LEGAL ISSUES IN THE CARE OF PRESSURE ULCER PATIENTS:
KEY CONCEPTS FOR HEALTHCARE PROVIDERS

A consensus paper from the International Expert Wound Care Advisory Panel

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Pressure ulcers are a significant problem across all healthcare settings in the United States. Annually, 2.5 million patients are treated in acute-care facilities for pressure ulcers. Patients with pressure ulcers are three times more likely to be discharged to a long-term care facility than those with other diagnoses. In addition, pressure ulcers are more likely to occur among those over age 65. Since the U.S. population aged 65 and older is expected to double within the next 25 years, the number of people with pressure ulcers probably will increase exponentially. By 2030, almost one out of every five Americans – some 72 million people – will be 65 years or older. The age group 85 and older is now the fastest growing segment of the U.S. population.

Medicare has looked at opportunities to grow better quality health care for the 90 million elderly, disabled and low-income Americans who use their programs. Faced with the financial situation that the Part A trust fund is projected to potentially be depleted by 2017, the challenge has been to improve quality for those beneficiaries while avoiding unnecessary costs. This has resulted in review of Medicare payments and new coverage decisions. In FY2007 alone, there were 257,412 Medicare beneficiaries with pressure ulcers, for which the average DRG payment per case was $43,180. The net cost of caring for pressure ulcers is estimated at $11 billion per annum. With Medicare expenditures projected at $486 billion in 2009, increased attention to pressure ulcers and the impact they place on the healthcare system has necessitated changes in healthcare policy.

As one of the largest purchasers of health care, Medicare desires quality for its beneficiaries. Several projects aimed at improving quality have been rolled out over the past several years. Long-term care was the first setting to have substantial regulations regarding pressure ulcers. With the revision in 2004 of guidance for surveyors – Tag F-314 – came renewed interest in pressure ulcer prevention and treatment. In 2005, pressure ulcers became reportable in acute care in certain states. With this increase in awareness, specific pressure ulcer collaboratives began to spring up as providers joined together to improve the pressure ulcer incidence within their locales.

Transforming Medicare from a passive payer to an active purchaser of higher quality, more efficient health care meant that the government needed to build policies that would support greater value for the costs associated with quality outcomes. To further support Value-Based Purchasing, one of the demonstration projects is the electronic health record (EHR), while another initiative is Hospital-Acquired Conditions and Present on Admission indicators.

There is universal agreement that we want quality medical care. The challenge of delivering quality care to our aging population, some of whom have multiple comorbid conditions, is highly complex. The Federal Register states that pressure ulcers can “reasonably be prevented through the application of evidence-based guidelines.” While “reasonably preventable” does not mean “always preventable,” the potentially significant implications of the statement “reasonably preventable” have been neither fully appreciated nor firmly established. There remains a lot of legal uncertainty about the true impact of this new Federal Register statement in the medical liability context. Healthcare workers and institutions are fearful of the increased risk of litigation, and fear for the financial viability of their organizations and their reputations as public reporting becomes the norm. The monetary losses resulting from litigation may be secondary to the loss of reputation and public scrutiny in the press, which can devastate staff morale and turn clients away at the door.
For all of these reasons, it is no exaggeration to state that it is more important now than ever for healthcare providers to fully understand, appreciate and adapt to the legal issues that arise from the care of patients with pressure ulcers. The interrelationship between medical decision-making, reimbursement and legal issues relating to pressure ulcers has never been greater. The medical-legal landscape itself has never been more treacherous or subject to change. The financial and personal risks from ignorance or misunderstanding of these legal issues have never been higher. Simply put, in today’s legal, regulatory and medical environment, no healthcare practitioner can both provide quality care to patients with pressure ulcers and provide financial and legal security to himself and his employees without full knowledge and accurate understanding of the legal issues inherent in that undertaking.

Lawsuits over pressure ulcers are increasingly common in both acute and long-term settings with judgments as high as $312 million in a single case. Why is this? The readily apparent nature of pressure ulcers is important because it means that, unlike many other medical complications, they never go unnoticed by patients and their families. The uniquely disturbing visuals that pressure ulcers create add to the financial potential of even the most medically meritless claims – and make even the frivolous ones appear to have some financial worth to the plaintiffs’ attorneys. One basis for the implicit yet incorrect assumption that pressure ulcers develop exclusively from improper care is the fact that many, if not most lay people do not appropriately view their skin as an organ. People understand and appreciate that individuals, particularly the elderly, can suffer from heart failure or kidney failure without there having been any medical negligence. “Skin failure” is not looked upon with the same degree of understanding. Implicit is the incorrect assumption that the development of pressure ulcers must have resulted from the lack of quality care.
Healthcare workers attracted to the industry for altruistic reasons may find inclusion in litigation to be a devastating and completely unexpected development. As already discussed, patients and their family members may engage in litigation primarily for the purpose of gaining answers to questions, and may perceive that they are suing institutions rather than people. However, it gets personal when the individuals within institutions are deposed and perhaps may have to testify in court. (See “Deposed: A Personal Perspective.”) Clinicians may even have the embarrassing experience of being publicly served with a subpoena by an armed law enforcement officer at their place of business or home.

The petition filed by the plaintiff states the way in which individuals were specifically negligent in their care of the patient. For example, plaintiffs may name specific non-physician healthcare workers (including administrators). Even though they may be employees of the institutions, they are still individually liable. However, their employer (the institution) is vicariously liable for their conduct as well. What this means is that monetary damages can be recovered from the institution. In many cases there is no attempt to seize the financial assets of healthcare professionals because their employer is an easier target for recovering damages. It is naive, however, to believe that healthcare professionals face no substantial risk when named in a lawsuit. They not only experience financial exposure, but also the risk of losing their professional license. This is especially true for consultants who are not employed by the institution.

Litigation becomes a very personal experience for any healthcare workers named in a suit, even if no personal assets are at stake. When personal assets are at stake, they could include cars, jewelry, bank accounts, etc. For all healthcare workers whose personal assets are at risk, the threat of litigation may dictate the manner in which all personal property is handled throughout their professional lives. This is an especially common issue for physicians. Involvement in litigation can be sufficiently traumatic to cause some healthcare workers to leave the industry, even when the outcome of litigation is favorable.

