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Committee Leadership

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Leadership Note

2019 Medical Liability and Health Care Law Seminar

By Barclay Wong

I had the distinct pleasure of attending our Medical Liability and Health Care Law Seminar from March 20–22 in beautiful Nashville, Tennessee. This year's seminar was a huge success, with over 500 registrants. A seminar this large and popular is the work of many people on the Steering Committee, but the Program Chair Erika Amarante and Vice Program Chair Andrew DeSimone deserve individual mentions and thanks. They put together an impressive faculty who kept the audience's attention throughout the seminar.

The seminar began with the first litigation skills add-on session ever held at this conference. A capped group of 30 attorneys received intense instruction from a very experienced faculty about deposing a life care planner. This interactive session was an opportunity to learn a great deal in a small group from people who have done exactly what they are teaching. Thanks to James Craven for taking the lead and coordinating the first litigation skills add-on session. We are looking for ideas for next year's litigation skills add-on session so please email me if you have any thoughts.

Also new to the seminar this year was our community service project: Operation Gratitude. Stephanie Wurdock graciously organized this event which gave our attendees the opportunity to make paracord bracelets for our troops. The quality of the bracelets may have varied, but the enjoyment of the attendees did not.

The best part of the first day of a seminar is always the networking reception and this year was no different. Attendees enjoyed appetizers and drinks in the beautiful lobby of the Hilton Downtown Nashville with live music playing in the background. Old friends and new friends mingled, networked, and enjoyed themselves before heading out to dinner. As the committee vice chair, I was lucky enough to be able to attend the faculty dinner where we had almost 30 people and lots of great conversation.

On Thursday morning, I was able to meet about 10–15 first-time attendees at their breakfast. It was very exciting to see people on the first part of their DRI voyage. After breakfast, Steve Plunkett and Erika got the seminar started. All the sessions were great, but a few stood out and must be mentioned. The highlight of the morning sessions were the two sessions about shoulder dystocia and brachial plexus claims. Michele Grimm, PhD, Michael Ross, M.D., MPH, and Meghan Yanacek were all excellent speakers and there may have been a birthing demonstration with a lubed baby doll. Check the DRI's Twitter feed for photographs.

A very pertinent presentation concluded the first day when Joseph Buchholz and Katherine Otto spoke about social media investigation and admissibility. This presentation was applicable to many areas of the law and represents a large part of the present and future of litigation.

At the conclusion of a long day of sessions, I had the pleasure of chairing the Medical Liability and Health Care Law Committee meeting. During this meeting we begin planning next year's seminar and discuss other pertinent committee matters. It was great to see so many new faces and receive many good ideas for next year's seminar. The location for next year's seminar is being discussed and decided right now, but I promise that it will be another great city.

The Thursday night networking reception was another great event especially after a day of CLE and the committee meeting. Almost all our dine-arounds were full, and I enjoyed Asian fusion/sushi at Virage. The highlight of dinner, food wise, was thinly sliced Wagyu beef cooked on a 1,400-degree rock for 3–4 seconds per side. The real highlight of dinner was the opportunity to spend time with old and new friends.

The last day of the seminar began with Jamie Dittert speaking bright and early at the Young Lawyers Breakfast about "Decoding HIPAA: What Every Health Care Lawyer Should Know." Friday also featured another full slate of excellent presentations. Cara Osborne, SD, MSN, CNM's presentation about "Defending a Claim Against a Midwife" was particularly applicable to my practice. (You can find the fine written scholarship that she provided to accompany her presentation reprinted in this issue.) The seminar concluded at 1:30 p.m. and there were still many people at the last session.

The success of this year's seminar sets a high bar, but our leadership for next year's seminar is up to the task. Andrew DeSimone is our 2020 program chair and Meghan Yanacek is our vice program chair. We are looking for active

members of the steering committee so please contact me if you would like to help plan the 2020 seminar or if you have a presentation that you would like to propose. Thank you to all who helped plan, sponsor, or held a panel counsel meeting at this year's seminar. I hope to see everyone in Chicago in September for our Nursing Home/ALF Litigation Seminar.

Albert Barclay Wong, an AV-rated Partner at Drewry Simmons Vornehm, LLP in Carmel, Indiana, represents health care providers. His practice focuses on defending physicians, hospitals, and nursing facilities in negligence claims. He also represents all licensed health care providers, including physicians, nurses, and dentists in professional licensure matters before all of Indiana's health related boards and committees. Prior to entering private practice, Mr. Wong was an Indiana deputy attorney general where he successfully litigated hundreds of administrative actions. Mr. Wong is the Vice Chair of the DRI Medical Liability and Healthcare Law Committee.

