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IHCA
presents

LEGAL and
REGULATORY
ISSUES
IN WOUND CARE

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Objective

- Identify Negligence, Risk, and Documentation Issues Related to Chronic Wound Care in the Long-Term Care Setting.
Challenges Faced in the LTC Sub-Acute Care Setting

- Delivering quality care to our aging population, some of whom have multiple comorbid conditions
- More complex patients/residents than years past
- Financial resources a challenge
- Other challenges?? (name some that come to mind)

Federal Register-2015

- 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.
Pressure Ulcers in LTC

More than 20% of Residents develop Pressure Ulcers after 2 years of life in the Nursing Home

Medical-Legal Aspects of Long-Term Care
Jeffery M. Levine, MD

LITIGATION

- Legal action, aka lawsuit, brought about by one party against another
- May be resolved in or out of courtroom
- Anyone can sue another person for anything

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"Grandpa, how did you settle things before litigation?"

"Negligence" means failure to use ordinary care, that is, failing to do that which a person of ordinary prudence would have done under the same or similar circumstances or doing that which a person of ordinary prudence would not have done under the same or similar circumstances.
PRUDENCE

Careful good judgment that allows someone to avoid danger or risks

www.merriam-webster.com

Legal Definition

- Professional Negligence or Misconduct.
- Failure of one rendering professional services to exercise that degree of skill and learning commonly applied by the average prudent member of the profession resulting in injury, loss or damages to the recipient of those services or to those entitled to rely upon them.
### Types of Lawsuits

<table>
<thead>
<tr>
<th>CIVIL</th>
<th>CRIMINAL</th>
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</thead>
<tbody>
<tr>
<td>□ Apply to the rights of individuals. i.e. the individual brings the case</td>
<td>□ Lawsuits created to provide protection to those injured by offenses against society.</td>
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<tr>
<td>□ Penalties involve monetary fines for damages and compensation.</td>
<td>□ Deals with offenses against the general public.</td>
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<tr>
<td>□ Licensure Suspension.</td>
<td>□ Prosecution.</td>
</tr>
<tr>
<td>□ Most lawsuits against health care providers fall under civil lawsuits.</td>
<td>□ Can You as a Healthcare Professional be charged criminally?</td>
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### It Has Been Suggested

Pressure Ulcers resulting from Institutional Neglect should lead to Criminal Prosecution of Caregivers

Homicide by Decubitus Ulcers
American Journal of Forensic Medicine and Pathology
Volume 23, Issue No. 1
V.J. DiMaio & T.G. DiMaio

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Plaintiff vs Defendant

- **Plaintiff** - individual who initiates the lawsuit
- **Defendant** - individual being sued

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4 Elements of Negligence or Malpractice Lawsuit

- **Duty** – legal obligation owed one person to another
- **Breach of duty** – violation of a law or duty *(such as in the Standard of Care)*
- **Causation** – Breach of duty caused injuries
- **Harm** - Damages to person
Damages

- Loss of Earning Capacity
- Lost Wages
- Additional Medical Expenses
- Loss of Companionship
- Compensation for Disfigurement
- Pain & Suffering

Standard of Care

- Minimum criteria for a nurse’s proficiency on the job
- Enable nurses and others to judge the quality of care given
- Degree of skill, care, and judgment used by an ordinary prudent health care provider under similar circumstances
- Some look at the standards as “pie in the sky” ideals that have nothing to do with the “reality of nursing practice.” This is a dangerous misconception.
Nursing Standards of Care

- Nurses are expected to meet standards of practice for every nursing task performed.
- Minimum standards for any nurse in any setting require that she or he develop:
  - a care plan for the patient
  - documentation in the patient’s record of the nurse’s actions and the response of the patient as the care is provided and evaluated

Documenting Care

- Healthcare provider actually writing a record of how well the standards are being met!
Breach in the STANDARD OF CARE

Attorneys and experts review the medical record to determine if a breach in the Standards of Care occurred.

Sources of Standards

- National Professional Organizations – ANA, WOCN
- Statues and Regulations (CMS SOM-F314)
- Authoritative Textbooks (Wound books)
- State Practice Acts (KNOW!!!) – It is the LAW!!!
- Rules and regulations - ensure patient safety and a competent level of behavior in the professional role of the healthcare provider
- Facility & Unit Policy and Procedures
- Job Descriptions
- Peer Reviewed Journals
- Equipment Manuals & Package Inserts (!!!)
Licensing Laws

- Define the scope of practice
- Will be used as partial evidence to determine whether the healthcare provider acted within the legal limits of the profession as defined in a particular state

Two Years in Idaho

- Statute of limitations establishes time periods within which a claim may be filed.
- Statute of Limitations is 2 years in Idaho for personal injury and medical malpractice
EXPERT WITNESS

- Addresses standard of care
- Is the standard of care applicable for this case?
- How the person/s named in the lawsuit failed to meet the standard of care
- Relationship of how breach in standard of care caused harm/damages

COMPLAINTS AGAINST NURSES

- Failure to Follow a **Standard of Care**
- Failure to **Communicate**
- Failure to Properly **Assess and Monitor**
- Failure to **Report Significant Findings**
- Failure to Act as a **Patient Advocate**
- Failure to **Document**

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Failure to Document

“Failure to document patient care in the chart is a violation of nursing standards of care, even if no actual harm comes to the patient”

Legal Eagle Eye Newsletter, March 2009

WOUND CARE ISSUES

Legal claims related to wound care can range from:

- Failure to perform skin assessments
- Identify risk factors
- Claims of wrongful death

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The following is an actual advertisement for a law firm

Pressure Ulcer Victims

- Has Your Loved One Developed a Pressure Ulcer?
- Pressure ulcers develop in nursing homes and hospitals because of patient neglect. Pressure ulcer lawsuits may be worth hundreds of thousands of dollars because they involve such a preventable tragedy.
  - Actual law firm ad taken from decubitusulcervictum.com
  - A legal advertisement
It is very important for the nursing home, hospital or assisted living facility to photograph and document pressure ulcer formation and progression.