It is perceived that the economic impact of litigation is only due to financial settlements or judgments. However, once a suit is filed, the economic impact begins immediately. Preparing for litigation is time-consuming, as old medical records and background materials must be reviewed. Meetings with legal counsel, depositions or testimony at trial may all require taking time away from patient care. The average case takes more than two years to resolve if a jury trial is necessary. This means clinicians who have moved on to new job opportunities may continue to be involved with legal proceedings. Independent practitioners must report all suits in which they were named regardless of the outcome — for the duration of their career. National reporting initiatives make all judgments public information. This means for many clinicians a law suit is never “over.” Settlement amounts are generally or often confidential. They are therefore, once again, generally or typically not publicly available.

**LEGAL ISSUES IN THE CARE OF PRESSURE ULCERS: KEY CONCEPTS FOR HEALTHCARE PROVIDERS**
In December 2008 a nine-member panel of invited experts was convened in Chicago to consider the current pressure ulcer regulatory and legal environment. The panel was tasked with assessing the various legal implications of these policies and identifying key concepts for helping healthcare professionals. The panel identified specific areas of exposure and ways in which healthcare workers can reduce their risk. The following summarizes the panel's discussion and recommendations.

Preventive Legal Care

Even if you prevail in defending yourself or your institution against a suit, the economic and personal costs are considerable. This means that time and money invested in PREVENTIVE legal care is well worth the cost to an institution. For decades healthcare practitioners have made it one of their highest priorities to emphasize the importance of preventive health care, to both manage medical costs and minimize healthcare-related risks to their patients. However, those same practitioners have often steadfastly failed to apply the same concepts of preventive care to their own legal issues and risks. All of the same justifications that medical providers use to convince their patients to engage in preventive medical care apply to the medical providers themselves with respect to preventive legal care. It is preventive legal care which, more than anything else, will help a healthcare practitioner to control, understand and ultimately minimize his or her legal risks and costs.

Institutional Areas of Vulnerability
In this section, we identify and describe eight key areas of vulnerability for institutions.


KEY CONCEPT: Healthcare facility policies and procedures are “guidelines” not rules or regulations—and should be created and treated as such. These guidelines should be carefully crafted and periodically reviewed with regard to their clinical currency as well as their legal and healthcare implications. Words such as "never," "must," "shall," and "immediately" should be rigorously avoided.

The word “policy” itself does not have a specific legal meaning. The problem arises when the legally vague word “policy” is used interchangeably with words such as “rules” or “regulations,” which (a) do have legal meaning and (b) imply mandatory and exact compliance in the mind of lay people. The use of “guidelines” is better for both reason (a) and particularly (b). If the facility has a written “policy” that pressure ulcer patients “must” be turned every two hours, failure to do so even one time potentially represents a breach of the standard of care. In this example not only should healthcare organizations formulate “guidelines” versus “policies” to assist rather than specifically regulate care, they should also carefully review their word selection. It is the use of the word “must” that causes problem (b) above.
In written guidelines, patient care plans, or any other documented expectations of care, avoid absolute words such as “always,” “never,” “must,” “shall” or “immediately.” Another example of an incorrectly written statement might be, “Abnormal lab values must be reported immediately.” That means drop everything—including a life-threatening emergency—to report the abnormal values or the hospital has failed to meet its own standard of care. The literal meaning of the words is what a plaintiff’s lawyer will advocate against you when it is to the plaintiff’s benefit to do so. And why not? You wrote the policy. You chose the words. Such statements should be written carefully to allow the rightful role of clinician judgment. A better way to phrase the example statement could be, “Report abnormal lab values in a timely fashion.”

2. Assessing Compliance with Prescribing Rules

KEY CONCEPT: Healthcare organizations and clinicians should review standing orders to ensure that they are in compliance with prescribing regulations.

Institutional practices need to be evaluated to ensure that they are in compliance with prescribing regulations. These should be routinely re-evaluated as well to ensure they remain in compliance with regulations, which change relatively often. For example, if a wound is debrided using an enzymatic debriding agent, a healthcare provider with prescriptive privileges such as a physician, nurse practitioner, or physician’s assistant, must sign the order, since such agents are pharmaceuticals. Some facilities may have evolved “standing orders,” incorporating enzymatic debriding agents, that nurses can then implement without a provider’s signature. However, such a practice would be out of compliance with prescribing laws.

3. Changing and Practicing Within Scope of Practice

KEY CONCEPT: Healthcare institutions should ensure that caregivers are practicing within their scope of practice with regard to pressure ulcer assessment and documentation.

As part of new CMS policy, pressure ulcers will be assigned ICD-9 (International Statistical Classification of Diseases and Related Health Problems) diagnosis codes according to their stage as well as location. Although pressure ulcer staging (which is a part of routine assessment and documentation) has long been the purview of nurses, this billing policy change could have legal implications, since only advanced practitioners and other CMS-defined “providers” can make medical diagnoses. CMS defines a provider as a physician or any qualified healthcare practitioner who is legally accountable for establishing the patient’s diagnosis.12

As a result, physicians now need to change their practice and incorporate pressure ulcer staging along with location into their notes. Given the limited physician knowledge about pressure ulcers reported in the literature,13 the need for educating physicians to acquire this competency is paramount. Clinicians at the generalist level also need to understand that they will be held accountable for doing a basic skin assessment and pressure ulcer risk assessment. For example, staff nurses might incorrectly delegate these assessments to the wound care specialists rather than understanding their responsibility for doing these assessments.
Pressure ulcer *assessment* cannot be performed independently by licensed vocational nurses or licensed practical nurses. However, institutions may have evolved practices delegating wound assessment responsibility precisely to these staff members. Clinicians can expose themselves to legal action by accepting responsibilities exceeding their scope of practice. Likewise, facilities may be found liable by routinely requiring such actions of their staff.