Feature Articles

Defending a Claim Against a Midwife: Scope of Practice, Standard of Care, and Common Claims

By Cara Osborne MSN, CNM, SD

There are approximately four million babies born in the U.S. every year. The vast majority (98.5 percent) are born in hospitals. Physicians attend greater than 90 percent of births with midwives attending just under 10 percent. These numbers are shifting. Out of hospital births increased 72 percent between 2004 and 2014 and births to midwives in all birth settings have shown steady increases.

Though midwives have been found to be less likely to be sued for malpractice than their physician colleagues due to their relationship based approach to care, the increasing prevalence of midwifery attended births means that the absolute number of claims in which a midwife is named is also increasing. The nature of the practice of midwifery in the United States may make defending claims against midwives less straight forward than defending claims against physicians or nurses, as midwives' scope of practice sits between the two and standard of care may be less clear.

Midwifery in the U.S.

Midwifery has been practiced in the United States in some form throughout the history of the United States, as it has been all over the world. Until the twentieth century, midwifery training in the United States was based on apprenticeship and often passed down among female members of families. Midwives cared for the majority of women giving birth in women's homes until the early 1900s.

Nurse-Midwifery, which is the most common form today, was brought to the United States by Mary Breckenridge with the establishment of the Frontier Nursing Service in 1928. Mrs. Breckenridge was a maternal and child health advocate and nurse who was inspired by her work with European trained midwives in France after World War I. The service and training program that she began at the Frontier Nursing Service in the mountains of Eastern Kentucky served as the foundation for the development of Nurse Midwifery in the United States.

Only with the advent of anesthesia for use during childbirth in the mid-nineteenth century did physician attendance at birth and birth in hospitals become common. As women's preferences for birth shifted to hospital-based birth with physicians, the practice of midwifery declined, only to see a resurgence in the late 1950s and 1960s as women began to choose natural childbirth after having traumatic experiences under anesthesia via controlled breathing methods such as Lamaze.

Types of Modern Midwives

In the United States today there are three types of midwives with varying training and scopes of practice. More than 90 percent of the births attended by midwives are attended by certified nurse-midwives (CNMs). However, there are also direct entry midwives and traditional midwives practicing in most states. This leads

to confusion both amongst the general public and the medical community.

Certified Nurse-Midwives (CNMs)

CNMs are advance practice nurses who hold a graduate degree. They are recognized by all 50 states and licensed similarly to all other types of nurse practitioners. CNMs have prescriptive privileges and the majority practice in hospitals. Certification is granted by the American Midwifery Certification Board (AMCB) after graduation from an accredited program and passing a certification exam. They are represented by the American College of Nurse-Midwives

Direct Entry Midwives

Direct entry midwives are midwives who are not nurses. Adding to the confusion, there are two sub-categories of direct entry midwives. Certified midwives (CMs) who are certified by the same body and against the same standards as CNMs, and certified professional midwives (CPMs) who are apprentice trained, rather than receiving training from an institution of higher education, and are certified by the North American Registry of Midwives (NARM) after completing their apprenticeship and passing an exam.

Traditional Midwives

Traditional midwives are midwives who—for religious, personal, and philosophical reasons—choose not to become certified or licensed. These midwives typically believe the relationship between the community and midwife to be a social contract and should not require third party validation. Examples of the practice of traditional midwifery persist in variety of communities including Native American, Amish, and Hasidic Jewish communities.

Scope of Practice

All types of midwives care for low-risk women during pregnancy, birth, and post-partum and many provide newborn care and breastfeeding support, well woman gynecologic care, and contraception to non-pregnant patients. CNMs typically practice in hospitals with a minority practicing in freestanding birth centers and homes. The majority of CMs also practice in hospitals although only in a handful of states in which licensure is available. Nearly all CPMs practice at home or in birth centers, as do all traditional midwives. All midwives believe pregnancy and birth to be physiologic processes that will most likely proceed normally without intervention. All midwives are monitoring for deviations from normal, but each type has a specific set of intervention that they are able to provide directly. Midwives do not provide anesthesia nor cesarean section and referral patterns for higher acuity care in hospital and/or provided by a physician vary greatly by type of midwife.

Standard of Care

Given the variety of practice settings and the differences in training, it is difficult to establish a single standard of midwifery care. As is the case across medical disciplines, standard of care can vary by geography and training. In considering whether a midwife provided care that was up to standard, it is important to refer back to the certifying body for that particular type of midwife as listed above.

