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Re: Knapp v. Northeast Ohio Obstetricians & Gynecologists
Portage Co. Common Pleas Ct.
Case No. 2000 CV 00115
BSMP File No. 460065

I am qualified to evaluate and render the following opinions based on my education, training and experience as a board certified obstetrician and gynecologist. I am an Associate Professor in the Department of Obstetrics and Gynecology at the Indiana University School of Medicine. In this capacity, I render obstetrical and gynecological care to patients, supervise the care rendered by medical students, residents in obstetrics and gynecology, family practice, emergency medicine and internal medicine as well as nurses, including general nursing staff and nurse midwives.

I have authored original research in the subject at issue, that is, shoulder dystocia and authored articles and book chapters on this same topic.

My objective opinions are based on reasonable medical probability taking into consideration what is expected of the average competent physician given due regard for the state of the art. The opinions that are drawn are based on the review of the records submitted and deposition testimony. I may expand or elaborate on my opinions as additional information becomes available.

Summary of Events:

I have reviewed the following medical records concerning the care of Tammie S. Knapp by Dr. Rosenwasser and Dr. Egdell.

Prenatal records,
Fetal Heart Rate Tracings,
Labor and Delivery records
New Born Records
Depositions
    Mrs. Knapp
    Dr. Rosenwasser
Various Reports
    Dr. Borrow
    Dr. Adler

Mrs. Knapp was a 38-year-old white female Gravida 4, Para 2012. Her obstetrical history reveals her first pregnancy in 1975 was terminated. The second pregnancy in 1980 resulted in a vaginal delivery of an 8 pound, 8 ounce male infant at term. The third pregnancy resulted in a preterm delivery, at 34 weeks of a 7 pound, 2 ounce male infant. Her medical history includes hypothyroidism, a herniated disc, and obesity.

In the pregnancy at issue, she was due 9/23/98. She weighed 199 lbs and was clinically obese. She did not choose to undergo genetic screening, which was indicated due to her advanced maternal age. She also had a prior child who died as a result of cardiac anomalies. The prenatal record indicates that this issue was discussed and she was "refusing amnio CVS." The record clearly shows that the choice to forego genetic screening was Mrs. Knapp's.

Her hypothyroid condition was treated with medication (Synthroid) and her thyroid status was closely monitored throughout her prenatal care. She had at least 17 prenatal visits. She was referred to other consulting physicians including a cardiologist. This clearly indicates attentive, thorough and excellent prenatal care.

She did have a screening blood sugar that was abnormal. The doctor followed this up with a three-hour glucose tolerance test (GTT) performed on 7/15/98. The GTT revealed only one value to be above the norm for GTT's done in pregnancy. By definition, an abnormal GTT in pregnancy must have two abnormal values. Thus, laboratory analysis indicates that she did NOT have gestational diabetes.

Nonetheless, she was instructed to follow a diet and testified in her deposition to that effect. Her initial weight was 199.5 lbs on 2/9/98 and on 9/21/98 she weighed 226 lbs. Thus, her total weight gain was only 26.5 lbs., indicating excellent dietary control. Clearly, Dr. Rosenwasser was well aware of her risk of having gestational diabetes and treated her aggressively even though the evidence did not support this diagnosis. Again, Dr. Rosenwasser's conduct was exemplary in his thoroughness for Mrs. Knapp's prenatal care.

To suggest that the patient was never given adequate or appropriate dietary counseling or exercise program is entirely inconsistent with the record. To imply that dietary control can prevent excessively large babies is decidedly misleading. Macrosomia will frequently occur in the most rigidly controlled diabetics, with or without insulin, and this fact makes the ability to predict macrosomia virtually impossible.

She underwent an ultrasound at approximately 17 weeks, which revealed that the fetal growth was entirely consistent for her due date. Ultrasounds prior to 20 weeks have a much greater degree of accuracy than those done in the last six weeks of pregnancy where the error rate in estimating fetal weight can be as high as 22%. The measurement of her fundal height was consistent for normal growth until 8/25/98. To evaluate this issue, an ultrasound was performed on 8/31/98 revealing a fetus with an estimated weight of 3363 grams, between the 75th and 90th percentiles. This indicates normal growth. Fundal heights thereafter were consistent with normal growth.

There was no evidence to support the notion that she would have an excessively large baby. The fact that an ultrasound was ordered to evaluate this risk is proof that Dr. Rosenwasser was attentive to this risk and he clearly complied with the standards of care to evaluate the baby's growth. There is no standard that requires serial ultrasounds to further document growth in this patient. To suggest such a standard exists and was breached is patently false and misleading.

