Neonatal Resuscitation: Standards and Current Practice

Occupational Therapy: Skills for the Job of Living

LNCs and Forensic Document Examiners Working Together

Non-Implementation of Patients’ Advanced Directives

The Advanced Life Support (ALS) Trip Record

Emergency Medical Treatment and Active Labor Act (EMTALA)

Statutes of Limitation: Purpose, Interpretation, and Application

Prescription Medications and the FDA’s Drug Approval Process
The Journal of Legal Nurse Consulting

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Transitions

With the advent of spring, we celebrate new beginnings: a new season on the calendar, a new AALNC President and board of directors, and a new journal editor. Due to many personal and professional issues, I am unable to continue in my role as editor of The Journal of Legal Nurse Consulting. I am very happy to welcome Holly Hillman as my successor. Holly has been a member of AALNC for many years, serving our association on a local level as the President of the Philadelphia Chapter and on the national level as the 2002 National Conference Coordinator and editorial board member. I know that Holly will do a fine job and that the journal is in good hands.

However, while celebrating new beginnings, we give pause to an ending that demands our attention: the passing of our colleague, Pat Fyler. I, like many, was very saddened and shocked to hear of Pat’s sudden and unexpected death, which occurred while she was traveling in Africa.

Whether you knew Pat personally or through her active participation in AALNC and LNC listservs, she always left an impression as someone who exemplified the profession of legal nurse consulting. Pat was a leader and mentor to many, both in her chapter and to the hundreds of LNCs who were lucky enough to belong to LNC listservs and avail themselves of the advice and wisdom she generously offered on a regular basis.

Many years ago, during my tenure as President of the Greater Baltimore Area Chapter, a number of issues arose concerning the management of AALNC. I sent letters to each chapter President, asking for their input into the management of our organization. Pat answered my letter and expressed similar concerns about the organization. She offered her support and that of her chapter in our mission to make our association stronger and representative of its membership. She truly was an ambassador for AALNC and will be sorely missed.

AALNC Secretary/Treasurer Dorothy Pollock remembered her friend and our colleague in the following excerpt from a letter Dorothy wrote to the LA Chapter:

“It is with great sadness that I inform you all of the sudden passing of our dear friend and longtime LNC associate, Pat Fyler, on Friday, February 5, 2005. After the passing of her husband, Bob, 2 years ago, Pat started taking trips that she wasn’t able to do before. She had traveled to Alaska, Russia, Italy, and Africa. Unfortunately, while in Africa, she became ill and was airlifted to a hospital in Nairobi, where she died.

Pat and I were very close. We traveled to four conventions last year, marketing her LNC business, Fyler Associates. Pat always treated everyone professionally and made a great impression on attorneys. Attorneys who may have been skeptical about using LNCs in their business were believers by the time they left the booth. Pat had a friendly persuasiveness about her. She was always right on target with her information. She was well-read and up on current events. Often she would share her opinions with the local newspaper by sending in editorials quite regularly.

I am fortunate to have known Pat as a friend, also. We enjoyed our travels together. She never mothered me but treated me as an equal. We spoke weekly about anything and everything like girlfriends do. Pat was a wealth of knowledge and offered me advice on various LNC issues. She was a great mentor. Pat was a contributor to the second edition of Legal Nurse Consulting Principles and Practice.

Pat was always out there marketing for all of us. She was a member of both the L.A. and the Orange County chapters of AALNC. She attended all of the AALNC national conventions. Her knowledge, support, and presence will be greatly missed.

I feel so bad because Pat was alone in a foreign land when she died. Due to the international situation, her daughters were unable to get to Kenya in time to be with her before she died. It saddens me the most that with all she gave to everyone over her lifetime, no one could be with her in her time of need. Pat was a trooper, a woman way ahead of her time. She made a lasting impression on the profession of legal nurse consulting and on my heart.”

Marguerite Barbacci, RNC MPH BSN LNCC
Editor, The Journal of Legal Nurse Consulting
The standards for neonatal resuscitation are determined by the American Academy of Pediatrics (AAP) and the American Heart Association (AHA). The neonatal resuscitation standards first published and distributed on a national basis by the AAP in the mid-1980s were based on materials developed by Catherine Cropley, RN MN, and Ronald Bloom, MD FAAP, at King Drew Medical Center in Los Angeles (Zaichkin & Simon, 2004). The original program by Cropley and Bloom was developed for the purpose of providing consistency at a teaching hospital and affiliated outlying hospitals in care of the newborn at delivery. In recent years, the AHA has partnered with the AAP for review, development, and distribution of the standards of neonatal resuscitation. This review process typically takes place every 6 years, so that recent research can be evaluated for appropriate inclusion in the recommendations. Most litigation involving resuscitation of the newborn begins before delivery; however, the training and expertise of the resuscitation team and the steps taken to resuscitate an infant may also be examined. The legal nurse consultant (LNC) involved in litigation of a newborn requiring resuscitation must review the case in relationship to the neonatal resuscitation program algorithm, the community setting, and practice in same or similar settings.

The American Academy of Pediatrics (AAP) and the American Heart Association (AHA) standards of neonatal resuscitation are meant to provide a framework for care of the newborn in the delivery room or, as is referred to in the latest set of materials, the “newly born” (AHA/AAP, 2000). This framework provides for decision points through the process of resuscitation or transition to extrauterine life. Only about 10% of all deliveries require any resuscitation, and only about 1% requires resuscitation beyond bag and mask ventilation (AHA/AAP, 2000). Resuscitation of the newborn after the first hour of life often includes elements of the Neonatal Resuscitation Program (NRP), as well as the Pediatric Advanced Life Support (PALS) program. The PALS program is focused more toward resuscitation for the pediatric patient, including infants but not newborns.

There are many physiologic changes that take place in the infant following delivery. In most cases, the infant is able to make this transition successfully and relatively independently (AHA/AAP, 2000). The 2000 guidelines address these infants as well as those needing full resuscitation, including medications (as shown in Figure 1 on page 7). In addition, a chapter was added to the 2000 program regarding special resuscitation circumstances as to when it may be appropriate not to begin resuscitation efforts or to terminate the resuscitation process once initiated.

Initial Steps in Resuscitation

The NRP begins with initial steps that apply to all infants at delivery. This includes drying the infant, removing wet linens to prevent heat loss and potential hypothermia that can render resuscitation less effective and may lead to post resuscitation sequelae. Positioning and suctioning of the newborn are performed next to provide for a patent airway and gas exchange. All infants will have some oral secretions at birth because they have just come from the amniotic fluid-filled intrauterine environment, and the first step in transition is to clear fluid from the airways and replace it with air. Most infants will be successful in clearing sufficient fluid for gas exchange to take place. Suctioning must be performed cautiously so as to remove excess fluid/mucus but to avoid vagal stimulation and corresponding bradycardia. This is particularly important during the first few minutes of life, as the infant is more vulnerable to vagal stimulation at this critical point (Cordero and Hon, 1971).

Positioning the infant is done in a “sniffing” position so the chin is neither hyperextended nor flexed (as shown in Figure 2 on page 7). Hyperextension or flexion of the neck may easily result in airway occlusion due to the size and pliable nature of the airway.

Once the initial steps are performed, respiratory effort, color, and heart rate are assessed in no particular sequence. If respiratory effort is present, the infant is not gasping, and color is not pink, blow by oxygen is given. In the presence of good respiratory effort, central color will transition from the relative cyanosis of the fetus to pink in the central portion of the body in a matter of minutes, often less than 5 minutes. If color is improving, there are no risk factors and respiratory effort is good, even blow by oxygen is not usually necessary. The NRP provides for care of these infants by allowing a decision point where these infants may simply be placed on the mother’s chest to maintain normal body temperature. These infants must continue to be observed by the nurse caring for the mother-baby couplet to ensure that successful transition continues (AAP/ACOG, 2002).
meconium. If adequate ventilation and oxygenation have not occurred, resuscitation must continue. If the infant has good respiratory effort and muscle tone as well as a heart rate over 100, intubation need not be performed (AHA/AAP, 2000). The resuscitation protocol continues as in any other newborn delivery.

Next Steps in Resuscitation

In the case of either clear or meconium stained amniotic fluid, once the initial steps have been completed, blow by oxygen be provided if respiratory effort is good or improving but color remains cyanotic. If respiratory effort is poor (apnea or gasping) or heart rate is less than 100, bag and mask ventilation should be started. This bag and mask ventilation, according to the NRP, should be provided with 100% FiO2. However, the current review of the guidelines includes use of oxygen levels less than 100% (Zaichkin & Simon, 2004). Many facilities are already integrating this research into practice, and it may therefore be community standard (Saugstad, 2004).

This practice is particularly important for preterm infants, as they suffer the effects of excessive oxygen administration more than term infants. These effects include retinopathy of prematurity and potentially damaging effects of oxygen free radicals (Saugstad, 2004). In this case, it is paramount to monitor oxygen saturation levels during resuscitation to ensure that adequate oxygen is being delivered to the patient.

In case of respiratory insufficiency or heart rate less than 100, bag and mask ventilation continues for approximately 30 seconds, at which time the heart rate is checked. In most hospital settings, a second provider is available to monitor heart rate. No further action is indicated until sufficient ventilation/oxygenation has occurred. If adequate ventilation has not occurred within approximately 30 seconds, other actions should be implemented. These include repositioning the face mask, ensuring an open airway by repositioning the head, increasing flow rate, and suctioning or increasing inflation pressure during bagging (AHA/AAP, 2000). If the heart rate is less than 60 despite adequate ventilation, further action is indicated. If the heart rate is above 60, ventilation continues until the heart rate is greater than 100 and the patient is breathing spontaneously.

The guidelines set forth in the Neonatal Resuscitation Program dictate that compressions start at a heart rate at or below 60. If the heart rate is quickly rising to a level greater than 60, compressions may not be given. Compressions may be given using two fingers or both thumbs. The two-thumb method is advocated in the 2000 NRP guidelines, as it is less tiring and one is able to better control the depth of compressions (AHA/AAP, 2000). However, this method may not always be practical, and the two-finger method is also acceptable (AHA/AAP, 2000). Compressions are to be continued for approximately 30 seconds, accompanied by ventilation.

The timing of intubation versus bag-and-mask ventilation varies, based on several factors. If bag-and-mask
ventilation is effective, resulting in chest rise and breath sounds, this mode of ventilation may be used for an unlimited time. In most cases, the decision to intubate is based on the initial response to bag-and-mask ventilation. Several factors temper the intubation decision, such as the need for long-term continuous ventilation, the level of expertise of personnel available to intubate, and the presence of an anomalous airway. Intubation attempts should be limited to approximately 20 seconds, in order to avoid extreme hypoxia and further bradycardia in the newborn. While the time may not be monitored specifically, the infant’s response must always be monitored. If the heart rate is falling during the intubation attempt, the health care provider performing the intubation must be made aware. The attempt should be suspended after an appropriate amount of time (usually 20 seconds), the infant ventilated again with bag-and-mask ventilation, and intubation re-attempted when the infant has recovered.

When the resuscitation protocol indicates the need for chest compressions, this is initially performed for about 30 seconds. If the heart rate is not greater than 60, medications are the next intervention. Epinephrine is the first medication to be given. The medication may be administered via the endotracheal tube or intravenously. Since the endotracheal tube is often in place at this point of the resuscitation, this is a common route for the first dose of epinephrine. The recommended intravenous route is via the umbilical vein, as this is easily cannulated in the newborn. Since, however, this is outside the scope of practice for the registered nurse in most states, either a physician or nurse practitioner must be present or it must be performed under a standardized procedure.

The cause of arrest in newborns is typically due to hypoxia and rarely involves cardiac arrhythmias other than bradycardia or asystole; therefore, the focus of the NRP is these conditions. Epinephrine, sodium bicarbonate, and fluid volume boluses of normal saline or lactated ringers are the medications addressed. Table 1 on the following page indicates the recommended doses, indications, routes, and frequencies for these medications. Naloxone is indicated when the mother has received a narcotic within 4 hours of delivery and the infant has poor respiratory status. This is addressed under special circumstances in the NRP guidelines, as this medication is not usually given in a cardiopulmonary arrest (AHA/AAP, 2000). If the mother has not received a narcotic during labor or delivery and the infant has poor respiratory effort, naloxone should not be given. If the mother has a history of substance abuse during her pregnancy, it is possible that naloxone given shortly after delivery could cause instantaneous withdrawal and severe seizures in the infant (AHA/AAP, 2000; Kandall, SR, 1999).

The epinephrine can be given every 3 to 5 minutes while the heart rate remains less than 60 in spite of adequate ventilation and compressions. Compressions should be stopped for approximately 6 seconds every 2-3 minutes to evaluate for spontaneous heart rate. If the spontaneous heart rate is less than 60, compressions may be stopped but until the heart rate is greater than 100, ventilations should continue. Once the spontaneous heart rate is over 100, the infant must be evaluated for spontaneous breathing. If present, manual ventilation may be stopped gradually, continuously evaluating the need for support.