In many circumstances, there are numerous methods for providing safe care and the providing a less common method should not necessarily be considered substandard. For example, fetal heart monitoring during labor is required to provide safe care. A CNM in a hospital may choose continuous electronic fetal monitoring for her patient while a CPM attending a birth at home might choose intermittent auscultation of the fetal heart rate. The literature suggests that the two methods provide equal means of assessment of fetal status. However, electronic monitoring has become ubiquitous and is therefore often considered "standard."

Physician Support

To provide safe care, all midwives must have a plan for accessing higher acuity care for their patient should it become necessary. Many midwives will have formal agreements with physicians and hospitals in place. Depending on the type of midwife and state of practice, this level of coordination may be required for licensure. However, particularly for CPMs and traditional midwives attending births at home, there may not be a requirement and the plan for escalation may simply be to seek care for mom or baby via the nearest hospital emergency department.

Common Causes of Action

Fear of liability has been commonly discussed as a deterrent to midwifery practice and collaboration between physicians and midwives. Physicians often have an outsized perception of their risk of vicarious liability when they collaborate with, supervise, and/or employee midwives. This risk has been discussed by Booth in his work for the *Journal of Midwifery and Women's Health.* Despite the lack of evidence of this risk, it continues to plague potential collaborative relationships between physicians

and midwives and is being addressed legislatively by removing requirements for written agreements between midwives and physicians and increasing the independence of midwifery practice.

The common causes of action against midwives are similar to those against obstetricians. In a 2015 review of 158 closed claims in which a midwife was named, McCool and colleagues found that the most common cause of action was fetal or newborn complications or death, followed by obstetric causes that included failure to call for or recommend a cesarean, failure to provide options for genetic counseling, provider negligence related to pregnancy care, shoulder dystocia, uterine rupture associated with vaginal birth after Cesarean (VBAC), and provider negligence related to the provision of gynecologic care. In all cases, it is important to establish that the standard against which the midwife is being measured is appropriate for her type of midwifery and practice setting.

Conclusion

In summary, the midwifery landscape in the United States is complicated and can create difficulty in defending claims against midwives. Establishing standard of care and the correct comparators for each individual case is the primary challenge. It is important to refer to certification and licensure standards for the specific type of midwife involved in the case as well as to any locally established standards represented in documents such as hospital bylaws and practice protocols.

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Dr. Cara Osborne MSN, CNM, ScD is a Certified Nurse Midwife by clinical training and holds a BA in Biology from Transylvania University, a MSN in Midwifery from Vanderbilt School of Nursing, and a MS and ScD in Maternal and Child Health from Harvard School of Public Health. Her academic area of interest is perinatal epidemiology. Dr. Osborne is the co-founder of and senior advisor to Baby+Company a multi-state, private equity funded network of freestanding maternity centers. Cara is an Assistant Professor in the Eleanor Mann School of Nursing at University of Arkansas and was co-investigator for the American Association of Birth Centers Uniform Data Set. She is a reviewer for the Journal of Midwifery and Women's Health and a technical adviser to the board of directors for Midwives for Haiti.

Anesthesia-Related Adverse Events

By Amy C. Robertson, MD

The safety of anesthesia has improved over the past several decades, primarily due to effective monitoring practices, technically advanced airway management equipment, and an enhanced understanding of anesthesia-related morbidity and mortality. The death rate resulting from anesthesia-related adverse events is estimated at 1.1 per million persons each year in the United States.1 However, anesthesia-related morbidity occurs more frequently. Relatively minor complications, such as postoperative nausea and vomiting or sore throat, typically respond to treatment and resolve within hours to days. Alternatively, hypoxia or hemodynamic instability related to anesthesia can result in permanent injury of vital organs. Many aspects attribute to these adverse outcomes. This article provides an overview of a select few complications and contributing factors. A discussion of specific clinical scenarios includes management of the patient with a difficult airway, providing anesthesia care in the non-operating room setting, and supervision of non-physician anesthesia providers and trainees.

Management of the Difficult Airway

Airway management is a critical component when providing safe anesthesia care to patients. A number of adverse

events can occur when performing airway management techniques, such as dental damage, airway injury, or aspiration. Failure to adequately manage a patient's airway can also lead to impaired ventilation and oxygenation. When this occurs for a prolonged duration, hypoxic brain injury or death are potential devastating consequences.