Healthcare institutions should be careful not to have specific written instructions mandating activities—not just beyond the scope of practice. You never want to institutionally strip a clinician of his or her clinical judgment. Again, since facility “policies” do change, written instructions and guidelines should be reviewed periodically and whenever CMS regulations change.

Particular emphasis should be given to how the institution handles these four main questions:

a. What constitutes a diagnosis?
b. Who is allowed to make a diagnosis?
c. Who documents or assesses pressure ulcers?
d. Who formulates the pressure ulcer plan of care?

### 4. Managing Expectations and Communicating Carefully

**KEY CONCEPT:** The *people* most likely to be asked difficult questions (regarding why, how and when pressure ulcers develop) by patients and their families are not always in the best position to provide an accurate big-picture response. Front-line staff should be trained in how to delegate questions professionally and with compassion.

All hospitals and many other healthcare organizations should have risk management or quality management teams that can assist clinicians in communicating with patients or family members. Clinicians should communicate carefully but openly with patients and family members.

**Invest in communication skills for all levels of the staff. Each individual needs to know what level of communication they are responsible for.**

While the high dollar amounts in certain healthcare lawsuits suggest that litigation is ultimately about money, attorney Kevin W. Yankowsky of Fulbright & Jaworski, LLP, in Houston, Texas, says that most medical lawsuits begin as a search for answers. Family members often assert that they were not informed that their loved one had developed a pressure ulcer or that the risk factors were not explained to them. Healthcare practitioners are urged to be open and honest with patients and their families to help manage expectations. Before pressure ulcers develop, family members of critically ill or terminal patients must understand the end-of-life process and the likelihood that skin breakdown may be part of the dying process. The Skin Changes at the End of Life (SCALE) document was developed in 2008 by a panel of key opinion leaders. The panel agreed that, like any other organ of the body, the skin (the largest organ) is subject to a loss of integrity at the end of life.  

Patient expectations and answers to their specific care questions should be managed by the physician or a designated, trained member of the facility, such as a representative from the quality or risk management department. Patients and family members should be informed of the risk factors that could
lead to a pressure ulcer and necessary risks that sometimes arise that could also lead to skin breakdown. Many times providing the best care to an elderly patient could mean balancing a large number of risks. Sometimes actions must be taken that actually increase pressure ulcer risks because they are necessary to advance another legitimate care goal. For example, the clinician’s decision to address the nutritional needs of a malnourished patient by keeping him on oral feeding in order to restart his gut rather than TPN may be justified despite the fact that it might increase the risk of a pressure ulcer. Notification and education of the patient and family of pressure ulcer risks should be noted in the patient’s chart. The concept of the skin as one of the many body organs affected by disease may be helpful.

Family members also should be notified when skin breakdown occurs, ideally by the physician. In New Jersey, notification of family about a facility-acquired pressure ulcer is already required by law in all care settings.18 Expecting busy bedside nurses to respond appropriately to detailed questions regarding the etiology of skin breakdown in patients with complex conditions is unfair to nurses and patients.

In reality, however, nurses and other clinicians may be put on the spot by a patient or family member. To help prepare for these situations, clinicians should be trained in terms of what level of information they can appropriately communicate to patients and families. Even if a question exceeds a clinician’s expertise, staff should learn how to acknowledge the family’s concern but also refer the question to the appropriate person.

For instance, a bedside nurse may be asked by a family how a patient with a broken leg developed a pressure ulcer on his buttock. The bedside nurse might reply, “I’m not the correct person to answer your question. I know who is, though.” The family may perceive this answer as being dismissive or incompetent, rather than a well-meaning attempt to refer the question to the appropriate clinician. In order to delegate a question and
remain sensitive to the urgency of the family's rightful concerns, the clinician’s reply should contain three parts:

**Part 1.** Acknowledge that the question is important and legitimate. “I understand that this is an important question.”

**Part 2.** Explain that in order to get the proper answer, the question must be delegated to a specific person. Be sure to name that person. “I’m not the correct person to answer your question, but Dr. Johnson is.”

**Part 3.** Take immediate action and tell the family what is being done. “I am going to get him right now” or “He’s not here right now, but I am going to leave a message for him.” The clinician must ensure prompt action.

Put more simply, the clinician should say, “I appreciate your concern, however, I cannot answer your question. But I do know who can. I am going to contact that person for you.”

Finally, be sure to document notification of the family in the chart.

In all communications with patients and their families, it is important to appreciate the legal implications of word choice. Even casual verbal statements by a healthcare professional can be interpreted to mean more (or less) than was actually intended. For example, a simple expression of sympathy such as “I’m sorry,” could be interpreted as an admission of responsibility. Clinicians also should avoid statements that might be perceived as blaming other caregivers.

A structured communication technique known as SBAR (Situation-Background-Assessment-Recommendation) can be helpful for healthcare teams to communicate effectively. Learning how to be an effective communicator takes training and practice, so all levels of staff need education and role-playing exercises to learn what should be communicated to patients and families and how.

### 5. Clinical Documentation

Clinicians rely on the chart, the patient and the clinical team simultaneously for patient information. They know omissions in the chart can occur without necessarily impacting the quality of care received. However, legally, plaintiffs frequently argue “what was not documented, was not done.” Here, the legal system is imposing an unreasonably high standard for clinicians. For example, from the legal perspective the chart should note every time the patient was turned, his wound cleaned, the patient instructed on wound care, and so on. The notion that every such event can be accurately and fully documented removes the focus from patient care and puts it on creating perfect paperwork.

Documentation must be balanced with patient care. Good documentation must be comprehensive, consistent, concise, chronological, continuing and also reasonably complete. This means documenting regular skin assessments, pressure ulcer measurements, turning, the use of any special products such as a support mattress or devices and conversations with the patient or family relating to the pressure ulcer.
Most litigation occurs long after the event – sometimes years later. Thus the chart becomes the “spokesperson” for the care rendered by the entire clinical team and the institution. For that reason, clinicians need to be mindful of not just the chart’s present role in a patient’s care, but also in its potential future role in litigation.