### Documentation

Documentation of resuscitations is, unfortunately, often lacking in clarity. While the usual practice for adult and pediatric codes is to summon the code team or “call a code,” this is not usually done for delivery room resuscitation. If assistance is needed in the delivery room, the appropriately trained personnel are summoned. This team must include personnel able to administer effective bag-and-mask ventilation and deliver medications that may be needed in a cardiac arrest. In some cases, these will not be physicians but registered nurses functioning under standardized procedures or via telephone orders, or respiratory care practitioners whose competency has been validated in care of newborns. This team does not usually include sufficient personnel for contemporaneous documentation of the resuscitation. Indeed, it is rare for resuscitation to progress beyond bag-and-mask ventilation except in large tertiary care facilities that care for and deliver high-risk pregnant women.

It is a matter of hospital policy as to when the resuscitation documentation form or code record would be utilized. Most often, the form is used when cardiac compressions are required but, in some cases, may be utilized when manual ventilation is necessary. In most cases, the delivery room record is sufficient to address intubation for meconium or the need for manual ventilation. Actions often not documented during a resuscitation include suctioning during the course of the procedure, precise timing of evaluating respiratory effort, color, auscultating breath sounds, and monitoring chest rise in order to evaluate effectiveness of manual ventilation. If documentation shows that there is no improvement in the patient’s status, it would be expected that those involved in the resuscitation would be able to articulate these items as part of their usual and customary practice. In addition, steps should be taken to alter the approach to resuscitation to address the infant’s non-response.

In many cases, deviations from the NRP algorithm may be evident or assumed in the documentation. Some deviations may not affect the outcome of the infant, while others may. Consultation with experts in the area of neonatal resuscitation would be recommended to evaluate deviations from the published standards and if a deviation from the care was appropriate for a particular case. In other cases, when damages result, experts will be able to opine whether a deviation may have been indicated but was not recognized by the team performing the resuscitation. The expert can also
determine whether a reasonably prudent professional should have been able to recognize the need for deviations in the standard approach.

Role of the Legal Nurse Consultant (LNC)

Most litigation involving resuscitation of the newborn begins before delivery. Damaged baby cases often center around intrapartum monitoring and timing of delivery; however, the training and expertise of the resuscitation team, as well as steps taken to resuscitate an infant, may also be examined. This often involves obtaining information about the availability of appropriately trained personnel, particularly a physician. The resuscitation of infants born with meconium in the amniotic fluid may present an additional risk due to the potential need for alternate airway management.

The LNC involved in litigation of a newborn requiring resuscitation must review the case in relationship to the neonatal resuscitation program algorithm (Figure 1), the community setting, and practice in same or similar settings. For instance, the personnel performing resuscitation may vary from a teaching facility to a community hospital and from an urban community hospital to a rural hospital. Despite the setting, however, the actions of the team should be essentially the same. The personnel must also be adequately trained to perform any step of the resuscitation procedure for which they are responsible under the hospital policy. In some cases, this may require a standardized procedure for the registered nurse to intubate, insert an umbilical venous catheter, or give medications in the absence of a physician. These also require continuing competency validation. A review of the state nurse and respiratory practice act in which the event occurred is recommended. In addition, the LNC must remember to review the NRP standards from the year of litigation, which may not be the current standards in practice at the time the medical records are being reviewed.

Hospital policy or medical staff bylaws may also be helpful in determining what the hospital has identified as an acceptable amount of time for the physician to attend the resuscitation, when needed, and when the physician is to be notified. This will vary, as will the training of the team, from a community hospital where the pediatrician or neonatologist does not stay in the hospital, to a teaching hospital where these physicians are in-house around the clock. The qualifications and experience of the physician to perform neonatal resuscitation should also be examined. In many cases, they are not required to complete the NRP. The LNC should evaluate the frequency with which the physician participates in the resuscitation of newborns.

In summary, the American Academy of Pediatrics sets forth standards for the care of the newly born patient. Most often, these infants transition to extraterine life with minimal intervention; however, in the event of respiratory arrest or failure to spontaneously initiate adequate respirations, intervention is required. The NRP makes recommendations for these interventions and the training of the personnel involved to take the necessary steps.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Indication</th>
<th>Route</th>
<th>Rate of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine 1:10,000</td>
<td>0.1 to 0.3 ml/kg</td>
<td>Heart rate remains less than 60 after 30 seconds of effective ventilation and compressions</td>
<td>Endotracheally; intravenously</td>
<td>Rapidly</td>
</tr>
<tr>
<td>Normal saline</td>
<td>10 ml/kg</td>
<td>Hypovolemia or evidence of shock</td>
<td>Intravenously</td>
<td>Over 5 to 10 minutes</td>
</tr>
<tr>
<td>Sodium bicarbonate 4.2%</td>
<td>2 mEq/kg or 4 ml/kg</td>
<td>Documented of suspected metabolic acidosis</td>
<td>Intravenously</td>
<td>Slowly , no faster than 1 mEq/kg/min</td>
</tr>
</tbody>
</table>


References

Sandy Sundquist Beauman, MSN RNC, began her career in Wichita, KS, in the Neonatal Intensive Care Unit after graduating from a diploma program in 1979. She spent almost 4 years in Texas at the University of Texas Medical Branch in Galveston before settling in California. She graduated from California State University-Dominguez Hills with her Master’s in Parent-Child Health in 1993 and has been a licensed Clinical Nurse Specialist ever since. Ms. Beauman has worked in the Los Angeles area for the last 19 years. Currently, she is the Neonatal Clinical Nurse Specialist at Pasadena’s Huntington Memorial Hospital, as well as Methodist Hospital in Arcadia, CA. She maintains an active clinical practice, implementing practice changes and providing education regarding care of the neonate across the country. In addition, she is a Pediatric Advanced Life Support instructor and has been a Neonatal Resuscitation regional trainer since 1986. She can be reached at CNSConsulting@earthlink.net.
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The ability to analyze each step of an activity, along with identifying the skills needed to perform each step of the activity, is the very core of occupational therapy training (Reed & Sanderson, 1999; Kielhofner, 2004). Occupational therapists (OTs) pride themselves in their “whole-person” approach to treatment and patient care: physical, psychosocial, and cognitive. Like nurses, OTs evaluate the impact of an illness or disability on a person’s physical well-being in addition to their emotional and social state as well. In the whole-person approach to occupational therapy, OTs are trained to work with different health care disciplines and refer a patient to other professionals when appropriate. A registered OT refers clients to appropriate resources when the needs of the client can best be served by the expertise of other professionals or services (American Occupational Therapy Association, 1995).

A past president of the American Occupational Therapy Association (AOTA), Karen Jacobs, EdD, OTR/L, FAOTA, once suggested that to understand the impact of occupational therapy, one should imagine an activity that is important to them and then think of what their life would be without it. Kielhofner (2004) explains: “…occupational therapists provide services to persons whose impairments interfere with satisfying participation in their everyday lives” (p.4).

OTs work with people of all ages with mental, emotional, or physical disabilities, providing formalized testing, treatment, special equipment, and training. Many OTs work in a specialty area such as pediatrics, geriatrics, hand therapy, mental health, ergonomics, or physical disabilities. In all areas of occupational therapy, a common link is helping people to be as independent as possible in their lives doing the things that are important to them. At times, OT may encompass the suggestion that some activities be relinquished so that one may have the energy to accomplish others.

OTs consider the impact of a disability not only on the person, but on the family as well. Caregiver instruction is a critical part of the OT evaluation and plan of care. Culture is an important consideration to the OT. In some cultures, independence is less valued than in the United States. In those cases, training family caregivers can be paramount and caring for the disabled person can be considered an honor (Reed & Sanderson, 1999).

**OT Case Studies**

Some case studies may be helpful in explaining the profession of occupational therapy:

- Max is a 3-year-old who suffered oxygen deprivation during a difficult delivery. He was diagnosed with cerebral palsy at the age of 6 months. Max’s OT listened to the family’s concerns for Max’s safety and helped the family choose an appropriate wheelchair, bath, and toilet equipment. For Max, the main “occupation” is play, eating, and exploring his environment. His OT provided activities and a treatment program to maximize his skills in these important areas. The parents were taught how to best position their son for participation in activities at home.

- Jane is a 30-year-old new mother who was injured in a motor vehicle accident. She sustained a spinal cord injury at the T-2 level. In addition to helping her choose an appropriate wheelchair, bathing, and toileting equipment, her OT developed an arm strengthening program and taught her techniques for dressing and bathing. They discussed energy conservation in the home and worksite, identifying areas that were the most meaningful to Jane. She was especially interested in learning ergonomically correct techniques to care for her infant from her wheelchair. With the OT’s counsel, the family decided to hire a housekeeper. They discussed possible modifications...
needed for Jane's worksite. Jane's "occupation" was returning to her home, employment, and the care of her infant son.

In many aspects, occupational therapy can look a lot like physical or speech therapy (Michaud & the Committee on Children with Disabilities, 2004). This can be especially true in work with children. The overlap is viewed by therapists as strength because the goals of both therapies are complementary. While the therapy may look the same to the observer, the goals may be significantly different. For example, both the physical and occupational therapists may have a goal of strengthening the trunk of a child with cerebral palsy. While both therapists may position the patient in a kneeling position to work on the goal, the physical therapist may also focus on a gross motor skill like throwing. The OT may have the child work on a fine motor activity such as writing. Trunk strength is a key element needed in both gross and fine motor skills.

Understanding the role of the OT in patient care continues to be a challenge to other health professionals and nurses. Without working closely with an OT, other health care providers may not truly understand the contribution of occupational therapy. A Swedish study of almost 1,000 medical, nursing, occupational, and physical therapy students placed students in a 2-week interdisciplinary education program to increase communication and understanding of the roles of other members of the medical team. The results of the study found that knowledge of occupational therapy was lowest both before and after the study, but study participants learned more about occupational therapy than any other profession. Nurses were noted to have learned the most about the role of the OT than of any of the other participants (Ponzer, et al., 2004).

OTs in most states have direct access and can evaluate patients without a doctor's order. For purposes of reimbursement, however, a physician's order is typically needed and often required by the facility employing the therapist. Depending on the physician, orders can be as broad as "evaluate and treat" and the specifics left to the skill and expertise of the therapist. In other settings, orders may be very specific, such as the order to "fabricate a wrist splint with the wrist at 30 degrees of extension to be worn full time and removed only for bathing and exercise."

Like nurses, OTs may specialize in a specific practice area. Some OTs evaluate patients for wheelchairs, seating, and other durable medical equipment for bath, toileting, and sleeping needs. Evaluation for adaptive aids and assistive technology needed for daily living skills and accessing computers are inherent in the practice of occupational therapy. OTs evaluate the need for splints or orthotics for the arms and hands, fitting or custom-making the splint/orthotic to the individual patient. Some OTs specialize in making recommendations for home and work modifications for people with disabilities. Others provide driver's training and make recommendations for needed driving adaptations.

OTs take a certification examination and are registered nationally by the National Certification Board of Occupational Therapy (NBCOT). Therapists are typically licensed by individual states. Beginning in 2007, all entry-level registered occupational therapists (OTR) will be required to have master's degrees to enter practice. While there have long been OTs holding doctoral degrees in occupational therapy, a new trend in OT education is emerging. Following their physical therapy counterparts, a new advanced degree, doctor of occupational therapy (OTD), is being offered at a few universities. The OTD is an advanced degree with an expanded clinical experience, different from a doctoral (PhD) degree which is research-oriented.

**The Uniform Terminology for Occupational Therapy** (3rd ed.) (UT-III) was the guideline used to describe the framework of occupational therapy intervention in the clinical setting (AOTA, 1994). In 2002, UT-III was replaced with Occupational Therapy Practice Framework: Domain and Process (The Framework). The Framework was drafted to "describe the domain that centers and grounds the profession's focus and actions and to outline the process of occupational therapy evaluation and intervention that is dynamic and linked to the profession's focus on and use of occupation" (American Occupational Therapy, 2002). The Framework describes in complex detail the domain and process of intervention for occupational therapy and includes terminology specific to the profession.

**OTs and Forensics**

Medical records generated by OTs, particularly in an in-patient setting, have moved from strictly narrative entries to a numerical rating, outcome-based format. Measurement tools such as the FIM (Functional Independence Measure) and its pediatric counterpart WeeFIM II have provided a common method of characterizing weekly patient progress on rehabilitation goals (Guide for the Uniform Data Set for Medical Rehabilitation, 1997). The tools are also used to identify problems areas, predict outcomes, evaluate effectiveness of treatment interventions, and plan for discharge. The format of measurement tools vary but generally cover self care, mobility, and cognitive skills. The sections designated for address by the OT may be somewhat different from center to center but typically include the self care section. The FIM, a very common tool used in adult rehabilitation centers, uses a score range of one to seven, with one indicating total assistance required to perform a task and seven indicating complete independence.