The American Society of Anesthesiologists (ASA) developed Practice Guidelines for Management of the Difficult Airway2 to assist anesthesia providers with a practical approach to performing airway management. According to these guidelines, a difficult airway is defined as the clinical scenario in which a trained anesthesiologist encounters a challenge with successfully performing facemask ventilation and/or tracheal intubation. Patient and clinical factors as well as practitioner skill level may contribute to adverse events related to airway management.3

Incorporated into the guidelines is the ASA difficult airway algorithm which outlines key steps and interventions when providing airway management to patients. Prior to induction of anesthesia, a medical history and airway examination should be conducted with the intent of identifying risk factors of a potential difficult airway. Patient factors that predict a difficult airway or contribute to airway complications include poor dentition, limited mouth opening, large neck circumference, decreased neck range of motion, and previous history of difficult intubation. It must be noted that this is not an exhaustive list. Furthermore, there is no single test or physical exam finding with absolute sensitivity and specificity to predict difficult facemask ventilation or intubation.

In the expected difficult airway scenario, awake intubation is generally indicated. If awake intubation fails, options include canceling surgery or establishing an airway with an invasive procedure such as tracheostomy. In the unanticipated difficult airway scenario, the intubation strategy depends on whether ventilation is adequate using a facemask or supraglottic airway. The ability to ventilate directs the anesthesiologist to the nonemergency pathway of the difficult airway algorithm, which involves alternative approaches to intubation, such as the use of a fiberoptic bronchoscope. In the life-threatening situation when mask ventilation and intubation are both unsuccessful, the emergency pathway should be followed and invasive or surgical airway access is recommended. If practical, awakening the patient from general anesthesia should be considered.4 In any difficult airway scenario, calling for help is imperative.

Providing Safe Anesthesia Care in the Non-Operating Room Setting

Medical innovations and trends in surgical practice have resulted in less invasive techniques and an increase in the number of procedures being performed outside of the traditional operating room setting. Many of these procedures require nonoperating room anesthesia (NORA). These locations include radiology departments, endoscopy suites, magnetic resonance imaging (MRI) scanners, cardiac catheterization suites, or dental clinics.

Patients receiving anesthesia for these procedures tend to be older and more medically complex, thus posing a higher risk for anesthesia.5 According to the ASA Closed Claims Database, the majority of claims related to NORA locations were due to respiratory events, including inadequate oxygenation and ventilation, and were judged to be preventable.6 Gastrointestinal endoscopy cases comprise the largest number of NORA malpractice claims involving anesthesiologists, with oversedation was a possible contributing factor in approximately 60 percent of cases.7

Challenges to maintain patient safety in this environment are numerous and extend beyond patient-related factors. Remote locations, limited work space, and a lack of additional resources such as drugs or skilled personnel are just a few of the circumstances that can impact the ability of anesthesiologists caring for these patients.6 Cardiology and radiology procedural areas contain bulky fluoroscopic equipment, often located at the patient's head, making access to patients and their airway physically difficult.

Anesthesiologists must be familiar with standards and guidelines to provide safe patient care in NORA locations. The ASA guidelines for NORA list specific criteria. These include a reliable source of oxygen, a well-maintained anesthesia machine, adequate drugs and supplies such as suction equipment, proper illumination, equipment to meet standards for basic monitoring, an emergency power supply, sufficient space, immediate access to an emergency cart with a defibrillator, reliable 2-way communication, and appropriately trained staff.8

Monitored anesthesia care (MAC) is provided for many of these procedures. Each patient should be prepared in accordance with general anesthesia because the level of sedation may be inadequate to safely perform the procedure and necessitate converting to general anesthesia. Regardless of anesthesia or sedation depth, vital organ function monitoring is mandatory. Most medications used for sedation cause some degree of respiratory depression. Over sedation and hypoventilation are more likely when

multiple types of medications (intravenous anesthetics, opioids, benzodiazepines) are administered together. Ventilation can be monitored with capnography which measures carbon dioxide during exhalation. Pulse oximetry is not sufficient as hypoxemia may be a late sign of hypoventilation.

Anesthesiologists must recognize potential risk factors when caring for patients in nonoperating room settings. Furthermore, they must understand critical components of the procedure, including patient positioning, how painful or stimulating the procedure will be, and the expected duration. Discussions with the proceduralist should include treatment plans if emergencies or adverse outcomes occur. Early identification of high-risk patients is imperative, and both procedural and anesthetic plans must be discussed amongst all personnel involved.