Many clinicians do not realize that the chart will be compared to the healthcare facility’s written regulations, policies, procedures and guidelines. For example, if the facility policy requires turning a patient with a pressure ulcer once every four hours, failure to do that even once constitutes a breach of policy. While that may sound relatively benign to a clinician, the opposing counsel will argue that this violation of the facility’s own policy represents substandard care.

The right tools can streamline documentation. Clinicians also need to know there is a difference between a skin assessment and a pressure ulcer risk assessment and that both need to be performed.

Since documentation is a broad topic, it will be broken down into skin assessments, risk assessments, pressure ulcer assessments, charting, electronic recording, photography and staging.

a. Skin Assessments

**KEY CONCEPT:** Skin assessments should be conducted regularly and in accordance with the guidelines of a particular institution. Note that the skin assessment is different from the risk assessment and both must be performed.

Skin assessments should be conducted upon admission to a facility as well as at regular intervals, with results documented in the patient’s chart. There is no clear consensus in the clinical community regarding minimum standards for such an assessment. Based on Tag F-314, there are five key parameters that any skin assessment performed in a long-term care facility should address:\(^\text{15}\)

- Temperature
- Moisture
- Color
- Turgor
- Integrity

When skin integrity is compromised, the correct etiology of the alteration needs to be documented in the medical record by the licensed provider. Ongoing assessment should be recorded in the medical record at intervals consistent with the care setting. For example, in acute care, these skin assessments could be daily, while in home care, skin assessment might occur with every registered nurse visit.

Pressure Ulcers – With the recent change in CMS billing, which denies payment of the higher diagnostic category to hospital-acquired pressure ulcers, documentation of skin assessment and pressure ulcer existence at the point of admission has new implications. This shifts even more accountability for skin assessment to physicians. There are two main
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b. Risk Assessments

KEY CONCEPT: Pressure ulcer risk assessment guidelines for an organization should be worded in ways that are compatible with federal terminology.

One of the best known and most widely used pressure ulcer risk assessment tools is the Braden Scale, developed by Barbara Braden and Nancy Bergstrom in 1988. It has been well studied and is generally regarded as valid and reliable, but with some limitations.

Clinicians caring for patients with pressure ulcers should be thoroughly familiar with their facility's pressure ulcer risk assessment process and tool. Wording that mirrors CMS terminology ensures congruence with federal and state regulations for the particular practice setting (e.g., MDS in long-term care; Oasis in home care). Using forms (checklists, multiple choice) can make things more convenient for busy clinicians. Remember that pressure ulcer risk assessment is more than just a number or a tool. It is a clinical decision that prompts intervention(s) that hopefully will prevent the occurrence of pressure ulcers.

c. Pressure Ulcer Assessment

KEY CONCEPT: The importance of reasonably complete documentation cannot be overemphasized. Medical record documentation from any provider involved in the care and treatment of the patient may be used to support the determination of whether a condition was present on admission. A “provider” means a physician or any qualified healthcare practitioner who is legally accountable for establishing the patient’s diagnosis.

The frequency of pressure ulcer documentation varies by care setting. In acute care, pressure ulcers require daily or more frequent monitoring, which mandates frequent chart entries. The following recommendations from Tag F-314 are also useful as a guide to practice in acute care. For example, the chart might state:

- Dressing status (note if changed or not, whether intact or not and whether there is any apparent leakage)
- Observation of peri-ulcer area
- Presence of possible complications, including duration, infection or increasing ulceration
- Pain, analgesia and the patient response
d. Charting

**KEY CONCEPT:** Good pressure ulcer documentation should include a wound description, measurement and wound care treatments as well as documentation of pressure redistribution devices and techniques, including support surfaces and turning schedules.

The patient’s chart is intended to be used contemporaneously with two other equally important sources of information: the patient and the clinical team. For example, if a patient’s wound size is not documented on a particular day, then that chart omission is clinically irrelevant because anyone with access to the patient can easily see the size of the wound. However, in litigation that may occur years after the event, the plaintiff may argue that failure to document wound size on a particular date means that the wound was neglected that day, adversely impacting the patient’s care.

When it comes to clinical documentation, the “C”s have it. Good documentation is consistent, concise, chronological, continuing and reasonably complete. However, good documentation must be balanced with good patient care. For example, in the course of caring for a patient with a pressure ulcer, events such as explaining heel pressure offloading to the patient’s family, regular turning of the patient or daily skin assessments are not always entered into the chart. Documenting every clinical action is not only an unreachably high standard, it could compromise patient care if clinicians become more focused on creating perfect charts than caring for patients.

Some facilities state that they practice “charting by exception,” recording only those events that deviate from the norm but not documenting all standard care practices. Clinicians should be cognizant that the charts they are handling today may be studied in the future in courts of law and that legal decisions have often been based on what is *not* in the chart.

Be consistent, document factual statements and use approved abbreviations. Would you recognize this patient when you read the note seven years from now? Did you record adverse events? Are the notes legible?

The quality of documentation may make the difference between a plaintiff attorney’s willingness to pursue potential claims and a decision to decline a case.23

Assessment of a pressure ulcer is more than staging. Minimal documentation of pressure ulcers, as described in Tag F-314 for long-term care facilities, includes (besides staging), location, exudate, pain, signs of infection and wound bed characteristics, such as type of tissue and surrounding skin.15
e. Electronic Health Records (EHRs)

**KEY CONCEPT:** Electronic record systems may not accommodate the documentation needs of pressure ulcer patients.

The Health Information Technology for Economic and Clinical Health Act (HITECH) was part of the recently passed federal “stimulus” package (February 2009).17 Under this mandate, The Secretary of Health and Human Services will create a national health information network driving the adoption of electronic health records. The program includes incentive payments by CMS through Medicare for the “meaningful use” (a term yet to be defined) of certified Electronic Health Record (EHR) technology by eligible professionals and hospitals.

Hospitals that meet the “meaningful use” definition will receive incentive payments, and those that fail to do so by 2015 will see their Market Basket Adjustment percentage reduced until it is non-existent by 2017. Thus, the use of EHRs for pressure ulcer documentation inevitably will increase.