Nurses and OTs have been shown to approach patient intervention differently. In a study using 20 observations of nurses and OTs doing dressing and grooming training with the same stroke patients, the therapists used "prompting and instructing" cues more often and facilitation techniques much more often than their nursing colleagues. Nurses spent more time in supervision of the task (Booth, Davidson,
Both professions have different skills and abilities to bring to the rehabilitation setting, and that is likely to be true in forensic work as well. Because OTs tend to look at a person with a different skill set than those of nurses, their input can be a valuable addition for the legal nurse consultant (LNC).

It is unusual for OTs to be involved in forensic work. However, OTs are uniquely able to quantify what a disability means in the day-to-day life of a person. OTs, like other health care professionals, tend to focus on and plan treatment based on the patient’s current needs and problems. It is a relatively new concept for the OT to consider the life-long needs of the patient at the time of the OT’s initial intervention. Explaining the impact that a child’s shoulder disability will ultimately have in their adult life is within the skills of an OT but may stretch the typical approach and thought process of the profession.

Because of the OT’s focus on immediate patient needs, medical records typically generated after an occupational therapy evaluation will likely not contain all of the information that would be helpful to the LNC or attorney. For example, an occupational therapy evaluation may state that a person is unsafe using a stove but may not go on to recommend that they will need supervision in their home setting. This recommendation may be critical in determining damages. It may be important for the LNC and/or attorney to find an OT in private practice to evaluate, make projections and recommendations, and generate a report that quantifies the impact of a person’s disability over their lifetime.

Finding an OT with the needed experience and willingness to enter forensic work may be a challenge and is typically accomplished by word-of-mouth referral. Significant encouragement by the LNC may be needed. At this time, it is very rare for an OT to be in private practice for the purpose of legal consultation. An entry-level degree in occupational therapy, like nursing, does not include forensic training to assist attorneys or insurance companies. Some OTs have made the transition into the forensic arena by becoming life care planners, with the additional training and education needed for certification in life care planning.

Many categories of a life care plan are within the domain of occupational therapy practice and expertise, such as projected evaluations, therapeutic modalities, need for and maintenance of durable medical equipment, aids for independent function, orthotics/prosthetics, home furnishings and accessories, transportation, health and strength maintenance, and architectural renovations.

A background in occupational therapy provides an ideal background for the transition to performing disability assessments and life care planning services to attorneys and insurance companies. To illustrate the impact of occupational therapy training in forensic work, Chris, a 20-year-old young man, had just moved into an apartment with friends and was working full-time in a bank when he sustained a brain injury in a motor vehicle accident. In the 2 years since his injury, Chris made a relatively good physical recovery but was left with significant residual cognitive problems. An OT/life care planner was asked to formulate a life care plan for Chris, who was now living with his parents and no longer receiving therapies. The medical records contained inadequate information about Chris’s current skills in the home setting, and his parents had taken over supervision of all aspects of his life.

As a part of the life care plan development, Chris was evaluated in the performance of daily living skills. He was given a check to write and a checkbook to balance. He was asked to make change. His inability to correctly balance his checkbook and make change underscored his need for financial management supervision and assistance. A trip to a local grocery store revealed great difficulty organizing the task, finding items, and a general vulnerability while performing the task without supervision.

Chris was asked to prepare a meal from a recipe that demonstrated disorganization and safety concerns, but he was safe heating soup in the microwave. A request to transfer into his bathtub showed subtle balance problems, and the OT/life care planner recommended the use of grab bars and a safety mat. The OT/life care planner knew that, with this equipment, Chris would be able to shower independently. In a walk in the community, Chris showed impulsivity when crossing the street. The client displayed the need for supervised living in a variety of settings, but also demonstrated his ability to become more independent in other areas of his daily activities.

The evaluation of functional tasks in the home and community brings strong foundation for the recommendations made in the life care plan. While it is critical to consult with treating health care providers in the formulation of the plan, they may not have complete knowledge of their patient’s current abilities. This assessment is a natural use of occupational therapy knowledge about daily living skills and equipment. An evaluation of a patient’s ability to perform functional tasks in the home and community may be helpful to the LNC, even in the absence of need for a life care plan or when a life care planner of another primary profession is used.

On some occasions, the OT may be retained by an attorney to generate a report about how a specific problem may impact a person’s life. For example, Amanda is an 8-year-old girl who sustained a fracture of her dominant arm in an auto accident. Amanda had a full recovery of strength, but in spite of splinting and therapy, she lacked 20 degrees of extension of her elbow. The question posed to the OT was, “What impact will lack of range of motion have on her life?” The therapist was able to list potential difficulties such as a decreased ability to reach into deep or high places, an inability to “lock her elbow” when performing household chores leading to decreased endurance for the task, interference with sports such as volleyball, gymnastics, or...
swimming, and an altered fit of clothing sleeves. Information such as this will not typically be found in the medical record. LNCs often have difficulty in deciphering the abbreviations used by occupational therapists. Some abbreviations are standard to the profession, while others are idiosyncratic to specific work sites and are not widely known or accepted. The abbreviations listed below are common and may be helpful to the LNC in OT chart reviews:

**AAC** Augmentative and alternative communication  
**AAROM** Active assistive range of motion (person needs assistance to complete the full range of motion)  
**ADL** Activities of daily living  
**A/E** Above elbow  
**A/K** Above knee  
**AROM** Active range of motion (person is able to move through their range of motion without assistance but may not be able to do with resistance)  
**AT** Assistive technology  
**B/E** Below elbow  
**B/K** Below knee  
**CGA** Contact guard assistance (direct contact with the person for safety but no physical assistance)  
**COTA** Certified occupational therapy assistant (typically an associate degree education)  
**IADL** Instrumental activities of daily living (activities of daily living beyond self care such as money management, meal preparation, child or pet care, telephone use, use of public transportation, and homemaking tasks)  
**LTG** Long term goal  
**OTR/L** Occupational therapist registered/licensed (Therapists are nationally registered but licensed by individual states. Historically, OT's have a bachelor's degree but beginning in 2007 a master's degree will be required. Many programs have already implemented this change.)  
**SBA** Stand by assistance (no direct contact with the person)  
**SI** Sensory integration (a type of therapy typically used for people with autism or learning or developmental disabilities who have difficulty appropriately interpreting sensory input)  
**SID** Sensory integration dysfunction  
**STG** Short term goal  
**TX** Treatment  
**VC** Verbal cue (provide short direct instructions)  
**WFL** Within functional limits (able to move within the limits needed to perform daily activities but may not have full range of motion or normal strength)  

OT's have an important and unique contribution to offer the world of forensics. They have the scope of knowledge to describe what impact a disability has and what it will mean in a person's daily life. Initially, OT's may be limited by their lack of training in forensics and the typical practice of concentration on the current problem and solution. They will most likely need encouragement to think outside their typical mode of practice to be of maximal assistance to attorneys and LNCs. OT's have great potential for being an important and valuable expert in the legal arena.

**References**


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Legal Nurse Consultants and Forensic Document Examiners Working Together

Emily J. Will

The medical record is one key to documenting what happened, when it happened, and who participated in medical treatment and procedures. In court, medical records are "evidence." But suppose the record has been altered; then the evidence has been altered. Or, if legitimate records are challenged without basis, their proper value as "evidence" is diminished. In these situations, a forensic document examiner (FDE) can help. The purpose of this article is to discuss document examination in general, and to explain how legal nurse consultants (LNCs) and FDEs can work together to resolve questions about medical records issues. As part of the discussion, real cases are presented. Although these cases have been adjudicated or settled, names have been protected where possible.

Forensic document examiners (FDEs) can evaluate claims or suspicions about the written record and support or discredit them. Typical questions that a FDE is asked regarding medical records include:

- Who authored the signature or handwritten entry?
- Has the record been altered, obliterated, erased, or overwritten?
- If so what was written originally?
- Was a particular phrase added at a later date?
- Was the record entirely rewritten?
- Were pages substituted?

Handwriting Identification

Most FDEs report that the largest part of their work is related to questions about handwriting identification (Ramsey, 1996). Did the same person who signed the known documents also sign the questioned document? Was all of the handwriting on the chart written by one person? Who wrote the anonymous note? The first question a FDE has to answer is: What is the scientific basis for handwriting identification?

Handwriting is a complex, learned motor behavior (Found & Rogers, 1999). When writing is first learned, intense concentration is required to grip the writing instrument and to reproduce “copybook” forms correctly. Over time, writing becomes habitual. When the writer is able to write without thinking about the act, but instead can concentrate on the message, the writing is said to be produced “automatically" (Saudek, 1978).

Although writing becomes habitual and automatic, individuals vary in their ability to perform complex motor behaviors. They vary in relation to other individuals and in their own repetitions of these behaviors (Found & Rogers, 1999). Each writer has a natural range of variation in his or her writing (Huber & Headrick, 1999). Humans also have the ability to distort or disguise their writing. Furthermore, handwriting as a behavior is subject to the influence of unusual internal or external factors (Found & Rogers, 1999).

The skill of the FDE lies in his or her ability to correctly evaluate the behavioral artifacts (the written line) and to attribute the proper significance to them (Harrison, 1958). The FDE relies upon several core concepts of handwriting identification. Some of those are:

- Each person’s handwriting is unique (Harrison, 1958).
- Each repetition of a person’s handwriting varies from all others (Harrison, 1958).
- An accurate and fluent simulation of someone else’s handwriting is very difficult to execute (Hilton, 1984).
- There are clues in handwriting that allow the evaluation of relative speed, line quality, rhythm, writing skill, and other characteristics (Hilton, 1984).
- Writers tend to use a small number of specific methods when disguising their handwriting (Wendt, 2000).
- As the complexity of writing increases, the likelihood of reaching a conclusive opinion of authorship increases (Found & Rogers, 1998).
- Inconspicuous handwriting characteristics usually are the most individualizing, and the most meaningful in terms of identification (Osborn, 1973).

People begin learning to form letters by copying a model. Many people may copy the same model, but each result will be different because the human is not a machine. An analogy to the identification of handwriting is looking for a suitcase at the airport baggage claim. There are a lot of black, soft-sided, rolling bags, but they don’t all have the same size and location of pockets. Even among those that do, how many have a dent in the top of the handle, a long, bright blue ribbon on the main zipper pull and a short red ribbon on the side zipper pull? As a cluster of individualizing characteristics builds up, the suitcase (or handwriting) becomes identifiable. If there is an unexplainable significant structural difference (for example, the suitcase has no wheels, and there is no evidence that
existing wheels were cut off of the suitcase), we can eliminate that suitcase (or handwriting) as being the one we are seeking.

Part of the job of a FDE is to demonstrate the observations that are the basis of the opinion. For example, differences in line quality can be demonstrated with close-up photographs of the writing line. In Figure 1, the writing on the left has smooth curves and a tapered end stroke. The writing on the right has less fluid curves and a blunt end to the final stroke. Close-up images assist the reader (juror) in looking at the relevant portion of the writing line.

Figure 1. – On the left is a writing with good line quality. Curves are smooth, and the final stroke is tapered. On the right is a writing with poor line quality. Curves are flattened or wavering, and the final stroke has a blunt ending.

In order to reach a reliable opinion about the questioned writing, it is critical to have appropriate exemplars. Several factors contribute to the appropriateness of exemplars (Hilton, 1984):

1. Provenance: Be able to demonstrate that the exemplars really contain known handwriting of the subject writer.
2. Timeliness: The exemplars should bracket and include the time period of the alleged writing of the questioned document.
3. Style: Cursive writing should be compared to cursive writing and hand printing to hand printing.
4. Content: The exemplars should contain the letters, letter combinations, words, and numbers of the questioned writing.
5. Materials: Writing instruments and materials (lined vs. unlined paper, same sized envelopes, etc.) similar to those used for the questioned writing should be used for the exemplars.
6. Sufficiency: There is no set number of exemplars required. It will depend on the nature of the case and the nature of the handwriting at issue. The FDE should advise you regarding the quality and quantity of samples needed.

There are two types of exemplars. Collected exemplars are produced in the normal course of business (or life) and are collected after the fact. Requested exemplars are produced by the subject writer by specific request. In some cases, collected exemplars are sufficient. In other cases, requested exemplars are needed to allow the examiner to consider specific aspects of the writer’s writing ability or because there are insufficient collected exemplars available.

Requested samples must always be accompanied by some collected samples in order to evaluate the possibility of attempts at disguise in the writing of requested samples. The LNC should consult with the FDE to plan the gathering of appropriate exemplars. The examiner will know what collected exemplars are needed for each individual case. If requested exemplars are required, the FDE could be present at the request writing session or assist you in preparing for and conducting the request writing session (Will, 1988).

Much of this background information was important in Case #1, which involves an anonymous note, allegedly written by a high school student named Tim. In Tim’s case, the anonymous note was written with an inconsistent style that alerted the examiner to the possibility of disguise (Hilton, 1984). Of course, disguise is not a surprise in a document that the author declined to sign. For this case, the collected exemplars consisted of several notebooks containing school lecture notes and assignments. The examiner also met with Tim to take a requested handwriting sample. While watching Tim write, the examiner noticed that Tim used an unusual method of letter construction. What the examiner saw during the request writing session was backed up by the occurrence of the same characteristics in the collected exemplars.