Supervision of Non-Physician Providers and Trainees

Anesthesia practice models vary among hospitals and regions of the country. Anesthesia care can be provided personally by an anesthesiologist. An alternative option is the anesthesia care team model in which anesthesia care is delivered by non-physician providers under the direction of the anesthesiologist. Non-physician providers include certified registered nurse anesthetists (CRNAs) and anesthesiology assistants (AAs). In addition, resident physicians can also provide anesthesia care under the supervision of an anesthesiologist. Billing requirements and compliance with Centers for Medicare and Medicaid Services (CMS) regulations determine how many cases an anesthesiologist can supervise or medically direct at the same time. Finally, CRNAs can practice independently in states that have exercised the option to opt-out of the federal rule that physicians supervise nurse anesthetists during administration of anesthesia. Currently 17 states have opted out, with increasing access to anesthesia services as the primary rationale.9

Medical supervision occurs when an anesthesiologist is involved in more than four concurrent cases with CRNAs. Medical direction allows an anesthesiologist to be directly involved in up to four concurrent anesthesia cases with CRNAs. When supervising trainees or AAs, the maximum number of concurrent cases is two. Requirements to bill for medical direction include the following: perform a pre-anesthetic examination and evaluation, prescribe the anesthesia plan, personally participate in the most demanding procedures in the anesthesia plan (typically induction and emergence), ensure that any procedures in the anesthesia plan are performed by a qualified anesthetist, monitor the course of the anesthesia administration at frequent intervals, remain physically present and available for immediate diagnosis and treatment of emergencies, and provide indicated post-anesthesia care.10

Based upon these requirements, the number of operating rooms that an anesthesiologist can supervise is limited by the likelihood of two or more critical events occurring simultaneously. Numerous cases starting at the same time in the morning increase the probability of needing to induce anesthesia for more than one patient simultaneously. Strategies allowing the anesthesiologist to be available during this critical component of the anesthesia care include staggered starts of the operating rooms and having additional anesthesiologists working at the start of the day.

Patient safety, complexity of the surgical procedure, and comorbidities or patient acuity also contribute to the decision-making process related to anesthesia staffing management. For example, staffing for a liver transplantation, one of the most complex surgical procedures, is often 1:1 with a CRNA or resident physician and the anesthesiologist is responsible for this case only. Healthy patients undergoing outpatient surgery tend to be staffed at ratios of 1:3 or 1:4 with CRNAs.11,12

The impact of physician supervision and staffing models on patient outcomes and adverse events remains controversial. A large, retrospective study published in 2018 demonstrated no difference in death rates, hospital length of stay, or hospital costs when comparing an anesthesia care team consisting of a physician anesthesiologist and a CRNA versus an anesthesiologist and an AA.13 A Cochrane review analyzed six studies to determine the safety of anesthesia provided by nurse anesthetists compared to physician anesthesiologists. Due to the complexity of perioperative care, confounding factors, and low intrinsic rate of complications, the authors concluded that no definitive statement can be made about whether one type of anesthesia care model is superior over another.14

Anesthesia-related morbidity and mortality is attributed to numerous factors. Recognizing physical examination findings and risk factors in patients with an expected difficult airway and establishing a thorough airway management plan is imperative. When encountered with an unexpected difficult airway, the ASA difficult airway algorithm provides key strategies for both the emergent and nonemergent scenarios. Medical innovations and trends in surgical practice have resulted in an increase in the number of procedures in the NORA environment, particularly for older and sicker patients. Although many procedures are

performed under MAC, excessive sedation and hypoventilation can easily occur and contribute to adverse outcomes. Anesthesiologists must be familiar with standards and guidelines to provide safe patient care in these locations and establish contingencies in collaboration with the specialist performing the procedure. Anesthesia practice models vary and are based upon CMS regulations. However, patient safety and acuity along with surgical complexity often guide staffing ratios of the anesthesia care team. The impact of specific practice models on patient outcomes and adverse events remains controversial.

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Dr. Amy Robertson earned her medical degree at the University of Wisconsin and completed an anesthesiology residency at Vanderbilt University Medical Center in Nashville, Tennessee. Upon completion of residency in 2006, she joined the faculty at Vanderbilt. In 2010, she attended Vanderbilt University Owen Graduate School of Management and earned a Masters of Management in Health Care. She currently serves in the role of Vice Chair for Clinical Affairs. Her clinical interests include liver transplant, vascular, and trauma anesthesia.