Unfortunately, rigidity is a problem with many electronic record systems. Many computer systems become electronic versions of checklists. Checklists are poorly suited for monitoring the continuum of care because they do not allow for the unique needs of an individual patient. They rigidly require specific documentation at specific intervals regardless of whether it is appropriate.24 They encourage “paper compliance” rather than patient-centered care.

An example of the difficulties of electronic records in this setting is the “every-two-hour turn” checklist.24 This type of record sets an expectation that can only be fulfilled by the proper number of checked boxes. Should that expectation not be met, even once, it can be used to argue that the patient received substandard care.

A properly designed EHR can be a highly useful tool for tracking wound progress, standardizing documentation, facilitating photographic storage and assessing the cost benefit of various products. The most useful electronic systems were designed specifically to meet the needs of wound care. Unfortunately, many standard hospital EHRs are poorly designed for wound documentation. For example, some limit typed “text” descriptions of unique findings, restricting staff to select from limited standard “menu” options. Furthermore, while the documentation may make sense when visualized on the computer screen, when the records are later printed out, it may be impossible to determine which description belongs to which wound. In some situations, handwritten notes may be superior to a poorly designed EHR. Healthcare organizations need to know what the paper version of their “paperless” system will look like before they select a product.

On the other hand, studies published in 2009 by Rennert, Golinko, Brem and colleagues, are showing positive patient outcomes with the use of the wound electronic medical record (WEMR), designed specifically for wound documentation. In one study, 76 percent of wounds with more than two consecutive WEMR entries showed a decrease in area at their final visit.25 Another study found that use of an objective documentation system such as the WEMR may help alert clinicians to subtle wound changes that require aggressive treatment.26
f. Photography

**KEY CONCEPT:** Photography has advantages and drawbacks in terms of litigation; know the guidelines set forth by the organization.

Without control, photography can be a legal detriment. The National Pressure Ulcer Advisory Panel (NPUAP)\(^27\) and the Wound, Ostomy and Continence Nurses Society (WOCN)\(^28\) neither recommend nor discourage the use of photography as a documentation tool for pressure ulcers, in that photography poses both advantages and drawbacks. Both NPUAP and WOCN recommend that organizations have written guidelines about if and when photography is to be used. Such guidelines should include, but not necessarily be limited to, these points:

- Obtaining informed consent
- Who takes the photographs, when, and under what conditions
- Type of camera equipment (digital versus other formats)
- Patient identifiers
- File maintenance and storage
- Under what conditions and how photography is released to families

Photo techniques that maximize correct imaging are well covered in three recent journal articles published in *Advances in Skin and Wound Care* \(^29, 30\) and *Today’s Wound Clinic*.\(^31\)

g. Staging

**KEY CONCEPT:** Training in the use of NPUAP pressure ulcer staging is recommended for all healthcare professionals, including physicians. When in doubt about a pressure ulcer's stage, all clinicians are encouraged to “describe what they see.” Careful attention should be given to the discharge ulcer assessment.

Remember that pressure ulcer assessment is more than just staging. Since staging has new billing implications and physicians are now being held to increased accountability in the documentation of pressure ulcer staging in acute care facilities, a detailed discussion of staging is included here as part of considerations in the overall documentation process.

The most commonly used system in the United States for staging pressure ulcers is that promoted by NPUAP,\(^12\) which was updated in February 2007.\(^33\) Pressure ulcers are staged I to IV with two additional categories added in 2007: “unstageable” and “suspected deep tissue injury (sDTI).” Staging is intended to describe the depth of tissue injury at the time the ulcer is assessed. Although the system is referred to as a “staging system,” ulcers do not progress up or down the numerical scale. This misconception of pressure ulcer progress “through the numbers” has legal implications.

Revised international pressure ulcer guidelines, which are being jointly developed by NPUAP and the European Pressure Ulcer Advisory Panel (EPUAP), are expected to be released some time during 2009.
CMS has classified Stage III & IV pressure ulcers as major comorbidity complications (MCC). If present on admission, these ulcers will be accounted for in the Medicare Severity Diagnosis Related Groups (MS-DRG) adjusted payment for care. Conversely, CMS has proposed to not include Stage I, Stage II or unspecified (i.e., you did not write the stage), or unstageable pressure ulcers in the comorbidity/complication classification (CC). This means that the way in which ulcers are staged has significant implications with regard to reimbursement in acute care and perhaps with regard to liability. Clinical documentation must be provided by the CMS-defined provider, and final staging at time of discharge is crucial for CMS billing purposes.

Some staging issues to consider:

- “Unstageable” ulcers are those in which the presence of necrotic material or slough prevents the assessment of the tissue base. Since Stage II ulcerations, by definition, exclude necrotic material or slough, “unstageable” ulcers must involve full thickness tissue injury and will eventually be staged as either III or IV after debridement. Regardless, if the ulcer is classified as “unstageable” at the time of hospital discharge, it will not qualify for the MCC reimbursement.

- Suspected deep tissue injuries (sDTIs) often change into Stage III or IV ulcers as tissue destruction evolves and the damage that began deep within the tissue by the bone becomes visible at the skin surface and ulcerates. The defining characteristics, natural evolution and prevention, as well as treatment of suspected deep tissue injury as a pressure ulcer stage have yet to be fully described and understood in the literature. Should staff members modify their initial assessment of the appearance of the ulcer over time, perhaps revising from Stage I to sDTI and then to Stage III or IV, the numeric nature of the system creates the impression that the ulceration is worsening, implying negligent care, when instead, an injury is evolving along a predictable path.

- Suspected Deep Tissue injury (sDTI), although recognized in the literature, is not recognized by CMS as a billing category. Unless the sDTI evolves and can then be staged as a Stage III or IV ulceration prior to discharge, the additional care required will not qualify the patient’s medical record for the MCC payment.

- At the present time, under MDS 2.0, caregivers in long-term care are instructed to use “reverse staging” to describe healing ulcerations even though CMS acknowledges this is physiologically incorrect. Unstageable and suspected deep tissue injury cannot be used on MDS 2.0, although they may be used when charting in the resident record. MDS 3.0, which is projected to be implemented in October 2010, is expected to remedy this problem by stating, “Do not reverse stage.”

liability. An obligation that may arise out of legal responsibility for an action.
6. Preventability: Avoidable, Unavoidable, Preventable or Never Events?