In a study of graphic behavior by Meulenbroek, Thomassen, Schilling, and Rosenbaum (1996), right-handed writers showed a natural preference to execute a vertical line from the top down, but Tim (right-handed) consistently started all letters from the bottom and pushed the pen up. This was important because it was opposite to the way the letters in the questioned note were formed. Of course, the examiner did not see the questioned note being written, so how could this be determined?

The physics of the writing instrument and writing process can add useful information. Details of ballpoint pen strokes viewed through a magnifier or microscopic can determine direction of stroke, as explained in Figures 2 and 3 (Hung & Leung, 1995; Fryd, 1975).

Figure 2 – Ballpoint pens striations start at the inside of a curve (solid arrows) and go to the outside of the curve, (dashed arrows) in the direction in which the pen is moving. This close-up of the questioned “T” shows that the stroke began at the top, moved to the left, and hooked back to the right and downward.

Figure 3 – This close-up of the known “T” shows that the letter begins at the baseline and moves upward. A ballpoint pen
often shows an “inkless” start as we see in the circle, and often deposits a blob of ink just after a curve, as noted by the arrow.

The “o’s” in the questioned writing begin and end at approximately the 9-12 o’clock position, while the “o’s” in Tim’s writing begin and end at the 5-7 o’clock position, whether Tim is writing with his right or left hand. He does the same with the number 8 as shown in Figure 4 below.

![Figure 4a](image1.png) ![Figure 4b](image2.png)
![Figure 4c](image3.png) ![Figure 4d](image4.png)
![Figure 4e](image5.png) ![Figure 4f](image6.png)

*Figure 4 – 4a, b, and c are Tim’s known writing, and 4d, e, and f are from the questioned writing.*

In any handwriting identification problem, the answer will be based on a cluster of characteristics or factors. It is rarely one single feature that leads to an opinion. There is, however, often a factor of particular importance, and this difference in method of construction was very significant in reaching the opinion that Tim was not the writer of the questioned note. The judge agreed, and Tim was found innocent.

**Altered Documents**

Handwriting identification is one aspect of document examination. Other often-asked questions are related to possibly altered documents. With a stroke of a pen, a “1” can be changed to a “4,” a “7,” or an “11.” A word can be overwritten or obliterated. In a medical case, it can be important to know whether there have been changes, or what was written before a change was made. If the original document is available, the examiner can examine the documents with wavelengths outside the range of human visibility to make the “invisible” visible.

Due to the reactions of various components of ink, two inks that appear to be the same under one light source may appear different under another light source. Two black (or blue) inks that look the same to the human eye in visible light may look entirely different when seen with an infrared viewer (Ellen, 1997).

A video spectral comparator is a device that uses electromagnetic wavelengths outside the range of visible light. Visible light wavelengths are approximately 400-700 nanometers (Ellen, 1997). The device allows the examiner to view reactions of ink and paper to “non-visible” ultraviolet and infrared “light” sources. (Note: The scientific term “light” applies to visible light only. Infrared and ultraviolet are more correctly called electromagnetic wavelengths, but that is a mouthful. The word “light” is commonly applied to infrared and ultraviolet, and will be used here as a simplification.) Infrared is typically the most useful in this type of examination (Ellen, 1997).

Case #2 started out as a signature identification case but in the end relied upon infrared examination for proof of the examiner’s opinion. A patient, Ronald X, was scheduled for a surgical procedure performed at ABC Medical Center. Following the ABC Medical Center policy, a representative of ABC asked Mr. X to sign a form stating that if there were any problems relating to the medical treatment, any claim would be dealt with by arbitration rather than through the courts. This was a standard form requiring two signatures of the patient. After the surgery, Mr. X was dissatisfied and retained an attorney to file a suit. ABC Medical Center filed a motion to instigate arbitration, claiming that Mr. X had previously agreed in writing to arbitrate any dispute.

A hearing on the motion to require arbitration was held. Mr. X’s attorney claimed that Mr. X had not signed the arbitration agreement form and accused someone (anyone) at ABC Medical Center of “forging Mr. X’s signatures on the form.” ABC’s attorney asked for, and was granted, a continuance in order to consult with a FDE.

This is the type of case that really did not need to happen, but sometimes the nature of the courtroom is that proof is required for something that might otherwise fall into the category of “common sense.” To the examiner, it was clear what had probably happened, and most of the work consisted of testing the hypothesis, documenting the result of the test, and demonstrating the findings in court.

These are the two questioned signatures. Only part of the first name is shown.

![Figure 5a](image7.png) ![Figure 5b](image8.png)

*Figure 5. – These are parts of the two questioned signatures of Ronald X.*
Anyone who has ever signed a form, contract, deed, receipt, or other document in the presence of an official or representative has probably had the experience of being handed a form and asked to “sign by the ‘x.’” The questioned signatures were questioned because of the “unusual formation of the ‘R’” and because “Mr. X. never writes an ‘R’ like that.” It seemed clear to the examiner that the problem feature was not part of the signature, but rather was an “x” used to mark the spot for the signature. Because the writer of the “x” wrote it all in one connected motion, it looks a bit like a fish. It happened that the signature overlapped the “x” and thus allowed a question to be raised. Luckily, ABC’s attorney did not let that challenge go unanswered.

The examiner’s approach was to examine the original questioned document with an infrared viewing device. It is important to examine the original medical record document if it exists. Many examinations cannot be conducted on a non-original document.

The images below were captured from the infrared device to a laptop computer. The ink of the signatures and the ink of the “x” marks react differently to the infrared wavelengths. The “x”s are seen as dark when displayed by the viewer, while the signatures “disappear.” When the writings are on one piece of paper, and the variable factor of the amount of ink on the paper has been accounted for by physical examination of the document, this is proof that the ink used to write the “x” marks was not the same ink used to write the signatures (Ellen, 1997).

![Figure 6a](https://example.com/figure6a.png)  ![Figure 6b](https://example.com/figure6b.png)

Figure 6. – The ink of the “x”s and the ink of the signatures react differently to infrared.

To ensure that the judge accepted this method, a live demonstration was presented in the courtroom. The judge ruled that since the “x” was the only feature of the questioned writing that caused concern, and it was clearly written with another pen, the signatures were genuine and the arbitration agreement would be enforced.

Case #3 involves a truly altered document. In this instance, a dispute arose between two hospitals. A patient was left in a hard collar for transfer from one hospital to another. At the second hospital, the hard collar was removed, and subsequently the patient sustained further injury. The patient sued both hospitals. At the time of patient’s transfer, a photocopy of the original medical record was made. The copy was stamped with a red inked stamp and sent with the patient to the second facility. When the suit was filed, each hospital produced its records. One record should have been an exact photocopy of the other, but it was not.

Hospital 1’s record stated that the patient was transferred with the collar to maintain “comfort and safety.” Hospital 2’s record had only the word “comfort” followed by a blank space. Hospital 1 accused Hospital 2 of altering the stamped photocopy by getting rid of “& safety” after the patient was transferred. Hospital 2 accused Hospital 1 of altering the original record by adding “& safety” after the photocopy was made. Differences in infrared absorption and reflection captured with an infrared viewing device prove that two different inks were used to write the original entry. The case settled before trial in favor of Hospital 2.

![Figure 7a](https://example.com/figure7a.png)  ![Figure 7b](https://example.com/figure7b.png)

Figure 7. – The original document (from Hospital 1) was examined with the infrared viewing device. On the left is the document viewed without the infrared filter. On the right is the document viewed with the infrared filter. The ampersand (“&”) and the word “safety” “disappear” because they were written with a different ink that has a different reaction to infrared. The horizontal lines in the images appear because these images were captured with a video device.

### Document Chronology

A common question about medical records relates to the sequence and chronology of preparation. Was a phrase added at a later date? Was the entire record rewritten? Which number was written on top of the other? These are difficult questions that cannot always be answered or can only be addressed by other fields of expertise. For example, if there is suspicion that a phrase might have been added after the fact, the FDE can use the infrared method already discussed and might be able to show that the phrase was written with a different pen. But if there is no result from the examination, this does not mean that the pens were the same. “Sameness” of ink formulation can only be determined by an ink chemist, and even then, knowing that the same formula of ink was involved does not prove that the same exact pen was used. (Consider the institutional purchase of a case of Bic black ink pens, which would all contain the same formula of ink.) On the other hand, some pens do develop individualizing writing characteristics, and in those cases the FDE may be able to reach an opinion (Cerlanek, 2004).

In Case #4, a doctor was accused of rewriting a multi-page set of medical treatment notes covering a several-year period. It was clear that different pens were used, and the record lacked a uniform appearance that is sometimes present in rewritten records. Again, the solution of this
problem could only be found by examination of the original record—copies would not suffice.

This case was solved by an indented writing examination. Pressure on a writing instrument can cause indentations on papers beneath the actual writing page. There are two methods to make indented writing visible: (1) photography with side lighting; or (2) examination with an electrostatic detection device (Ellen, 1997). Actually, there is a third method: the “Perry Mason” method. Perry Mason TV fans may have seen episodes where Perry or Paul find a pad with indented writing on the top sheet. They rub the side of a pencil lightly over the paper and the white paper is darkened except for the indented areas that are below the surface and stay white. The phone number of the killer is revealed. However, FDEs do not use “destructive” methods such as rubbing pencils over questioned documents. In this case, the side-lighting feature of the video spectral comparator worked well.

Interpretation of indented writing requires analysis of the situation. It is best if the FDE knows the alleged physical circumstances of the preparation of the document. With this information, the examiner can analyze the significance of his/her observations. Also, the statements of all parties should be recorded before the results of any document examination are released to ensure that the parties do not adjust their statements to fit the findings of the examination. This concept is true in any document examination case—not just those involving indented writing.

Many mentions have been made about the importance of original documents. Medical records are an important subset of documents, and their examination requires special consideration. The FDE should be familiar with HIPPA requirements and should be expected to maintain confidentiality. Many examiners can travel with equipment to the site where the documents are housed if that is necessary. It is not unusual for representatives from both sides of a dispute to be present to observe the FDE conducting the examination.

The cases discussed here are just the tip of the document examination iceberg. Looking back to the stated purposes of this article, the first was to acquaint LNCs with document examination in general. Toward that end, a range of possibilities for finding information beyond the textual content of a medical record has been presented. LNCs can look at medical records in a new way, knowing more about what could be hiding there.

The second purpose was to explain how LNCs can most effectively work with FDEs to resolve questioned document issues. It may be the task of the LNC to contact and/or select the FDE(s) to examine a particular set of medical records. FDEs can be located through professional organizations, the Internet, expert witness services, legal directories, and word-of-mouth. As with any potential expert witness, the FDE’s credentials must be evaluated to determine his/her ability to do the work, to qualify as an expert in court, and to communicate clearly to the trier of fact. Important factors might be education and training, experience, proficiency testing, certification, communication skills, and references.

As soon as a question about documents arises, preserve the original documents. Treat them like gold. Make copies for daily use, and store originals in archive-quality folders or sleeves away from light and moisture, and minimize handling. If possible, contact a FDE early in the case to plan the gathering of exemplars and collection of relevant information, to discuss the possible approaches to solving the problem, and to get referrals to other types of experts if they are required. Submit original documents whenever possible. Some examinations can only be conducted with original documents. The examiner may have to qualify an opinion if it is based on non-original documents. The best results are obtained when the best materials are provided.

FDEs and LNCs are working toward the same end: to learn everything that a document has to offer. By doing this well and working together, LNCs and FDEs give the best service to clients and to the legal and medical communities.

References


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In today's health care delivery system, attitudes toward end-of-life care have taken on new dimensions, with death and dying having risen to a level of increased sensitivity and awareness for both the public and health care providers alike. Many health care professionals have not been educated in end-of-life care issues, yet are facing more exposure and challenges in how to deal with end-of-life care wishes of their patients both orally and in writing—through advanced directives. When health care providers fail to implement their patients' advanced directives, they may be faced with liability claims for medical battery, negligence, and malpractice. The intent of this educational article is to provide the legal nurse consultant (LNC) with relevant information and guidelines that the LNC may use when evaluating a medical battery case for merit which alleges a breach in the standard of care relating to advanced directives. This information is not intended to be a substitute for contacting an attorney when questions may arise during the medical review process.

Federal and State Laws on Advanced Directives

In today's health care delivery system, informed consent is a fundamental right of patient autonomy. The doctrine of informed consent is based upon the fundamental right of self-determination and the fiduciary nature of the health care provider-patient relationship. Under traditional tort law, a health care provider who performed medical treatments or procedures beyond the scope of the patient's consent was sued under the intentional tort theory of battery (Croke, 2003).