Identifying and Combatting Standard of One Expert Opinions in Medical Negligence Litigation

By Ryan M. Wiesner

Expert testimony is the foundation of medical malpractice litigation. All claims asserting that a health care practitioner breached the standard of care require reliable testimony from a qualified medical professional. And though not legally necessary, a robust defense of medical negligence actions should surely be predicated on the supporting opinions of at least one expert able to reinforce the care and medical decisions made by the defendant.

One major issue that arises in complex litigation, and especially in medical negligence cases, is a party's use of a Standard of One opinion. Simply put, a Standard of One opinion is a conclusion reached by an expert that is based solely on his or her own experience or personal preference and, therefore, is not based on or fails to take into account the standards, methods, or principles of the field in which he or she practices. Ultimately, it's an ipso facto opinion—because they said so.

This article explores the Standard of One issue in medical negligence cases, discusses a recent Wisconsin Supreme Court decision highlighting this issue, and addresses techniques for combatting the problem and ensuring that Standard of One opinions are recognized by defense counsel, known to trial judges, and ultimately excluded from trial.

The Standard of One problem

Standard of One opinions have been utilized and admitted in courts for some time and in just about every substantive legal area. Medical negligence cases are most susceptible to Standard of One opinions because there doesn't exist a universal standard for the practice of medicine. There are no OSHA, ANSI, or NFPA standards providing black and white rules on how to adequately provide medical care and treatment. Rather, professional judgment is key, and this opens medical negligence cases up to attacks from experts who try to impose their own personal preferences into cases and criticize defendant-physicians for simply failing to provide the same care as the individual expert may have provided.

A Standard of One opinion contradicts the very standard governing medical negligence cases. Medical negligence occurs when a health care provider breaches the applicable standard of care, which is predominantly defined as the same degree of care, skill, and judgment that a reasonable professional would use in similar circumstances. The standard of care is meant to account for the state of medicine at the time the care was rendered and represent the standard of the medical field in which the defendant-physician practices. A Standard of One opinion trades a single medical expert's beliefs for the standards accepted and followed by the medical community.

Additionally, Standard of One opinions fly in the face of expert reliability standards. The majority of jurisdictions, including federal courts, follow the same standards for the admissibility of expert opinions, which adhere to or are based on the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702. *Daubert* is concerned with ensuring courts only permit reliable testimony from a qualified expert. Standard of One opinions, even from a qualified professional, are not reliable under the *Daubert* framework.

Case study from the Wisconsin Supreme Court

A perfect case study exists courtesy of the Wisconsin Supreme Court's 2017 decision in *Seifert v. Balink*, 2017 WI 2, 372 Wis. 2d 525, 888 N.W.2d 816. *Seifert* involved the defense's attack of the alleged personal preference opinions of an Obstetrician/Gynecologist testifying for the plaintiffs in a shoulder dystocia birth injury case. The case is ripe for discussion given the recent influx of shoulder dystocia litigation and the plaintiffs' expert's seemingly Standard of One opinion.

Seifert arose from a shoulder dystocia delivery of a new born infant. Shoulder dystocia is a life-threatening event that occurs during labor and delivery when an in utero infant becomes lodged on the mother's pelvic bone and is unable to travel through the birth canal. In this case, the infant was born with a severe brachial plexus injury—nerve damage in his shoulder caused by the traction on his neck and shoulder during delivery performed with the aid of a vacuum device.

The parents of this infant sued Dr. Kay Balink, the family practice physician who delivered their son and retained Dr.

Jeffrey Wenger as an expert. Dr. Wenger was an OB/GYN with over 36 years of experience who was critical of Dr. Balink's handling of the mother's prenatal care and conduct during delivery.

Dr. Wenger's most crucial opinion was that Dr. Balink failed to perform necessary testing to confirm the mother did not have gestational diabetes during her pregnancy, which is one risk factor for shoulder dystocia. Dr. Balink tested the mother for gestational diabetes during her pregnancy by performing a one-hour glucose screen and ruled out the condition based on a result of 131 mg/dl.

Dr. Balink ultimately concluded the mother did not have gestational diabetes by relying on standards set by the American College of Obstetricians and Gynecologists (ACOG). The ACOG standards provided that a test result between 130 to 140 mg/dl was a normal glucose score and, most importantly, recommended that a physician perform a follow-up three hour glucose test only if the score was higher than 140. Dr. Balink relied on the 140 threshold and chose not to perform further testing on the mother.