Mrs. Knapp started contractions in the morning of 9/28/98. On admission she was 3 cm. dilated and 80% effaced with a presenting part at minus 2 (-2) station. She was still in a latent phase patter throughout the afternoon and reached 4 to 5 cm by early evening. There was no evidence of a progression into active phase labor and Dr. Rosenwasser appropriately augmented her labor with oxytocin. A prolonged latent phase is NOT an arrest of labor and to characterize it as such is an error frequently made by inexperienced physicians. The appropriate management, in this case, was to augment labor. Thus, Dr. Rosenwasser, who was present and evaluating his patient, complied with the standards of care in managing her labor. Moreover, to suggest that oxytocin increases the risk of shoulder dystocia is simply not true.

Multiparous (more than one delivery) patients are often encouraged to "push through the cervix" when it is almost completely dilated. This is an acceptable practice and NOT a deviation from the standard of care. This is because, in such patients, the cervix is easily stretched to accommodate the descending head. This is exactly what occurred in this case where Mrs. Knapp brought the head down from a –1 station to well into the birth canal at a plus 3 station (almost out).

Noting that the Mrs. Knapp had successfully pushed the baby into a position that would allow for a vacuum assisted delivery, this option was offer to her. In fact, Dr. Rosenwasser wrote a note suggesting that a Cesarean Section was also an option. Mrs. Knapp agreed to a trail of vacuum with the provision that a Cesarean delivery would be performed if it failed. Such was the case and with three attempts at

vacuum delivery the head was delivered. It should be noted that three attempts with vacuum, in normal sized babies, is the norm.

In addition, Dr. Rosenwasser requested a consult from the anesthesia department well before the delivery, consistent with excellent care. The record clearly indicates that she was not a candidate for epidural anesthesia because of her previous herniated disk. Thus, in this multiparous patient undergoing vacuum assisted delivery, the choice to use local anesthesia for any repairs is appropriate and complies with the standard of care.

A shoulder dystocia was promptly recognized and Dr. Rosenwasser began the appropriate series of maneuvers required by the standard of care. The maneuvers included McRoberts maneuver, suprapubic pressure, large episiotomy and an attempt to deliver the posterior arm. Unfortunately, these maneuvers did not initially disimpact the shoulder. Shoulder Dystocia is a true obstetric emergency and requires expeditious delivery, otherwise the umbilical cord will be trapped between the baby's body and maternal pelvis and the baby will suffocate.

Dr. Rosenwasser did what is expected of every physician in this situation, that is, repeat the maneuvers with the notion that this baby is in an extreme obstetrical emergency and is at great risk for being severely compromised by a compressed cord if not delivered expeditiously. Dr, Rosenwasser was ultimately able to deliver the posterior arm and thereby effect the delivery of the baby at 2332 hours. The baby weighed 4880 grams (10lb. 9 oz) and had Apgar scores of O at 1 minute, 1 at 5 minute, 4 at 10 minutes, 6 at 15 minutes, and 6 at 20 minutes.

After the baby was resuscitated and stabilized, it was noted that the baby had a right sided brachial plexus injury, a fractured left humerus, and a suggestion of a subgaleal hemorrhage. As of 4/26/00, James Knapp has residual weakness of his right upper extremity.

Clinical Observations:

Dr. Rosenwasser's prenatal care of Mrs. Knapp was thorough, complete and excellent. He paid attention to the details of Mrs. Knapp's problems and was obviously well aware of the risks of gestational diabetes and large babies. He tested her for diabetes and notwithstanding the fact that the tests did not meet well-established criteria for gestational diabetes, he counseled her about diet.

Mrs. Knapp gained 26 lbs. She did not have any evidence of a large for gestational age (LGA) baby at the 17-week ultrasound and at the 36-week ultrasound. The fundal height measurements were never consistent for an LGA baby. When a fundal height measurement was larger than expected, it was promptly followed up with the 36 week ultrasound that revealed a baby in the 75 - 90th percentile. By definition, an LGA baby must have consistent measurements greater that the 90th percentile. Even if another ultrasound was done, there is no assurance that it would have revealed an LGA baby. Thus, to suggest that this doctor, or any other, knew or should have known this was going to be a LGA baby is unwarranted.

Similarly, because there was no expectation that the baby was LGA, nor was there any evidence to suggest LGA, to state that a cesarean delivery should have been performed prior to the onset of Mrs. Knapp's labor is likewise unwarranted. In addition, there was no evidence of fetal intolerance to labor on the electronic fetal monitor. Thus, there was no indication for a cesarean delivery for suspected fetal distress. Finally, there was no arrest of labor. There was a prolonged latent phase that was correctly treated. Even if there was an arrest of labor, the treatment is initially oxytocin and cesarean is reserved for those who did not respond to oxytocin. Thus, there was no indication for a cesarean as a result of any aspect of the labor. In a word, at no time was there an indication for a cesarean delivery for Mrs. Knapp and Dr. Rosenwasser did comply with the standard of care in this patient's labor.