End-of-life care issues, such as living wills, patient competency/incompetency, substituted judgment, institutional rights and beliefs, and withdrawal of medical
In response to the Cruzan case, the U.S. Congress introduced in 1990 the Patient Self-Determination Act (PSDA), as part of the Omnibus Budget Reconciliation Act, and in 1991 enacted it into federal law. This law underscored the widespread public concern regarding patients’ rights and decisions on life-sustaining treatment. The law does not “create any new rights for patients nor does it change state law” (Guido, 2001, p. 157). The PSDA requires all health care facilities receiving Medicare or Medicaid funding to implement the following regulations:

- Ask the patient on admission to the facility about the existence of an advanced directive;
- Provide written information to all patients on admission to their facility about their rights to accept or refuse medical or surgical treatment/procedures under state law;
- Patients must be given the right to complete an advanced directive, though the law does not mandate that the patient execute an advanced directive;
- Health care providers must document advanced directives in each of the patient’s records;
- Health care facility/providers must provide education to staff, caregivers and patients on advanced directives;
- Health care facility/provider must not discriminate in care for or against patients with an advanced directive;
- Every health care facility must have in place and communicate to staff, caregivers, and patients a policy about implementing advanced directives;
- The health care facility must include a clear and precise explanation of any conscious objection a provider, facility, or provider’s agent may have to follow an individual’s advanced directive. Only the conscious objections permitted under state law may be included in the facility policy (Painlaw, 2004).

### State-Specific Stipulations

Advanced directives (living wills to durable power of attorney for health care) are based upon common law and authorized by state law, (exceptions noted in New York and Massachusetts), and allow competent adults, 18 years of age and older, to direct the medical treatments or procedures he or she would want or not want if they are later incapacitated by illness (Painlaw, 2004). In New York, the Living Will is authorized by law created by New York courts, not through legislative enactments. As a result, there are no specific requirements guiding its use. Similarly, Massachusetts does not have a statute governing the use of Living Wills (Partnership in Caring, 2004). Some states honor oral advance directives. For example, in California, Maryland, and Virginia, only a physician may accept a patient’s oral advance directive (Frederick Memorial Healthcare System, 2002; University of Virginia Health System, 2004).

In July 2000, California’s Natural Death Act and the Durable Powers of Attorney Health Care laws were replaced by the Health Care Decisions Law (AB 891). Even with this...
new law, California law permits “Patients with existing Durable Powers of Attorney for Health Care NEED NOT execute new ones. They remain valid even if executed on or after July 1, 2000. All properly executed Natural Death Act declarations remain valid. Also valid Emergency Medical Services Pre-Hospital Do Not Resuscitate (DNR) forms remain in effect” (Drake & Groszkruger, 2002, p.1). The Federal Health Care Privacy Law—Health Insurance Portability and Accountability Act (HIPAA at 45 CFR 164.524) (2003) does not require any language changes in advanced directives and a person (proxy, surrogate, agent) authorized under his or her state advanced directive law to make health care decisions on behalf of a patient may still receive medical information on that patient. There are restrictions and limitations to personal representatives if a health care provider suspects “domestic violence, abuse, neglect, or endangerment” by the personal representative against the best interests of the patient (Partnership in Caring, 2004).

Laws pertaining to advanced directives may vary from state to state. Health care providers need to be cognizant of federal advanced directive laws as well as their state advanced directive laws to help decrease liability when dealing with end-of-life care issues. State-by-state laws pertaining to advanced directives, as well as state-approved advanced directive forms, are available at pfc@partnershipforcaring.org.

Types of Advanced Directives and Do-Not-Resuscitate Orders

Formats of advanced directives vary by state law. Advanced directives inform health care providers what type of care the individual would like to have or not have if the individual becomes unable to make health care decisions. Two types of advanced directives are the durable power of attorney for health care (DPAHC) and living wills.

The durable power of attorney for health care allows an individual (patient) to appoint someone (agent, proxy, surrogate) to make health care decisions for him or her. It becomes effective (active) when the patient becomes unconscious, loses the ability to make decisions, or is incapable of communicating his or her wishes. The health care agent is responsible for carrying out the patient’s wishes as they are expressed in the advanced directive or in discussions with the agent. The health care agent may not change the patient’s wishes expressed in the DPAHC.

Living wills (e.g. 5 Wishes) only come into effect when the patient is terminally ill, usually defined as less than 6 months to live. The living will provides specific instructions to health care providers about the particular types of treatment or procedures the patient would want or would not want to prolong life. Not every individual wishes to think about the possibility of developing a dementing disease such as Alzheimers, but this form of advanced directive can also be tailored to include the individual’s own personal philosophy about the potential loss of capacity in the future. Oral advanced directives are allowed in some states if there is “clear and convincing” evidence of the patient’s wishes. Advanced directives can be revoked at any time by the patient—verbally or in writing. A physician’s order in a patient’s medical record is required to execute the end-of-life care issues expressed by the patient in the advanced directive.

A Do-Not-Resuscitate (DNR) order (or “no code order”) is another type of advanced directive. The DNR allows a patient to declare that he or she does not want certain resuscitative measures (e.g. cardiopulmonary resuscitation—CPR) performed. DNR orders require specific written orders from a physician (some health care facilities require two physicians to implement a DNR order). Documentation must be noted in the patient’s medical record of the factual discussion between the patient and physician (and family members, if present). If the patient is in a nursing home or is at home, a DNR order alerts health care professionals and emergency medical personnel (EMS) not to perform emergency resuscitative measures and not to transfer the patient to a health care facility for CPR. Depending on state DNR statutes, a patient’s DNR order is not appropriate for use by EMS providers, as most state laws require EMS personnel to attempt resuscitation. A patient may complete a valid Emergency Medical Services Pre-Hospital DNR form and should also wear a bracelet alerting EMS personnel to a DNR order. If a med alert bracelet is worn, it must include the patient’s name and address, as well as the name and telephone number of the patient’s attending physician. All health care providers must know their state’s DNR law and their health care facility’s policy and procedures for implementation of DNR orders (Medi-Smart, 2004).

Common Causes of Action Claims for Non-Implementation

Unlike consent forms, advanced directives “are not used to inform people about risks and benefits before treatment in a particular situation. Instead, they are used to cover refusal of treatment in an unknown future situation, which can lead to unintended consequences” (Valko, 2001, p. 5). Medical battery constitutes an intentional tort—due to the health care provider’s unauthorized treatment (without informed consent) to the patient—and as such, courts may compensate the patient by awarding him or her damages for injuries and other expenses. Punitive damages may also be a plaintiff request. Besides intent, a successful plaintiff must prove the following elements: harmful/offensive contact, lack of consent, causation, and damages. Medical battery must be distinguished from a cause of action claim of “wrongful living.” Wrongful living is a new cause of action claim based upon a health care provider’s intentional or negligent interference with an individual’s right to refuse medical treatments or procedures (Painlaw, 2004).
In most states, health care providers who follow (compliance) an advanced directive in good faith (immunity) are not subject to criminal or civil liability or discipline for unprofessional conduct. Failure to follow an advanced directive may result in the health care provider’s liability for damages and for liability claims of battery, negligence, and malpractice.

In *Leach v. Shapiro* (1984), Mr. Leach, acting as his wife’s agent, brought a cause of action suit against the hospital and physician for wrongfully placing and maintaining his wife on life-support systems, contrary to the expressed wishes of his wife and without obtaining his informed consent. Mr. Leach sought damages for the time his wife was on life support; sought to recover damages for defendants’ alleged conduct that invaded Mrs. Leach’s right to privacy; sought to recover pain, suffering, and mental anguish for Mrs. Leach and family; and sought to recover punitive damages. The trial court awarded summary judgment to the defendants, ruling that Mr. Leach had failed to meet a cause of action claim under Ohio law. An Ohio appellate court ruled that there had been harmful contact when Mrs. Leach was placed on life support without her consent (while in a vegetative state) and reversed the trial court’s rulings. The cause of action claim was remanded for further proceedings. The Court also ruled that a patient has the right to refuse treatment and that such refusal cannot be overcome by implied consent (at 397). The lower court ruling allowed only the claim for battery.

In *Anderson v. St. Francis-St. George Hospital, Inc.* (1996), plaintiff Mr. Winter brought suit against the hospital for damages resulting from the hospital’s failure to follow his “no code blue” order. Mr. Winter had a known history of cardiac problems. He was resuscitated by a nurse (battery) and later suffered a stroke. The Supreme Court of Ohio determined that Mr. Winter’s “wrongful life” cause of action claim was not satisfied—there was no evidence linking Mr. Winter’s stroke with the resuscitative measures performed by the nurse. In its analysis, the court found the that “…the ‘harm’ that was proximately caused by medical professional’s breach of duty in a prolongation of life case was the ‘benefit of life,’ a harm which courts have repeatedly refused to allow compensation” (at 85).

In *Duarte v. Chino Community Hospital* (1999), the California Court of Appeals found no civil liability for a physician who had refused to withdraw life-sustaining treatment against the Duarte’s family wishes and in the absence of an advanced directive. No award for money damages was made for the refusal to comply with the family’s instructions, as they found that their sole remedy was to request the court for an order forcing compliance.

Martin (1999) identified the following various causes of action claims for which patients may recover monetary damages:

- An action for battery if a health care facility or provider fails to comply with the requirements set forth in the PSDA;
- An action for battery if the patient’s refusal of treatment or procedure is ignored;
- An action for pain, suffering, and mental anguish for both the patient and family if treatments or procedures are administered without consent and if the treatment or procedure caused discomfort beyond which the patient would have otherwise suffered.

Various reasons for health care providers not implementing their patient’s advanced directives include:

- Fear of a lawsuit when a patient’s advanced directive is opposed or disagreed with by family members;
- Patient’s wishes were in opposition to the health care provider’s own clinical judgment (health care provider’s belief in using their judgment as the best for their patient, a type of for-your-own- good reasoning);
- The health care provider may not believe in patient autonomy;
- Health care provider’s uncertainty about the meaning and application of the advanced directive;
### Relevant Guidelines for Health Care Providers to Implement When Dealing With End-of-life Care Patient Issues—Reducing Potential Liability

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<thead>
<tr>
<th>Guidelines</th>
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<tr>
<td>Know federal and state laws on advanced directives and ensure advance directive compliance.</td>
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<td>Know policy and procedures relating to advanced directives at their health care facility.</td>
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<td>Health care providers must remember, that, as their patient’s advocate, they have an obligation to be knowledgeable about their patient’s “moral and legal rights” and must work to protect and support these rights.</td>
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<tr>
<td>Health care providers must be aware of the absence or existence of an advanced directive of their patients. Documentation must be recorded in the medical record whether or not the patient has executed an advanced directive.</td>
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<td>The advanced directive must be placed in the patient’s medical record, and all health care providers must be made aware of its existence.</td>
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<td>Health care providers must be cognizant of their patient’s end-of-life care wishes.</td>
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<td>Health care providers should review the advanced directive with the patient or agent to make sure the advanced directive is understood exactly as the patient wishes.</td>
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<tr>
<td>Health care providers must not discriminate against a patient based on whether the patient has executed an advanced directive. Advanced directives should be discussed in the patient’s preferred language. If an interpreter is used, the interpreter must sign the medical document.</td>
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<td>Health care facilities and providers must provide staff, patient, family, and caregivers information on advanced directives.</td>
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<td>Some states mandate that advanced directives be notarized, and state law and forms must be followed.</td>
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<td>If the health care provider is unsure whether the advanced directive meets the state’s requirement, the hospital’s legal department should be asked to review the document (Weiler, Eland &amp; Buckwater, 1999).</td>
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### Guidelines for Use by an LNC When Evaluating a Medical Record and Associated Documents for a Case Alleging Damages Caused by a Health Care Provider’s Failure to Implement a Patient’s Advanced Directive.

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<th>Guidelines</th>
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<tr>
<td>1. Know federal laws on advanced directives as well as state advanced directive laws where the alleged breach in the standard of care occurred. Does the health care facility receive Medicare or Medicaid funding?</td>
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<tr>
<td>2. Review policy and procedures of health care institution relating to advanced directives. Knowing about a health care facility’s policy and procedures relating to advanced directives may assist the LNC in investigating if documentational evidence indicates that the health care facility followed its own P&amp;P. If advanced directives are violated, the LNC may be able to show that the health care facility breached the standard of care relating to advanced directives.</td>
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<tr>
<td>3. Know the alleged cause of action claim(s). Patient or personal representative may have co-existing claims of medical battery, negligence or malpractice.</td>
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<td>4. What was the type of advanced directive executed by the patient?</td>
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<td>5. Was the advanced directive document readily visible in the patient’s medical record?</td>
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<tr>
<td>6. Was there documentation in the patient’s medical record that the physician reviewed the contents of the advanced directive with the patient, family, caregiver, or agent?</td>
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<tr>
<td>7. Was the advanced directive in the patient’s preferred language and, if an interpreter was used, was it signed by the interpreter?</td>
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<tr>
<td>8. Was there any type of patient discrimination noted in the medical record documentation?</td>
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<td>9. Were there any medications taken by the patient that might alter his or her competency status?</td>
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<tr>
<td>10. What were the patient’s medical diagnoses? Are there any known medical diagnoses that may alter his or her state of competency?</td>
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Summary

End-of-life care issues are among the most difficult subjects for health care providers, patients, family, and caregivers to openly discuss. Advanced directives are open to varying interpretations based upon the ambiguity of the advanced directive terminology, state law requirements, and the health care provider's willingness to make subjective value judgments concerning quality of life (Trevor, Barbour, & Schwartz, 2003). To decrease the potential liability for failure to implement advanced directives, it is important for health care providers to know the existence of their patient's advanced directive, review the document with the patient and family/surrogate for clarity of the patient's desired end-of-life care wishes, be willing to implement the advanced directive and—if unable or unwilling—transfer the patient to another health care provider willing to implement the advanced directive, and know federal and state advanced directive laws.