Dr. Wener was critical of Dr. Balink's reliance on the ACOG numbers and believed she breached the standard of care by not following the same glucose screening standard he utilized during his years of practice. He noted that he followed a strict 130 mg/dl threshold during his career and performed additional glucose testing for any pregnant woman with initial results above that number. Dr. Wenger concluded that the results of a three hour test on this mother, coupled with her weight and fetal size, would have supported a serious risk of shoulder dystocia and required pre-labor ultrasounds and contraindicated the use of a vacuum device during delivery.

Dr. Balink's counsel sought to exclude Dr. Wener's opinions as unreliable under Wisconsin's version of Fed. R. of Evid. 702 (Wis. Stat. §907.02) in pretrial motions. The crux of defense counsel's argument was that Dr. Wenger's opinions constituted inherently unreliable Standard of One conclusions based only on his personal preference as a physician. Worse yet, his opinions contradicted the standards promulgated by ACOG, which supported Dr. Balink's decision not to perform additional glucose testing. The trial court refused to exclude Dr. Wener's opinions, noting that defense counsel was free to cross examine him on his allegedly personal opinions and contrary standards. The jury returned a significant verdict in favor of the plaintiffs after finding that Dr. Balink breached the standard of care in her management of the pregnancy and delivery of the infant.

The Court's Lead Decision and the Standard of One Dissent

Defense counsel unsuccessfully renewed their *Daubert* challenge during post-trial motions and on appeal. The Wisconsin Supreme Court agreed to review the case and in January 2017 provided its first decision assessing *Daubert* since Wisconsin adopted that standard in 2011.

The lead opinion (and concurrences) found Dr. Wener's opinions admissible. The majority of justices relied heavily on the general principle from *Kumho Tire Company, Ltd. v. Carmicael*, the Supreme Court's other notorious expert testimony decision, in which the Court noted that an expert witness's past experience could work to render his or her opinions reliable. 526 U.S. 137 (1999)

The lead opinion relied on several federal decisions that distinguished the practice of medicine from other fields of scientific knowledge, finding that "medicine is not a science but a learned profession, deeply rooted in a number of sciences." This conclusion paved the way for the court to determine, essentially, that there is no one, universal standard for the practice of medicine and that personal experience is sufficient to render a life-long clinician's opinions and methods reliable.

The dissenting opinion is the most interesting. Two judges agreed with the majority that personal experience could, in certain cases, lay the foundation for an admissible and reliable expert opinion. However, they also recognized the Standard of One issue plaguing Dr. Wener's opinion and concluded that his opinions and testimony were not reliable under *Daubert*. Identifying the standard of care in medical negligence claims, the dissenters believed Dr. Wener's personal preference conclusions abrogated the standard of care and created a "What Would Wener Do" standard for the jury. Simply put, the plaintiffs were able to improperly advocate that a defendant breached the standard of care by violating the individual preferences of a sole medical professional.

Combatting the Standard of One Issue

Standard of One opinions present added challenges for attorneys, undermine the adversarial process, and provide inconsistency and confusion for juries. In medical malpractice litigation, lay jurors are expected to base a decision on testimony offered by medical experts and rely on the court to ensure that testifying experts are qualified and that their opinions are reliable and trustworthy. Additionally, jurors are instructed to assess expert testimony when determining if the defendant-practitioner breached the standard of

care applicable to a reasonable professional in the same field. Standard of One opinions clearly undermine the basic standard of care instructions because they replace a reasonable physician or community standard with a standard based on a single physician's beliefs and they contravene reliability standards due to their failure to be based on testable methods accepted by the medical community.

The first line of defense for combatting Standard of One opinions is to understand and utilize the standards governing expert reliability. Federal Rule of Evidence 702, and states following that rule and the *Daubert* standard, impute onto trials courts a "gatekeeper" function requiring judges to confirm the reliability of all expert testimony, whether based on "scientific, technical or other specialized knowledge." Understanding the standard, applicable factors, and helpful case law are the best ways to educate the trial judge on the impropriety of a Standard of One opinion and the negative consequences of admitting these types of unreliable opinions.

Trial courts are given broad discretion to make this call by using any relevant combination of myriad factors identified by the U.S. Supreme Court and Advisory Committee. Those factors, which are fluid based on the facts and experts presented, include:

- Whether the methodology can and has been tested;
- Whether the technique has been subjected to peer review and publication;
- The known or potential rate of error of the methodology; and
- Whether the technique has been generally accepted in the scientific community.