KEY CONCEPT: Government regulations and governmental language can be used to help juries decide healthcare malpractice and wrongful death cases. Understand these documents and how reimbursement terminology maps onto clinical practice.

There is widespread misconception that in the acute care setting, CMS views pressure ulcers among its “never events.” In the Federal Register detailing this policy, CMS does list four conditions that are termed, “serious preventable events,” but pressure ulcers are not on this list. Pressure ulcers are listed under “Hospital Acquired Conditions (HAC).” CMS has acknowledged that in long-term care (according to Tag F-314) pressure ulcers can be “avoidable” or “unavoidable.” In acute care CMS states pressure ulcers are “reasonably preventable.”

CMS documents on pressure ulcers govern reimbursement in the acute-care setting, but in long-term care, CMS has provided language that controls civil monetary penalties. The surveyor’s job in long-term care is to determine if the pressure ulcer is avoidable or unavoidable with regard to determination of compliance with Medicare law. The revision to Tag F-314 was to assist surveyors in consistently applying the most recent evidence to this assessment. In this context, “avoidable and unavoidable” are not medical determinations, but rather assessments of compliance with federal law. The criteria for evaluation specify that the facility is to:

- Evaluate the resident’s clinical condition and pressure ulcer risk factors
- Define and implement interventions that are consistent with the resident’s needs, goals and recognized standards of practice
- Monitor and evaluate the impact of the intervention or revise the interventions as appropriate

If the facility failed to do one or more of these, the pressure ulcer is “avoidable,” whereas if a resident developed a pressure ulcer even though the facility met all of the above criteria, that pressure ulcer would be “unavoidable.” Under Tag F-314, avoidable pressure ulcers can result in deficiencies and financial penalties, even loss of license for the facility and inability to receive Medicare payments.

Staff needs to understand the difference between neutral factual statements about pressure ulcers and personal opinion. Facility education is indispensible here. It is surprising to learn how many nurses think statements such as, “pressure ulcers are always avoidable” or “pressure ulcers are caused by failure to turn” are neutral factual statements rather than personal opinion that could result in harmful consequences for the facility.

7. Education: The Need for Learning Never Ends

KEY CONCEPT: Since clinician knowledge of pressure ulcers has been linked to pressure ulcer incidence, initial and ongoing education about best practices is essential. Patient education should do more than address the basics of skin care; it should help patients formulate realistic expectations about their treatment, risks and recovery.
Professional Education—Each healthcare profession has its own set of competencies, or care-related skills required for that role. A nursing assistant’s competencies are different from those required for an advanced practice nurse, which are different from those required for a physician. Facilities must evaluate individual competencies related to pressure ulcers and determine which clinicians should be performing related care based on the requirements of their role.

All new employees need initial training in skin and pressure ulcer assessment. While clinicians should be encouraged to learn about skin assessment and pressure ulcer prevention and treatment at scientific sessions, online or through other sources, in-house training is the more pragmatic approach to reach most clinicians. Clinical rounds and other techniques that translate didactic knowledge to the patient point-of-care have been shown to be effective in knowledge retention and practice change. Training should be repeated at regular intervals because staff changes, guidelines are modified, and “lessons learned” at the institution must be addressed. Educational models should vary since models that work well for one level of staff, e.g., nurses, physical therapists, dietitians, do not necessarily work well for others, e.g., physicians or unlicensed workers such as CNAs.

Patient and Family Education—Moreover, it is important to educate patients and families about pressure ulcers. Lack of knowledge about pressure ulcers fuels unrealistic expectations about their treatment and prognosis and could set the stage for potential litigation. Nearly every clinician point-of-contact offers the opportunity for patient education, wherein clinicians can explain the basics of skin and pressure ulcer care. This might include skin assessments, turning the patient, changing dressings, explaining why the patient has a different type of mattress and so on. A booklet written at an appropriate reading level can serve to supplement the verbal teaching and provide a tangible reference when the patient is discharged.

Of course, even short verbal communications between clinician and patient have legal implications. While neutral, factual information about pressure ulcers is appropriate for most clinicians to give patients, sensitive communications, such as prognoses, are better delegated to colleagues trained in delivering such messages. This is especially important when communicating with patients and families who may already be confused, bewildered or angry.

8. Preventive Clinical Care

KEY CONCEPT: “Bundles” work and should be implemented when appropriate. While there may be insufficient data for evidence-based product and device selection in pressure ulcer care, evidence-guided selections can be made.

Few healthcare organizations have a transdisciplinary skin and wound care team; pressure ulcer prevention guidelines may be lacking. Bundles, or targeted systematic interventions often described in an acronym, have been shown to be effective in reducing the incidence of pressure ulcers. Because bundles are simple, they work well and can sometimes be implemented quickly. An awareness campaign and systematic training can help launch a new bundle. Certification requirements can help formalize and drive training compliance. However, the institution’s corporate culture can impact training efforts, positively or negatively.
Here are three examples of pressure ulcer bundles:

1. The New Jersey Pressure Ulcer Collaborative was designed to improve patient safety and the quality of care provided in all healthcare settings where the elderly might develop pressure ulcers. Participating hospitals worked with national faculty and leading experts in pressure ulcers and patient safety, and with each other, over the course of one year focusing on several dimensions of care including assessment, prevention, staging, pressure-relieving devices and nutrition. The mean for all participating organizations was a 70 percent reduction in the incidence of pressure ulcers.37

2. The Institute for Healthcare Improvement (IHI) developed the “how-to” guide. The 27-page document is a step-by-step set of evidence-based guidelines for practical use by clinicians to prevent pressure ulcers.38

3. Ascension Health, a healthcare system with hospitals and healthcare facilities in 20 states, created and implemented care methods under the SKIN™ bundle. SKIN stands for Surface selection, Keep turning, Incontinence management and Nutrition. The SKIN bundle was tested in all of Ascension’s acute care and long-term care facilities and has reduced pressure ulcer incidence to about 1.4 per 1,000 patient days systemwide.8

Despite the value of bundles and systemized approaches, clinicians also must consider the unique needs of each patient, including overall condition, comorbidities, need for immobilization, drug regimen, age and other factors. Patient management involves balancing risks. For example, a person at risk for ventilator-associated pneumonia may have to be immobilized in a way that increases his risk for developing a pressure ulcer on his head. Such situations should be discussed openly with the patient (or family) and documented. The clinician must respect the family’s input but also help manage expectations. (See also section 4, “Managing Expectations and Communicating Carefully.”)