References

In re Quinlan, 70 N.J. 10, 335 A.2d 647 (1976).
Schloendorf v. Society of New York Hospital, 105 N.E. 92 (N.Y. 1914).

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The Advanced Life Support (ALS) Trip Record

M. Thomas Quail, MS Ed RN NREMT

The advanced life support (ALS) trip record is a vital medical record and part of the patient’s hospital medical record when such services are required. ALS monitoring or treatment may be conducted in the course of an inter-facility patient transfer, or as another tier of a properly functioning Emergency Medical Services (EMS) System (Quail, 2004). ALS services may be provided by municipal fire departments, volunteer agencies, and private ambulance companies, or as a hospital-based service. Collectively, this article will refer to these as “providers.” The legal nurse consultant (LNC) must be familiar with the operation of the EMS System, providers, ambulance and regulatory requirements, Emergency Medical Technician (EMT) training and licensure, and specific ALS documentation when performing an ALS trip record review.

Regulatory

EMTs operating at the ALS level of care are authorized to carry and stock approved medications that are subject to state and federal drug laws. In addition, they must comply with each state drug control program, Office of Emergency Medical Services (OEMS), and licensing board, based on the territory where they regularly perform business.

In Massachusetts, for example, any pharmaceutical product approved by the OEMS for pre-hospital utilization must comply with State Regulations, 105 CMR 7000.000 et seq., and the Federal Schedules I - Schedule V, identified in the Control Substances Act of 1970. Massachusetts has incorporated an additional state schedule (Schedule VI), which contains drugs and other medical equipment that require a prescription and are not currently listed in Schedules I - V (CSFM, 2000; MDPH-DCP, 2004; MGL C. 94C).

ALS Training/Licensure

Each state determines the level of care provided to the patient, which may complicate the trip record review from state to state. EMTs operating at the ALS level of care may vary based upon their level of training, certification, licensure of the provider, crew configuration, staffing waivers, special project waivers, treatment protocols, and expanded scope of practice.

In Massachusetts, these entities are included in regulations and overseen by the OEMS within the Department of Public Health (MDPH-OEMS, 105 CMR 170.000). To avoid confusion in EMS regulatory language, the term “licensure” refers to the provider, while the term “certification” refers to the individual EMT. If the OEMS decides upon legal action against the EMT’s certification, the EMT may request an adjudicatory hearing through the Division of Administrative Law Appeals, similar to other licensing boards of registration.

Individual EMT certification in Massachusetts includes: EMT-Basic, EMT-Intermediate, or EMT-Paramedic levels of care. EMTs certified at the Basic Life Support (BLS) level must complete 110-150 hours of didactic and practical skills; Intermediate level (ALS), 260-320 hours; Paramedic level (ALS), 800-1200 hours. The initial training course guidelines adhere to the United States Department of Transportation (DOT) course core content, located on the World Wide Web (DOT, 2004).

Massachusetts providers may be licensed at the BLS or ALS level of care and are required to perform treatment at that level. The provider’s crew configuration must be equal to or greater than the license of the ambulance provider who ultimately transports the patient and staffed by a minimum of two EMTs (MDPH-OEMS, 105 CMR 170.000). Thus, an ambulance licensed at the BLS level will have two EMTs operating at the basic level, and the ideal ALS ambulance will have two EMTs operating at the advanced level.

Treatment

Massachusetts allows a staffing waiver that waives the requirement for two EMTs, certified at the ALS level, to staff the ambulance transporting the patient. Due to limited ALS resources, the waiver was designed to utilize the available resources maximally. Waivers insure that every patient will receive equal access to ALS treatment. Staffing waivers are applied for in advance by the provider; however, staffing waivers may occasionally be implemented for 24 to 48 hours by the OEMS during emergency weather related situations or disasters (MDPH-OEMS, 105 CMR 170.000).

The staffing waiver creates various ambulance crew configurations operating at various certification levels. For example, an ambulance is licensed at the Paramedic level, and today the second Paramedic is sick. The ambulance service may staff the ambulance with one Paramedic and one Basic EMT who provides patient care at the Paramedic level, if a staffing waiver is in place. If the provider has no staffing waiver, that same crew configuration would provide care at the Intermediate level.

In addition, some states have a provision for a special project waiver, defined in the regulations, that allow for EMTs to provide treatment and operate beyond their scope of practice (MDPH-OEMS, AR 5-211, 105 CMR 170.000). The provider must submit an application for prior approval to the regulatory agency identifying the project, explaining why
treatment beyond the EMTs scope of practice is necessary and how that treatment demonstrates an innovative delivery of emergency medical care. A BLS special project waiver would allow for an EMT–Basic to intubate or administer nebulized Albuterol—normally a Paramedic’s function. An ALS special project waiver would allow for an EMT–Paramedic to administer Thrombolytics or provide Continuous Positive Airway Pressure (CPAP)—normally not in their scope of practice (MDPH–OEMS, AR 5–211).

Finally, states may have statewide, regional, or county-approved pre-hospital treatment protocols authorizing EMTs to provide ALS care both within their initial training and beyond, as in an expanded scope of practice. The EMT practicing in an expanded scope of practice must be trained under direct physician oversight, demonstrate knowledge, and prove competency, prior to performing expanded scope of practice treatment. Frequently, critical care transport (CCT) providers are staffed by a registered nurse and paramedic who are cross-trained and authorized to provide expanded scope of practice treatment procedures (MDPH–OEMS, AR 5–211, 105 CMR 170.000). The LNC should inquire with each state-licensing agency for provider and specific EMT information for each entity mentioned.

ALS Trip Record Documentation

ALS providers may also designate another vehicle other than an ambulance to deliver ALS personnel to the scene, including fire apparatus, rescue units, helicopter, watercraft, bicycles, and off-road vehicles (MDPH–OEMS, 105 CMR 170.000). It is unusual to transport a patient to a health care facility using these vehicles; therefore, it is necessary for the LNC to obtain the trip records or patient care reports from each provider who monitored and treated the patient, in addition to the trip records of the provider who ultimately transported the patient to the health care facility.

The basic template for an ALS trip record is similar to the BLS trip record (Quail, 2004), using a combination of check-off boxes and a section for documenting in descriptive narrative format (see Figures 1 and 2 below and Figure 3 on the following page). ALS staff commonly use a second page to document detailed treatment information, consisting of a partially blank page with additional lines to continue the narrative report (Figure 4 on the following page). (See “The Basic Life Support Ambulance Trip Record” in the Spring 2004 issue of The Journal of Legal Nurse Consulting for an in-depth look at the BLS trip record.)

The ALS trip record documentation should include treatment provided to the patient by any layperson or rescuer and the BLS and ALS treatment performed (MDPH–
OEMS, 105 CMR 170.000). ALS treatment and interventions consist of routine standing orders or direct orders after contacting the medical control physician, based on the approved pre-hospital treatment protocols (MDPH-STP). Documentation should include the treatment as either routine or as an emergent life-saving intervention, provided on scene or en route to the health care facility.

The ALS trip record must document a clear and concise report, signed by the physician who provided medical control. A copy of the trip record must be left with the patient at the receiving facility and included in their medical records. ALS treatment and interventions include—but are not limited to—blood glucose readings, fluid therapy, electrocardiogram interpretation, medication therapy, advanced airway management, defibrillation, and cardiac pacing. A thorough documentation on the trip record should include the following details:

- Basic Airway management: Oropharyngeal airway (OPA), Nasopharyngeal Airway (NPA), type, size, route, patient response, person administering.
- Advanced Airway management: Endotracheal Intubation (ETI), Rapid Sequence Intubation (RSI), Laryngeal Mask Airway (LMA), Combi-Tube.
- Fluid therapy: site location, catheter size, type of fluid drip rate, time administered, patient response, person administering.
- Medications: name, dose/rate, route, time administered, patient response, person administering.
- Extrication Equipment: Kendrick Extrication Device (KED), Long Backboard (LBB), Hurst Tools, other special extrication devices and the amount of time it took to extricate the victim.
- Baseline Vital Signs: including capillary refill, pulse oximetry, frequent updates, time recorded.
- Scores: Glasgow Coma Scale (GCS); Trauma: Revised Trauma Score (RTS), Pediatric Trauma Score (PTS).
- Automated External Defibrillator (AED): Analysis, number of shocks delivered if applicable, provided by whom (Layperson, Police, EMS agency).
- Positive Pressure Equipment (PPE): device, settings, assessments, complications.
- Comfort Care/Do Not Resuscitate Program (CC/DNR) or similar type DNR program, where applicable. Include the identification or tracking number on the patient’s bracelet and/or certification.

**Intubation Issues**

A major basis for paramedic malpractice suits are from allegations of improperly placed endotracheal tubes (ETT)

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**Figure 3**

![Trinity EMS Inc. ALS/BLS Patient Care Report](image)

**Figure 4**

![Patient's Medical Information Form](image)
Wang (2004) reported, “Endotracheal intubations (ETI) are recognized as difficult procedures that may result in significant morbidity and mortality if not performed properly. Although ETI has been performed in the pre-hospital setting for over 20 years, recent reports suggest that ETI success rates have not improved.” Dislodged or misplaced ETTs are not uncommon in the pre-hospital emergency environment especially when patients are physically moved or repositioned (AHA, 2000; Bledsoe, 2004, 2000; Katz, 2003; Margolis, 2004; Matera, 2004).

In addition, limited pre-hospital data is available or required to evaluate pre-hospital ETI placement. Wang (2004) contends, “A further hindrance to evaluating pre-hospital ETI is the lack of uniform definitions, terminology, and reporting formats. For example, there is no clear definition of an ETI ‘attempt’; it varies from medical specialty and clinical practice.” Anesthesiologists and Emergency Department (ED) physicians typically define an “attempt” as insertion of the laryngoscope blade, (Wang, 2004); however, some providers define an “attempt” as each time the ETT passes the lip line (Harrison, 2001). The ability to recognize and develop an ongoing ETI Quality Assurance/Quality Improvement (QA/QI) program or an ETI standard of care is greatly lacking in the pre-hospital setting.

In 2002, the American College of Emergency Physicians announced a new policy recommending the use of a carbon dioxide monitoring device as secondary confirmation of ETI placement (ACEP, 2002). Paramedics are required to perform a minimum number of secondary confirmation techniques to verify tube placement after the initial insertion, and as an ongoing verification including documentation throughout the patient transport to the arrival at the receiving facility (ACEP, 2002; AHA, 2000; Bledsoe, 2004; MDPH-OEMS, STP; Margolis, 2004).

The primary confirmation techniques (ACEP, 2002; AHA, 2000; Bledsoe, 2004; Margolis, 2004) are visualization, observation, and auscultation by:

- Direct visualization of the ET tube passing through the cords;
- Observation of the chest rise with assisted positive pressure ventilation;
- Auscultation of the epigastric region for absence of gurgling; and
- Auscultation of the anterior and lateral chest walls for presence of breath sounds.

The secondary confirmation techniques (ACEP, 2002; AHA, 2000; Bledsoe, 2004; Margolis, 2004) utilize electronic and mechanical device combinations of exhaled carbon dioxide (CO2) detectors and esophageal detector device (EDD) that include:

- End Tidal Carbon Dioxide detection device (ETCO2)
  - Qualitative capnometry (end-cap; colorimetric device)
  - Quantitative capnometry (electronic or digital readout)
- Quantitative capnography (continuous waveform capnography)
- Esophageal Detection Device (EDD)
  - Syringe aspiration
  - Flexible bulb (turkey baster (TB))

Additional documentation on the trip record should consist of:

- Breath Sounds (BS);
- measurement of ETT at the lip line (LL); and
- the number of ETT attempts before intubation was successful.

In their Internal Standard of Care Policy on Airway Management Documentation, Boston Med Flight (BMF) Program have identified critical indicators when performing ETI (Harrison, 2001). These indicators include:

- Size of ETT
- Routes: Oral, Nasal, Cricoid placement
- Number of attempts by operators
- Number of failed attempts by operators
- Level of tube, lip or naris line
- ETT has been secured
- Operator who placed the tube
- Breath sounds auscultated in bilateral axillae
- No air movement is heard in gastric region
- Drugs utilized to facilitate intubation
- Oxygen Saturation (SPO2)
- End tidal CO2 level (EtCO2)
- Location where the intubation was performed (on scene, in aircraft)

BMF flight crews are expected to document these indicators on their trip records, based on their definition of an attempt as “when the ETT passes the lip line.” ETI documentation varies from individual EMTs, providers, and protocols which utilize most—but not all—of these indicators when documenting ETI attempts on their ALS trip record (MDPH-OEMS, STP). As with all life saving interventions, confirming ETI placement with ongoing assessment and precise documentation is imperative for all ALS staff to achieve.