A Standard of One expert opinion inherently disregards the *Daubert* standard and, ultimately, fails to satisfy any of the factors used when assessing reliability. The prevailing factors identified by the Supreme Court focus on reliability by ensuring that juries only hear expert testimony and opinions that are able to be tested, are based on supported methodologies, and represent the beliefs of the applicable scientific field.

Although the practice of medicine is fluid based on other learned professions, and treatment offered on a patient-by-patient basis, medical professionals worldwide receive education and training based on predominantly identical treatment principles. Defense counsel must be ready to educate judges (and lay jurors) about the medical profession and how physicians and nurses are trained to provide care.

Effective care and treatment is not the result of ad hoc conduct of one medical professional, but the byproduct of centuries of scientific research. ACOG standards, for example, are the result of endless data accumulated from the treatment of countless prenatal and labor and delivery patients. A medical opinion offered by a proposed expert is reliable when it takes into account the standard of care taught in academia, promoted by leading authorities, and practiced regularly in the profession. Medical professionals may offer care to patients on a case-by-case basis and every human body is different. But physicians absolutely follow their training, education, and foundational principles representative of their specific fields when conducting examinations, identifying a differential diagnosis, and treating a suspected condition. Personal preference opinions naturally discount a community standard; if they were based on time tested medical standards they wouldn't be the personal opinions of a single practitioner.

Standard of One opinions are vulnerable to attack by focusing on these general principles and the four factors identified by the Supreme Court in *Daubert*. A personal preference, Standard of One opinion is not subject to testing or, more appropriately, comparison to a practice standard universally utilized or recognized. Nor is a Standard of One opinion supported by publications or peer review or testable based on error rates. Worst of all, the opinions represent the beliefs of one practitioner, not the medical community as a whole.

The linchpin to a successful *Daubert* attack of a Standard of One opinion is to highlight the correlation between the inherently unreliable opinion and its negative effect on the medical negligence instructions discussing the medical standard of care. The trial court may initially believe that a qualified expert's opinions should go to the jury subject to cross examination, but may rethink that decision and exercise its gatekeeper function if admitting the testimony would confuse the jury as to the appropriate standard for assessing negligence.

Cross examination, of course, is always available to make sure jurors are aware of less-than-credible or unsupported facts and opinions. But medical testimony presents a unique challenge, since medicine is such a complicated field and jurors may be willing to put faith in a medical expert with decades of practical experience, even if his or her opinions vary from literature. Cross examination of a Standard of One opinion should focus on any differences between the expert's personal belief and standards provided in literature. In *Seifert*, for example, defense counsel hammered Dr. Wener's 130-plus standard as being

contrary to the standards promulgated by ACOG, but that clearly wasn't enough.

Cross examination of a Standard of One opinion is ultimately inadequate without specific information that can counter the medical expert's personal opinions. ACOG or similar standards are a good start but a logical argument is that defense counsel should be entitled to request and receive information about treatment provided by the testifying expert, including records supporting the expert's treatment opinions. The only information or documentation that could truly have been used to prove or disprove Dr. Wener's glucose opinions were the medical records demonstrating that he in fact had utilized his personal standard over his 36 year career.

Defense counsel should be ready to request and advocate for any materials that can assist in verifying the Standard of One expert's opinions, including other (redacted) patient records, academic records and transcripts, and personal publications. Courts may not be willing to grant a discovery request focused on the production of other individuals' confidential health records or an expert's personal education files, but hopefully the court will read between the lines. Absent ordering the expert to produce this information to verify an otherwise unverifiable personal opinion, the Standard of One opinion should not be admitted.

Lastly, pretrial motions, pleadings, and hearings provide ample opportunity for defense counsel to educate courts on the underlying medicine. Most judges handle cases touching on a vast array of substantive areas, and have likely never read-up on, let alone mastered the medicine behind preventing shoulder dystocia, testing for gestational diabetes, and the mechanics of a complicated labor and delivery. An educated trial judge is a valuable tool. Explaining the medicine and incorporating the applicable standard of care to the *Daubert* standards are an effective way to advocate for the exclusion of unsupported, Standard of One opinions.

Conclusion

Defense counsel must be able to recognize and attack Standard of One opinions that try to circumvent *Daubert*'s reliability requirements and manufacture a plaintiff-friendly standard of care. Defending medical negligence claims is difficult enough without having to worry about presentation of personal preference opinions that may be difficult to combat on cross examination.

Understanding the governing reliability requirements, identifying any applicable standards in the medical field, and being able to educate trial judges on the medicine are the best means to succeed on striking Standard of One opinions.

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