It is well established in Obstetrics that shoulder dystocia is an unpredictable event and that is certainly true in this case. In fact, the data in this case points away from shoulder dystocia. In addition there was no evidence that the baby was in any kind of distress prior to delivery. Thus, to suggest that the doctor failed to have a pediatrician in the room where the standard does not require a pediatrician and where there is no indication for a pediatrician is just plain wrong.

Likewise, where a patient has a contraindication for epidural anesthesia (and also spinal) the doctor's options are either general anesthesia or some form of local anesthesia. General anesthesia was not indicated for this delivery. Thus, there is no basis to suggest that the doctor should have had an anesthesiologist present for this delivery. In fact, the standard of care indicates that repair of an extensive episiotomy is best accomplished with local anesthesia. Thus, the use of local anesthesia was, at all times, entirely within the standard of care in this case.

Finally, the fact of an injury IS NOT, by itself, any indication that there was negligence. Even though this is a well known legal concept, it is also taught to physicians.

Subgaleal hemorrhage is a well-known complication of vacuum delivery and generally results in no permanent injury. There is no evidence in this case that James Knapp suffered any result of a suspected sugaleal hemorrhage.

In this case, Dr. Borow hypothesizes that "numerous maneuvers were needed to deliver this baby and that these maneuvers resulted in harm to this infant." He goes on to postulate that "excessive downward traction with lateral flexion of the head and rotation of the head against a fixed shoulder, are associated with increased risk for brachial plexus injury as indeed occurred on the right arm and shoulder of this baby." Dr. Borow's implication is clear, that is, since there was an injury, there must have been excessive downward traction.

Dr. Adler is more forthright. He just states outright that the "etiology of this injury is that of excessive traction on the neck," even though he has no evidence to support the notion that there was excessive traction other than the presence of an injury.

Although the American College of Obstetricians and Gynecologists (ACOG) has noted that brachial plexus injuries may be caused by extreme amounts of traction placed on a baby's neck, there is little evidence to support this hypothesis. In fact, the research and data is just the opposite where observers have noted severe injuries with little to no traction being applied and injuries occurring in spontaneous deliveries.

There are three articles in the obstetrical literature that contains substantial data about the use of traction, in the delivery of infants during a shoulder dystocia, described as greater than normal or excessive.

On it's surface, an article by Gross in 1987 indicates that fundal pressure, in the absence of other maneuvers, resulted in a 77% complication rate and was associated with orthopedic and neurologic damage (Gross SJ. Shime J. Farine D. Shoulder Dystocia: Predictors and Outcomes - A five year review. 1987;156:334-336). Within the next few years, references to this article were cited as the reason not to use fundal pressure in shoulder dystocias. However, a closer look at this article clearly reveals that some of the conclusions are not scientifically valid and its use to admonish fundal pressure is unwarranted. In addition, with respect to this case, it did not establish the standard of care in 1988.

Gross retrospectively reviewed 10, 662 vaginal deliveries where 91 shoulder dystocias were identified. (Gross SJ. Shime J. Farine D. Shoulder Dystocia: Predictors and Outcomes - A five year review. 1987;156:334-336). The shoulder dystocia cases were divided into two groups: group 1 (n = 24) included "true" shoulder dystocia defined as deliveries requiring maneuvers in addition to downward traction and episiotomy while group 2 (n = 67) included deliveries that required "increased

traction." The authors noted that fundal pressure was used in 13 patients in group 1. In addition, there were 6 brachial plexus injuries (6/24 or 25%). However, in group 2, where increased traction was used, there were no injuries.

Unfortunately, Gross, did not indicate whether any of the Erb's palsies were permanent, thus there is no information in this study to indicate that fundal pressure causes any type of permanent injury.

At best, only two valid conclusions can be made in the Gross study. First, there were 6 brachial plexus injuries in 24 "true" shoulder dystocia cases (incidence = 25%). Even this conclusion is suspect because the authors failed to note whether increased traction was used in group 1. Second, there were no injuries associated with 67 cases of shoulder dystocia where "increased traction" was applied. This latter observation refutes the theory that increased traction causes neurologic injury.

In the second study, Baskett documented that where only "strong downward traction" was used in 48 shoulder dystocia cases, there were only 12 brachial plexus injuries (25%). In other words, 75% of babies delivered with strong downward traction were NOT injured. (Baskett TF and Allen AC. Perinatal Implications of Shoulder Dystocia. Obstet Gynecol 1995;86:14-17).