In conclusion, the ALS trip record is a unique and essential document with specific entities known throughout the EMS system. The ALS trip record is a synopsis of the greater picture of what occurred when patients require advanced level treatment and interventions, during an inter-facility transfer or in the pre-hospital setting.
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• Trinity EMS, Inc. (Lowell, MA)

References


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After World War II, it was apparent that health care in the United States needed to be expanded and modernized. In 1946, Congress passed the Hospital Survey and Construction Act, also known as the Hill-Burton Act. In return for federal grants and loan guarantees, hospitals were obligated to provide care for free or at reduced cost to indigent patients. Emergency treatment was included in this act.

By 1986, 22 states had enacted laws or regulations dealing with this problem. Despite this, indigent patients were still being denied care. Following reports of a practice commonly known as “patient dumping,” the United States Congress enacted legislation entitled the Emergency Medical Treatment and Active Labor Act (EMTALA). EMTALA was passed as part of the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) (Lizner, 2003).

EMTALA was enacted to ensure public access to emergency services regardless of ability to pay. Enforcement of the EMTALA regulations can result in severe penalties against a hospital or a physician, including fines up to $50,000.00 per violation ($25,000.00 for hospitals with <100 beds). Physician EMTALA fines are usually excluded from malpractice coverage, and there may also be a suspension from the federal Medicare and state Medicaid programs. Congress has charged the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) with enforcement of EMTALA. The actual day-to-day enforcement operations are performed by the Centers for Medicare and Medicaid Services (CMS) and by state survey agencies with whom CMS contracts (Lizner, 2003).

There have been various updates of EMTALA since its enactment. The 2003 Final Rule provided clarification about the changes to ensure uniform and consistent application of the policy, in an attempt to avoid any misunderstanding of EMTALA requirements by individuals, physicians, or hospital employees.

To Whom Does EMTALA Apply?

EMTALA applies to all hospitals that participate in the Medicare program and provide emergency medical care. The Act does not apply to United States military hospitals. Most Veterans Administrations hospitals do not participate in the Medicare program and are thus exempt. In addition, the Act does not apply to physician’s offices, clinics, or independent urgent care centers. Under the new 2003 Final Rule, EMTALA does not apply to the following on- or off-campus facilities: physical therapy, pharmacy, hospital-owned outpatient clinics, skilled nursing facilities (SNFs), hospital cafeterias, or provider-based entities (e.g., on campus physicians’ offices). A key provision of the 2003 Final Rule provides that if a hospital admits an individual for further treatment, after screening the patient for an emergency medical condition, the hospital’s obligation under EMTALA ends (Peth, 2004).

The federal regulations under EMTALA may be divided into “substantive” and “custodial” requirements. There are four legal duties imposed on hospitals under the substantive requirements of the Act:

1. Medical Screening Requirement

A. If an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) comes to a hospital emergency department and a request is made on the individual’s behalf for examination or treatment for a medical condition, the hospital must provide an appropriate medical screening examination (MSE). To determine whether or not an emergency medical condition exists, the MSE is completed within the capability of the hospital’s emergency department, including ancillary services that are routinely available (COBRA/EMTALA online; Peth, 2004).

B. Although “appropriate medical screening examination” was not defined by Congress in the EMTALA Act, the best translation of what was intended is the requirement that the examination and work up is specifically tailored to the patient’s presenting complaint. The work up is an ongoing process that evolves as the evaluation of the patient progresses (Peth, 2004).

C. The medical screening must be provided without undue delay and may not be delayed to inquire about a patient’s payment status (COBRA/EMTALA online; Peth, 2004; State Operations Manual 2004). The entity designated by the hospital to perform the MSE must be identified clearly in its rules and regulations or policies and followed uniformly for each patient who presents for treatment (Peth, 2004).

D. Under the revised definition of the term “emergency department” in the 2003 Final Rule, departments of a hospital are considered “dedicated emergency departments”
if they are held out to the public as places that provide care for emergency medical conditions on an urgent, non-appointment basis (Peth, 2004).

E. Triage is not a medical screening examination. Triage merely determines the order in which patients are seen according to the nature of a presenting complaint. Triage does not identify the presence or absence of an emergency medical condition (State Operations Manual, 2004).

F. Hospital-run ambulance services are exempt from EMTALA if the service operates under community-wide Emergency Medical Services (EMS) protocols or EMS protocols that direct the ambulance to transport the individual to a hospital other than the hospital that owns the ambulance. CMS changed the language of the provisions to read “closest appropriate facility” rather than “closest hospital” (Linzer, 2003; CMS 2003).

2. Necessary Stabilizing Treatment

There are certain stipulations regarding necessary stabilizing treatment for emergency medical conditions and labor. In general, if any individual (whether or not eligible for Medicare benefits and regardless of ability to pay) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must either:

A. utilize the staff and facilities available at the hospital for such further medical examination and such treatment as may be required to stabilize the medical condition; or

B. transfer the individual to another medical facility, as outlined in the regulations (Peth, 2004).

3. Restricting Transfers Until Stabilized

If an individual at a hospital has an emergency medical condition which has not been stabilized, the hospital may not transfer the individual unless:

A. The individual (or a legally responsible person acting on the individual’s behalf), after being informed of the hospital’s obligations under this section and of the risk of transfer, requests transfer in writing to another medical facility; or

B. A physician has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another facility outweigh the increased risks to the individual and, in the case of labor, to the unborn child from effecting transfer; or

C. If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person has signed a certification, after a physician in consultation with that qualified medical person, countersigns the certification; and

D. The transfer is an appropriate transfer (COBRA/EMTALA online; Peth, 2004), as outlined in the regulations.

4. Duty to Accept An Appropriate Transfer

A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or with respect to rural areas, regional referral centers) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities if the hospital has the capacity to treat the individual (Peth, 2004).

Although physicians are not required to take calls 24/7, hospitals are expected to work with their medical staff to develop an appropriate on-call schedule. The 2003 Final Rule clarifies the provisions of EMTALA related to the subject of on-call physicians. The 2003 Final Rule permits physicians to be on-call simultaneously at more than one hospital and to schedule elective surgery or other medical procedures during on-call times, without risking EMTALA sanctions, provided that back-up plans have been established by the hospital (Department of Health & Human Services, 2003; Lizner, 2003; Peth, 2004). An example of a back-up plan would be the development and implementation of an appropriate EMTALA transfer protocol, in the event that the on-call physician is called while performing elective surgery and unable to respond to the emergency situation.

Custodial Requirements

EMTALA stipulates that five custodial requirements of the Act fall to the hospital.

1. Requirements to Post Signs

Hospitals that provide medical services must post signs:

A. specifying the rights of individuals under the Act with respect to examination and treatment for an emergency medical condition and women in labor, and;

B. providing information as to whether or not the hospital participates in the Medicaid program (Peth 2004).

2. Maintenance of Records

The following records must be maintained by the hospital:

A. Medical and other records related to the individuals transferred to or from the hospital for a period of 5 years from the date of transfer;

B. A list of physicians who are on call duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition; and

C. A central log on each individual who comes to the emergency department seeking assistance and whether he or she refused treatment or whether he or she was transferred, admitted and treated, stabilized and transferred or discharged (Peth, 2004).
3. Maintain Adequate Staffing

A hospital must provide adequate medical and nursing personnel, qualified in emergency care, to meet the written emergency procedures and needs anticipated by the facility (Peth, 2004).

4. Reporting Requirement

A hospital is required to report to CMS or to the state survey agency promptly when it suspects it may have received an improperly transferred individual. The receiving hospital must report to CMS or the state survey agency any suspected incidents; failure to report improper transfers may subject the receiving hospital to termination from the Medicare program (Peth, 2004).

5. Policies and procedures

Hospitals must maintain updated policies and procedures that address anti-dumping provisions. The unique policies and procedures adopted by the hospital governing board and administration, in consultation with its medical and nursing staff, must demonstrate the hospital's commitment to comply with the Act. Once a hospital adopts a particular set of EMTALA policies and procedures, that hospital is obligated to abide by the terms it has adopted and its failure to follow its own policies is itself an EMTALA violation (Peth, 2004).

Case Example

After falling and striking his head on concrete pavement, Jimmy Newsome went to the United Methodist Hospital Emergency Department in Pikeville, Kentucky. The Emergency Department physician, Dr. Ronald Mann, noted that Mr. Newsome was disoriented, and ordered x-rays and a head CT scan. Mr. Newsome’s family refused the treatment, having informed Dr. Mann the Mr. Newsome suffered from a seizure disorder that could have caused his fall. Dr. Mann discharged Mr. Newsome to the care of the family with instructions that Mr. Newsome return to the Emergency Department if he became more disoriented.

Mr. Newsome’s condition soon worsened and his family took him to another Emergency Department where he underwent surgery for an aneurysm. Mr. Newsome sued Dr. Mann and the United Methodist Hospital in Federal Court for violating EMTALA by having failed to provide him an appropriate medical screening. Both sides moved for summary judgment.

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The US District Court for the Eastern District of Kentucky held that Mr. Newsome’s EMTALA claim failed to present evidence that the defendants’ actions were based on an improper motive. The court explained that the 6th Circuit required a plaintiff to establish that a defendant hospital failed to provide an appropriate medical screening under EMTALA based on inappropriate feelings about the plaintiff’s inability to pay, race, gender, political beliefs, or social status. (See Cleland v. Bronson Health Group, Inc. 917-F, 2d 266 [6th Cir. 1990].) The Court also noted that Mr. Newsome had presented no evidence that his discharge by the defendants was based on improper motive or similar spite or personal animus (animosity) and, accordingly, granted summary judgment in favor of the defendants and remanded the related state medical malpractice claim to the State Trial Court (The Sullivan Group, 2001).

Summary
Between 1987 and 1997, there were 79 hospital settlements for EMTALA violations. Between 1987 and 1993, 12 hospitals were terminated from Medicare participation based on EMTALA infractions. According to the General Accounting Office (GAO), the OIG had collected more than $5.6 million in fines from 189 hospitals and 19 physicians between 1995 and 2000. During the fiscal year 2001-2002, the OIG collected $630,000 in fines from 26 hospitals and physicians (Lizner, 2003).

This column was intended to be an introduction to the EMTALA requirements of Medicare participating hospitals that provide emergency care. The Department of Health and Human Services Web site provides detailed guidelines for hospitals, physicians, and employees, as well as a detailed State Operations Manual related to the investigative procedures for possible EMTALA violation. The information presented in this article, particularly the substantive and custodial requirements of EMTALA, should function as a starting point for LNCs as they review potential EMTALA violation medical records. The listed references and Web sites of interest provide further information regarding EMTALA regulations.

Web Sites of Interest
American Academy of Emergency Medicine: www.aaem.org
American Medical Association: www.ama-assn.org
American College of Emergency Physicians: www.acep.org
Centers for Medicare & Medicaid Services: www.cms.hhs.gov
COBRA: www.acces.gpo.gov/su_docs/
Emergency Nurses Association: www.ena.org
MDConsult: www.mdconsult.com

References
Specific responsibilities of Medicare hospitals in emergency cases.
COBRA/EMTALA online: Weblaw.com, Regulation 489.24.

Charlotte M. “Charlie” Campbell, BSN RN, has been a practicing legal nurse consultant for 7 years and has an independent consulting business, Legal Nurse Consulting Services, Inc. She has experience with plaintiff and defense, medical malpractice, personal injury, products liability, and toxic torts. She remains clinically active in the ambulatory care setting and emergency department triage. Her varied nursing experience of 22 years has provided her a broad knowledge base that has been an asset as she reviews cases. She is the Past President of the AALNC San Diego Chapter. She can be reached at charliemcl@cox.net.
Limitations statutes set forth the maximum period of time after an event during which legal proceedings can be commenced. Although both civil and criminal proceedings are governed by statutes limiting times of filing, this article will focus on the application to civil actions—more specifically to medical negligence, or malpractice, cases.

Time limitation periods, set by the legislature at the state level, are unique to the state of origin. This can lead to confusion and misunderstanding as to the interpretation and application of the appropriate limitations statute because these laws can differ dramatically from state to state. Statutes of limitation related to medical malpractice are generally shorter than those in other areas of law such as contract, real estate, and other types of personal injury.

Proponents of the shorter statute of limitations for medical malpractice claims believe that shortening the time requirement is necessary as a matter of public policy to avoid undue burdens imposed on the delivery of health care, and also allows timely closure for defendants. This premise is based on health care providers’ contributions to society. Opponents believe that singling out medical malpractice actions for shorter filing time requirements is unfair to victims of medical malpractice, maintaining that political clout and lobbying has given certain defendants such as physicians and insurance companies an advantage over others. Shortened statutes of limitations have been included in the push for tort reform in recent years.

Purpose

Limitation statutes exist as an encouragement to bring legal action in a timely manner, while witnesses are still available and memories are fresh. Justice is difficult to accomplish when essential evidence is no longer available, or when witnesses have died, cannot be located, or do not clearly recall the event.

