal age among infants who avoided early death.

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Thus, the study showed that the ability to predict long-term morbidity and death in extremely low birth weight infants did not improve significantly after the first week of life, probably because most of the commonly used variables are predictors of early mortality and not a longer-term outcome. However, the effects of different variables varied with postnatal age.

#### **Suggested Reading**

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