Healthcare organizations must determine which skin care products to use. A lack of wound care data (even among new and increasingly advanced products) makes product selection difficult; however, evidence from related fields may guide product selection.

Thus, we urge healthcare organizations first to make use of bundles, tools, and products already at their disposal as they gather evidence for future improvements. Clinicians should create workable pressure ulcer guidelines (subjecting all such draft guidelines to peer review).

What to Do If This Happens to You

Like some pressure ulcers, litigation over pressure ulcers may be unavoidable. For this reason, knowing how to react when it occurs is no less important than knowing how to minimize the risk of pressure ulcer lawsuits themselves.

Litigation over a pressure ulcer begins when the plaintiff’s lawyer first appears on the scene—when he or she first contacts (even informally) a healthcare provider as the patient’s representative. So healthcare providers must act quickly to defend themselves. At this stage, the financial interests of the plaintiff and the plaintiff’s attorney outweigh the patient’s likely initial interest in obtaining answers. Efforts to apologize or otherwise diffuse the situation are generally too late. Although finding out you are being
sued can be shocking and upsetting, it is crucial to stay calm and take some simple steps to allow for the best possible results.

- Notify your institution and malpractice carrier immediately and find out who your attorney (counsel) is.
- DO NOT create notes on your own – separate and apart from a meeting with your lawyer. These notes could easily be discoverable in litigation.
- Avoid the temptation to talk to anyone about the case until you have discussed it with your attorney. Your attorney will likely advise you to avoid talking to colleagues about the case; this is important advice.
- Your attorneys or legal department are your resources, so ask them about terminology or procedures that are unfamiliar to you.
- As part of the litigation, you may be deposed. You can be deposed even if the case is not about you. (See sidebar, “Deposed: A Personal Perspective.”) If you face a deposition, meet with your attorney first to go over the procedure and talk about the sort of questions the other attorneys are expected to ask.
- While not all litigation goes to court, sometimes you will find yourself taking the witness stand. Talk to your legal representatives before testifying in court. It is important that you understand the procedures and can go over what you likely will be asked.

If you have questions during any point of the process, consult with your attorneys or legal department. Healthcare providers tell patients to be assertive and informed consumers of medical services, but they have a tendency to forget this advice when it comes to being a consumer of legal services. It is not unusual to see physicians and other highly educated professionals meekly follow bad advice from lawyers. Insist on getting answers, explanations and face-to-face time with your legal counsel.

Clinicians have important responsibilities: They are to provide the best possible care for their patients and document that care as accurately and thoroughly as they reasonably can. However, litigation can occur even when excellent care was provided.

Before any legal action is taken, it is important to take stock of the things that may expose you and your institution to legal risk. Here are some simple proactive steps you can take right now.

- Take time to familiarize yourself with the “policies,” “procedures” and guidelines of your institution. You should not only familiarize yourself with your institution’s “policies” – you should also review them with in-house or outside litigation counsel to fully understand and recognize their legal implications separate from the clinical issues.
- Participate in training sessions whenever possible to keep yourself up-to-date.
- If you are responsible for writing documentation for your institution, become familiar with CMS terminology and work with legal counsel to develop verbiage that aligns with official terminology (when possible) and does not put your organization at legal risk.
- Be mindful that even verbal communications with patients can be used in court; avoid ambiguous statements that may be interpreted to mean more or less than what you intended.
• Document as clearly and thoroughly as possible; use consistent terminology and abbreviations and write clearly. Document in such a way that you would understand what you meant years from now.

• If you are involved in any legal action, avoid discussing the case with your friends or colleagues and follow your attorney’s advice.

(For more ways to help avoid litigation, see “Ten Tips to Keep You Safe Legally with Wound and Skin Care.”)

**Final Thoughts**

The information shared here is intended to create awareness of the legal issues associated with pressure ulcers, while also providing guidance for the healthcare practitioners who face these challenges.

Pressure ulcers represent a staggering burden, both in terms of healthcare cost and human suffering. We applaud efforts to reduce their incidence through improved quality of care, and it is the hope of this panel that this laudable goal can be achieved without an increase in litigation.

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**TEN TIPS TO KEEP YOU SAFE LEGALLY WITH WOUND & SKIN CARE**

Diane Krasner PhD, RN, CWCN, CWS, BCLNC, FAAN

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<th>TIP #1</th>
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<td>Describe what you see as specifically as possible; be cautious with diagnoses unless you are a wound or skin specialist or physician.</td>
<td>Be especially vigilant in your admission and discharge documentation of wound &amp; skin conditions – no matter what your specialty. Carefully describe the wound or skin condition, including dimensions, whenever possible.</td>
<td>If a wound or skin condition warrants referral to a specialist, obtain the referral in the most expedient manner (or recommend that the referral be obtained). Urgent referrals should be communicated directly to the healthcare professional involved.</td>
<td>Wound and skin treatments must be consistent with the overall plan of care for the patient. Determine if the wound or skin care is to be aggressive, maintenance or palliative before initiating treatment whenever possible.</td>
<td>Use caution when initiating special treatments if complete testing has not been done and contraindications have not yet been ruled out.</td>
<td>Carefully document your interventions and the responses to your interventions. If you have notified another member of the interdisciplinary team, document the date, time and what was communicated.</td>
<td>Change your plan of care as the patient and the wound or skin condition change and document your rationale for the change, obtaining orders PRN.</td>
<td>Carefully discuss “unavoidable” pressure ulcers in the patient record.</td>
<td>When you see a red flag related to wound or skin conditions, notify the appropriate manager or risk manager.</td>
<td>Maintain your own liability insurance policy. Be sure that it covers you for state practice board action.</td>
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The unthinkable happened to me.