The third study is most interesting. (Allen R, Jagadish S, and Gonik B. Risk Factors for Shoulder Dystocia: An Engineering Study of Clinician-Applied Forces. Obstet Gynecol 1991;77:352-355). In this study of 29 vaginal deliveries, there were only 2 shoulder dystocias, 7 deliveries characterized as "difficult" and 20 classified as "routine." An obstetrician wore a specially designed glove that measured the forces applied in these deliveries.

As expected, the peak force rates in the shoulder dystocia group was substantially higher than in the normal deliveries. However, the peak force rate used in the 2 shoulder dystocias was NOT significantly different from those used in the "difficult" deliveries. There were no injuries in the latter "difficult" group. And in the 2 shoulder dystocia cases, where there was one injury (a transitory Erbs palsy and fractured clavicle) the peak forces were identical but the rate of application and duration of the force in the "injured" baby differed somewhat. Both of these babies weighed 4790 and 4775 grams respectively. In summary, there were big babies,

excessive traction and one baby was uninjured and the other was not permanently injured.

In summary, Allen's study showed that even when the baby is LGA and the force is clearly excessive, there was no correlation to any level of injury. Overall, in this study there were 9 deliveries where the force was excessive and there were no injuries. Moreover, there were a total of 124 deliveries in the three studies with a total of 19 brachial plexus injuries (15%), some of which were not permanent.

Virtually every study of the injuries associated with shoulder dystocia distributes the injuries, both brachial plexus and fractures, among the entire population of shoulder dystocia cases. In this way, artificial bias tends to be diminished. For example, Gherman's study identified 285 cases of shoulder dystocia in 50, 114 vaginal deliveries with 71 injuries (24.9%) (Gherman RB, Ouzounian JG, and Goodwin TM. Obstetrical maneuvers for shoulder dystocia and associated fetal morbidity. Am J Obstet Gynecol 1998;178:1126-30). In this study, there were 48 brachial plexus injuries (16.9%), 28 fractured clavicles (9.5%) and 12 humeral fractures (4.2%). No use of fundal pressure occurred in this study, yet there were brachial plexus injuries and fractures. In addition, only 4 of the brachial plexus injuries were permanent.

Similarly, Nocon identified 185 shoulder dystocias among 12, 552 vaginal deliveries with 44 injuries (22.7%). (Nocon JJ, McKenzie DK, Thomas LJ, Hansell RS. Shoulder dystocia: an analysis of risks and obstetric maneuvers. Am J Obstet Gynecol 1993; 168:1732-9). There were 28 brachial plexus injuries and 14 fractures. There was one permanent Erb's palsy in this study and fundal pressure was not used in any of the shoulder dystocia cases.

Like wise, Baskett clearly showed that fundal pressure was not used in a series of 187 cases of shoulder dystocia where there where 28 brachial plexus injuries and 12 fractures (21.4% total injuries). (Baskett TF and Allen AC. Perinatal Implications of Shoulder Dystocia. Obstet Gynecol 1995;86:14-17). In this study, about 80 % of infants with brachial plexus injuries improved by the time they were discharged from the nursery.

Gherman, Nocon and Baskett reported the three most extensive studies on shoulder dystocia and injury in the recent obstetrical literature. When the Gross and Allen studies are included for comparison, only a few valid conclusions can be made:

1. No method of delivery in a shoulder dystocia case is free of injury.
2. Permanent brachial plexus injury is a rare event and is clearly not associated with the method of delivery.

Finally, there is no conclusive evidence that either excessive traction, increased traction, difficult traction, extreme traction, or strong downward traction actually causes brachial plexus injury.

Conclusion:

Dr. Rosenwasser clearly complied with the standard of care in providing prenatal care to Mrs. Knapp. In fact, his care was excellent. In addition there was no indication for a cesarean delivery at any time and Dr. Rosenwasser complied with the standard of care during Mrs. Knapp's labor. Finally, Dr. Rosenwasser managed the obstetrical emergency noted to be a shoulder dystocia in a prudent and thorough manner and thereby completely complied with the standard of care in managing the delivery.

There is no evidence that Dr. Rosewasser applied excessive or undue force to the Baby's head in this delivery. There is no evidence to support the notion that excessive traction causes brachial plexus injuries. Moreover, to look backwards from the injury and conclude that there must have been excessive traction applied by Dr. Rosenwasser is patently wrong. Thus, the actions and conduct of Dr. Rosenwasser, in the Delivery of Mrs. Knapp, more likely than not, was not a proximate cause of the injuries of James Knapp.

Sincerely,

James Nocon

James J. Nocon, M.D.

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