Interpretation and Application

While the attorney handling the case is ultimately responsible for tracking the statute of limitations to assure that it does not expire, the prudent legal nurse consultant (LNC) will also pay close attention to the dates the statute begins to run and expires. After all, no one wants the time period to expire while the case is sitting on his or her desk. Statutes of limitation are strictly construed, meaning that filing even one day late is too late. While the plaintiff might still try to file the case, the defense will be quick to jump on the opportunity to have the case dismissed.

Interpreting and applying the correct time deadlines can be tricky because many factors influence the analysis and decision. In many states, the statute “on the books” has been challenged and interpreted by the courts, resulting in case law (driven by the judiciary) changing what was written in the statute (as drafted by the legislature). Researching only the statutes of a particular state is a dangerous practice because the case law decisions by the courts will not be evident in that research.

For example, if one researched the statute of limitations as it applied to minors (those under age 18) in the state of Missouri as recently as 1 year ago, the statute would have identified the 12th birthday as the latest date any action could be filed on behalf of the minor (Section 516.105, RSMo (1976) and Section 516.105, RSMo (1994). Unbeknownst to those who are not trained in legal research, Stahler v. St. Lukes Hospital challenged this statute as unconstitutional in that it denied minors their constitutional right of access to the courts to redress wrongs (Strahler v. St. Lukes Hospital, 706 S.W.2d (Mo. Banc 1986). The dilemma presented was that, in order to file a lawsuit, one must be at least 18 years of age; but by that time, the statutory time period for filing had already elapsed. In Strahler, the Missouri Supreme Court decided that a minor should have the same right as an adult to file a lawsuit. In 2004, the state legislature revised the old statute allowing the minor to file 2 years from the age of majority, or until the 20th birthday (Section 516.105(3) RSMo. (2004). Many states still have very short statutes of limitation for minors, notwithstanding the challenges posed in Missouri and several other states.

It should also be noted that many Web sites listing statutes of limitation by state have been found by this author to be inaccurate, resulting in a warning to not rely solely on these types of resources. Thorough research of both statutory and case law is necessary to locate all factors determining the correct statute of limitations.

Terms

Some terms used in conjunction with statutes of limitation have unique meanings when used in this context. Understanding them is essential to applying the statute of limitations correctly. Some of these terms are: run, discovery, repose, toll, minor, and notice.

The statute of limitation “runs” for a limited period of time. It begins and ends at the time set by the laws (statutory
and/or case law) of a particular state. In some states, the statute of limitations begins to run on the date the negligent act occurred; in other states, it does not begin to run until the time when the reasonable person should have discovered that negligence occurred.

This latter stipulation is called a “discovery” provision. For instance, if medical negligence happened to a competent adult in the state of Missouri on June 30, 2004, the statute would begin to run on that date and run through June 30, 2006, because Missouri has legislated a 2-year statute of limitations for adults who claim medical negligence caused them an injury, regardless of when the negligence was or could have been discovered (Section 516.105 RSMo. (2004)).

If the same incident occurred in Illinois, which has a “discovery” provision, the time period does not commence running until the plaintiff should reasonably have discovered the wrongdoing, and then runs until 2 years after that date, assuming the injured party is a competent adult (735 Ill. Stat. Ann., Section 5/13-212 (1992). For instance, if the incident occurred on June 30, 2004, but could not reasonably have been discovered until July 31, 2005, the statute commences running on July 31, 2005, and runs through July 31, 2007. Generally speaking, the discovery provision allows the injured party more time to file the lawsuit. Some states have a discovery provision, and others do not.

In states having the discovery provision, the statute of limitations is not left open-ended. These states also have what is called a statute of “repose,” which places an absolute time limit, notwithstanding the previous extension granted. Statutes of repose can be anywhere from a couple of years to several years, depending on state law. In Tennessee, for example, the statute of limitations is 1 year from the date the incident should reasonably have been discovered, with a 3-year statute of repose (Section 29-26-116 Tenn. Code Ann. (1980). So if an incident occurred on February 27, 2005, but could not reasonably been discovered until March 28, 2006, the lawsuit could be filed without challenge. But if the incident was not discovered until March 28, 2008, the lawsuit would likely be dismissed in favor of the defendant(s).

Even in states with no discovery provision, in which the statute commences running on the date of injury regardless of when the occurrence of malpractice was discovered, the time period can be “tolled” or extended in certain situations, including the existence of the following:

- Continuous treatment for the same condition;
- Fraud, concealment or misrepresentation by the health care provider;
- Retention of a foreign body during surgery;
- Mental incompetence; or
- Minority.

If the health care provider commits malpractice, and the patient continues to be treated for the same condition, the statute of limitations might be tolled and does not begin to run until treatment ends. If the health care provider engages in any fraudulent concealment or misrepresentation, many states permit tolling the statute, thereby allowing the injured party more time to learn of the medical malpractice and file the lawsuit. If a foreign body is left behind during surgery, most states allow tolling the statute until such time as the foreign body should reasonably have been discovered, and some states do not impose a statute of repose as with other actions. If a victim of malpractice is mentally incompetent, the statute is usually tolled until the mental disability is removed.

Generally speaking, statutes of limitations for adults in medical malpractice actions range from 1 to 3 years. Provisions regarding minors differ so greatly from state to state that it is difficult to generalize. Some states have a very short statute of limitations for minors with very little tolling allowed, while some add the adult statute of limitations to the age of majority, using either age 18 or 21. In addition, some states set out specific exceptions for cases related to birth injuries. Careful analysis is necessary to determine exactly how the statutory provisions would apply in a given situation involving a minor.

Many states require advance “notice” of intent to file the lawsuit. Six months, or a specific number of days such as 182, is sometimes the designated time period set forth in those states that have the notice provision. Notice of intent to file the lawsuit must be served on the appropriate party/parties, and the proper amount of time must pass before the lawsuit can be filed. In some cases, the statute of limitations might otherwise expire during this waiting period, so it is tolled until the notice period expires. Close attention must be paid to all the provisions of the notice requirement.

In a recent Michigan case, Burton v. Reed City Hospital, the plaintiff filed the requisite notice of intent on October 18, 1999 (Ingram, L., 2005). The lawsuit was filed on February 10, 2000, 115 days later. Michigan law clearly states that a person shall not commence an action alleging medical malpractice until the expiration of the statutory notice period of 182 days (MCL 600.2912b(1), and MCL 600.2912b). The premature filing of the lawsuit led to a defense motion for summary disposition, which was granted by the trial court, reversed by the Court of Appeals, and reinstated by the Michigan Supreme Court. The plaintiff in this case was barred from successfully pursuing his case; however, it is possible that he might have a cause of action for legal malpractice against the attorney who failed to conform to the statute.

If the victim died as a result of the medical malpractice, the case is often classified as a wrongful death action, in which case a different statute of limitations might attach. In addition, in most situations, the provisions for tolling the statute of limitation due to minority are not applicable because the wrongful death action is brought by the survivor(s), not by the victim.

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Advice to LNCs
1. Be familiar with all aspects (both statutory and case law) of the statute of limitations in your state and in other states in which you are working.
2. Know the differences between statutes of limitations for adults and minors.
3. Know if your state law has a discovery provision, and if so, be aware of the statute of repose.
4. Know what situations will toll the statute of limitations (continuing treatment, concealment, retained foreign body, mental incompetency, minority) in your state.
5. Be wary of Internet sites purporting to know the statute of limitations in many states.
6. Be sure the statute of limitations does not expire while the case is on your desk!

References
Ingram, L, Med-Mal filing did not trigger tolling provision.

Mary Ann Shea, JD BS RN, is an attorney and a registered nurse who has a diversified background in medical/legal issues. She serves as a consultant to attorneys, has authored several chapters in textbooks, and travels extensively presenting risk management seminars to nurses around the country. She served on the American Association of Legal Nurse Consultants Board of Directors from 1999 through 2005, serving as AALNC President from 2003-2004. She can be reached at masheajdrn@aol.com.
As questions abound regarding the approval of prescription medications, the Editorial Staff of *The Journal of Legal Nurse Consulting* thought that a review of the FDA’s drug approval process would be of interest. The following information is a compilation of material published by the Food and Drug Administration.

**Q: Which Branch of the FDA is responsible for Evaluating Drugs?**

A: The FDA’s Center for Drug Evaluation and Research (CDER) evaluates all new drugs before they are approved for general sale to the public. The goal of the CDER is to promote and protect the health of Americans by assuring that all prescription and over-the-counter drugs are safe and effective.

**Q: What Does the Center for Drug Evaluation and Research Do?**

A: CDER’s best-known job is to evaluate new drugs before they can be sold. The Center’s review of new drug applications “not only prevents quackery, but it provides doctors and patients with the information they need to use medicines wisely.”

The goals of CDER are: to ensure that safe and effective drugs are available to improve the health of consumers; that prescription and over-the-counter drugs, both brand name and generic, work correctly; and that the health benefits of available drugs outweigh known risks.

CDER promotes itself as a consumer watchdog for the more than 10,000 drugs on the market to ensure that they continue to meet FDA standards. The center routinely monitors TV, radio, and print drug ads to verify that the ads provide “truthful and balanced information.”

The Center determines the safety and effectiveness of drugs, based on information provided by the pharmaceutical company that conducted the preclinical testing. CDER ensures truth in advertising for prescription drugs and monitors the use of marketed drugs for unexpected health risks. If unexpected risks are detected after approval, CDER takes action to inform the public, change a drug’s label, or—if necessary—remove a product from the market.

**Q: Does the FDA Test Drugs?**

A: FDA does not develop, manufacture, or test drugs. CDER oversees but does not conduct the research, development, manufacture, and marketing of drugs. The CDER bases its opinions and decisions on information submitted by the pharmaceutical company or companies sponsoring the drug.

Drug manufacturers submit full reports of a drug’s studies so that the Center can evaluate its data. The studies answer the question: “Does this drug work for the proposed use?” By analyzing the data, CDER reviewers assess the benefit-to-risk relationship and determine if the drug will be approved. The Center reviewers rely on receiving accurate and complete data from the drug company when making a determination about a drug.

**Q: What Is Required for a Drug to be Approved by CDER?**

A: Under current law, a drug’s sponsor must provide proof that the new drug is effective and safe before it can be approved for marketing. CDER decides, as quickly as a thorough evaluation allows, whether the studies submitted by the drug’s sponsor (usually the manufacturer) show it to be safe and effective for its intended use. When a proposed drug’s benefits outweigh known risks, CDER considers it safe enough to approve. Once a drug receives CDER approval, marketing of the drug will occur as soon as the pharmaceutical company is able to produce and widely distribute the drug.

**Q: What Drugs Are Regulated by CDER?**

A: The Center has oversight responsibilities for prescription, over-the-counter, and generic drugs. This responsibility includes products that many consumers usually do not associate as drugs, such as fluoride toothpaste, dandruff shampoos, and sunscreens. CDER evaluates the benefits and risks of drugs to ensure that consumers have access, as quickly as possible, to promising new treatments.

**Q: Are Generic Drugs the Same as Brand Name Drugs?**

A: Before approving a generic drug product, CDER requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. CDER bases evaluations of substitutability or “therapeutic equivalence” for generic drugs on scientific evaluations. By law, generic drug products must contain the identical amounts of the same active drug ingredient as the brand name product. Drug products evaluated as “therapeutically equivalent” can be expected to have equal effect and no difference when substituted for the brand name product. FDA considers drug products to be substitutable if they meet the criteria of therapeutic equivalence, even though the generic drug may differ in certain other characteristics (e.g., shape, flavor, or preservatives).

**Reference**

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Submission Guidelines

The Journal of Legal Nurse Consulting (JLNC), a refereed publication, is the official journal of the American Association of Legal Nurse Consultants (AALNC). The journal’s purposes are to promote legal nurse consulting within the medical-legal community; to provide both the novice and the experienced legal nurse consultant (LNC) with a high-quality professional publication; and to teach and inform the LNC about clinical practice, current national legal issues, and professional development.

The journal accepts original articles, case studies, letters, and research studies. Query letters are welcomed but not required. A manuscript must be original and never before published, and it should be submitted for review with the understanding that it is not being submitted simultaneously to any other journal. Once submitted, articles are subject to peer review (publication is not guaranteed).

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Manuscripts should not exceed 3,000 words in length. The title page should include the title of the manuscript and the authors’ names, credentials, work affiliations and addresses, daytime phone numbers, fax numbers, and e-mail addresses. One author should be designated as the corresponding author. The title page, the tables and figures, and the reference list should each appear on a separate page. Pages, beginning with the title page, should be numbered consecutively.

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10. The pages are numbered consecutively, beginning with the title page.
11. Photographs are black-and-white glossy prints.
12. One author has been designated as the corresponding author.
The challenges of owning a business are many: developing a business plan, marketing services, astutely handling financing, buying the right software and hardware, hiring subcontractors and employees, developing and keeping strong relationships with clients, and avoiding ethical conflicts, to name a few. This text is designed to help legal nurse consultants with these challenges.

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