In my 46 years of nursing, I have always felt that I was a patient advocate. In fact, I have told many a patient, “If I were you, I would want me to take care of you.” I was shocked when I opened the door one evening and was handed a subpoena to report for a deposition.

One of the patients I had cared for a few years ago had brought a lawsuit against the hospital and I was implicated as one of the wound care specialists who had rendered service.

I was devastated. I have always done my best to keep patients in my charge clean, dry, comfortable and safe. So how did this happen and what does it mean for me? What would happen next?

I remembered the patient quite well. She was a very complex and difficult patient. Here’s what my review of her medical record revealed. She was a 54-year-old morbidly obese (425 lbs.) female who was admitted to the Emergency Department after three days of being febrile, unable to eat, experiencing liquid stools and being lethargic. The paramedics had been called to the home earlier, but she had refused to be taken to the hospital. Later that night, her daughter was able to persuade her to go to the Emergency Department. Her admitting diagnosis was right leg cellulitis. She had a history of multiple co-morbidities including venous disease, diabetes, morbid obesity, hypertension, chronic anemia, chronic kidney disease, asthma, and of non-adherent behavior. She had called the membership services over 100 times during her years of coverage, reporting various incidents regarding her care.

A few hours after admission, she was taken to the operating room, where she had a soft tissue incision and fasciotomy for compartment syndrome of the right leg. On post-op admission to the intensive care unit, her initial skin assessment was clear of bruising or wounds. She developed sepsis, had an altered mental status with bouts of confusion, uncooperative behavior, lethargy, difficulty awakening and agitation; she was verbally abusive to the staff. Her hospitalization was fraught with complications, including pneumonia with subsequent need for intubation. Her behavior became combative. She pulled out the nasogastric tube and intravenous lines and had to be placed in restraints.

Eight days after admission, two pressure ulcers (Stage I and Stage II) were noted in the sacral area. As per our protocol, photographs were taken. On post op day 12, the orthopedic surgeon requested a wound care consultation for recommendations regarding the management of the open fasciotomy incision. During the skin assessment, the wound care nurse documented a 9 x 20 centimeter unstageable pressure ulcer on the sacral area, 75% black, 20% yellow, 5% red. The patient was on the bariatric air support surface.

The post-op leg wound continued to heal; however, the sacral pressure ulcer needed multiple surgical debridements. At the base of the pressure ulcer, an abscessed area was found. Once the sacral area was clean, a negative pressure wound therapy closure device was applied over the wound.

Upon discharge, she spent an additional six months in a skilled nursing facility for pressure ulcer management. Eventually, she returned home with a small open wound. Her lower leg cellulitis had extended into an eight-month saga due to the complication from the hospital-acquired pressure ulcer.

Now what?

I was a fact witness (required to help relate the specific facts of this one case) rather than expert witness (who is usually called in to offer an opinion). The hospital’s attorney represented me for the deposition. I was called by the defense and counseled not to give any opinions.
My attorney sent a file box filled with medical records for me to review. I was frustrated as I reviewed these records. Notes were handwritten, difficult to read and fragmented with different disciplines writing in various sections. Very few notes were made in the comment section of the nursing notes. Flow sheets were not completed. It was challenging to determine if the patient actually had been turned, cleansed and repositioned consistently. Although the patient was incontinent of stool, there were very few episodes of incontinence noted. Even though I remembered that she was placed on a special mattress for pressure redistribution, I was unable to determine this fact from the chart, despite the fact that a special bed was ordered on day eight.

The Deposition
The attorney for the plaintiff handed me the nurses’ notes for the first seven days of the patient’s hospitalization and asked me to read the Braden Score, the integumentary, neuromuscular section, turning/repositioning section of the flow sheet and the nurses’ comment section. There was very little charted in any of the sections. The Braden Score showed the patient to be at high risk for pressure ulcer development. I was unable to find a plan of care in any of the files. Although the hospital had just implemented a new pressure ulcer program, none of the new forms or the pressure ulcer trending were filled out. The attorney had me go through the chart looking for documentation of instances of patient non-adherence. I was stunned at the lack of documentation by both physicians and nurses about her behavior, the skin and the pressure ulcer throughout her hospitalization.

The opposing counsel had me read my own charting for the times I had interacted with the patient and asked if the doctor had been informed consistently regarding the skin changes and wound management of the pressure ulcer. I was embarrassed with my own charting and lack of information charted. The photographs taken throughout her hospitalization were not labeled properly and were out of sequence. There were no follow-up notes to indicate the patient or family received education about pressure ulcer prevention or treatment. There was also no discharge note detailing the pressure ulcer other than the order to continue negative therapy.

Lessons Learned
Some of the common complaints registered against nurses in a lawsuit are failure to follow a standard of care, failure to communicate, failure to assess and monitor appropriately, failure to report significant findings, failure to act as a patient advocate and failure to document. That certainly applies in this case. Documentation is essential! Here are the main lessons I learned from this experience:

- On admission, it is important for the wound care specialist to assess the patient’s skin and wound and write a detailed, initial, focused assessment. If a wound is present on admission, document the wound profile.
- Document the type of support surface the patient is on or whenever a support system change is ordered.
- Take a clear photograph of the wound according to your organization’s guidelines. For me, that would mean using a measurement label and a black marking pen to clearly identify the patient’s name or initials, medical record number, date and location of the wound on the photo.
- Review and follow the guidelines related to skin and wound care.
- Label and place the prevention protocol standing orders and, if a wound is present, the wound and skin care treatment standing orders. Complete the required sections and sign.
- Notify the physician regarding the skin/wound condition. Based on your findings, document if the wound is healable or non-healable and document the interventions for prevention and treatment of the skin/wound.
- Make sure you do a follow-up note.
- Record in the discharge note the skin and wound status.
- Remember the power of words. Pay attention to “words not to use.”

After a few months, the case was settled out of court in favor of the patient. I hope by my sharing my own story of doing a deposition, you will gain from my pain!