Often times, nursing homes or hospitals fail to photograph these wounds because they are caused by staff negligence. **Do not let the staff conceal the wound from you.** Demand that they share the pressure ulcer photographs with you.

Pressure sores in patients are not OK. A pressure ulcer lawsuit holds the negligent staffers responsible for their wrongdoing.

If you or a loved one developed a pressure ulcer, call, email or fill out the free case evaluation form on the right to see if you have a valuable pressure ulcer case.

**Do You Have a Case?**

An actual law firm ad taken from decubitusulcervictum.com

A legal advertisement

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**Interesting Facts**

Taken from: A consensus paper from the International Expert Wound Care Advisory Panel.

- By 2030, 1 in 5 Americans will be 65 years or older
- 85 & older age group -fasting growing segment of population
- In 2007 there were over 200,000 Medicare beneficiaries with pressure ulcers
- Average cost of each case was approximately $43,000
Interesting Facts
Continued

- Federal Register states pressure ulcers can “reasonably be prevented through the application of evidence-based guidelines”
- Despite “tort reform” in many states lawsuits related to pressure ulcers still prevalent in acute and long-term care settings-cap of $200,000 per defendant except pressure ulcers-considered elder abuse
- Some judgments have reached as high as $312 million dollars
- Photos of pressure ulcer wounds add to frivolous claims due to assumption that pressure ulcers are caused by improper care
- WHY? Think laypeople
What Can You Do?

Avoid This!

DOCUMENTATION or LITIGATION?
“When care is not documented in the chart there is a legal presumption of an even more serious departure from the professional standards, that is, that the care in question was not given at all”

Legal Eagle Eye Newsletter, March 2009
Facility Found Liable, Patient’s Legal Case Supported By The Inadequacy Of The Nursing Documentation.

- The ICU records contained no documentation that the nurses carried out any interventions that would have prevented the pressure lesion from getting worse after it was discovered.
- Physician should have been notified at once when a small skin tear on the tail- bone was first seen. The physician was not told until the next day.
- Physician ordered a wound-care nurse consult and special bed
- Only follow up to physician’s orders was the wound care nurse coming in three days later
- By then they were dealing with a serious pressure ulcer

Settled in COURT OF APPEALS OF TEXAS July 21, 2006 for $240,000.00

Facility Hit With Substantial Judgment For Poor Nursing Care

- The Supreme Court of Mississippi approved a $1,000,000 judgment against a nursing home after a resident died with a six by ten inch pressure ulcer on her coccyx
- Resident’s chart showed she was turned at three to eight-hour intervals
- Documentation showed she remained in one position for more than sixteen hours, which was immediately before her lesion progressed to Stage III Pressure Ulcer
Nursing Documentation Leads Court To Dismiss Negligence Lawsuit.

- Patient's chart contained nursing documentation showing he was repositioned every 2 hours on 177 of his 183 days in the hospital.
- Progress notes each day state incontinence care was routinely provided.
- Existing Lesions Were Documented On Admission
- Stage IV pressure ulcer on tailbone and a Stage III ulcer on left heel were staged and documented on admission.
- Resident developed new pressure ulcers on left and right hips during his stay.
- Court was unable to find any concrete evidence that the patient's nursing care was substandard or any logical basis to conclude substandard care caused the eventual outcome.

Kerns v. HCA Wesley Rehab, 2009, Kansas

- Nurse changing dressing, dropped it on the floor, picked it up and applied it to the patient's surgical wound.
- Patient was discharged home the next day.
- 8 days later the patient was admitted to the hospital with an E. coli wound infection. The patient's hip prosthesis was removed and re-implanted months later.
- The nurse was found negligent and the facility found negligent for failing to train their nurses in wound care and infection control.
- The patient was awarded $437,000 for damages.
Haymore v. Chadwick, 2014, Mississippi

- 79 year old admitted to facility with a hx of stroke & dementia.
- On admission it was noted there was a 2.0 x 1.0 cm wound appearing as an old bruise.
- Over the next 3 months it was documented the wound progressed to a 3.0 x 3.0 cm stage II pressure ulcer.
- Patient was sent to a wound care clinic at the suggestion of the family. The wound care clinic documented at stage III pressure ulcer measuring 5.0 x 3.0 and 100% eschar.
- Patient was admitted to the hospital, diagnosed with MRSA, osteomyelitis and requiring above knee amputation.
- Court found the inaccurate documentation led to faulty communication with the physician and caused the patient’s damages.

Where Did The Underlined Statement Come From???

- “The legal standard of care for a patient with pressure sores states the patient must receive necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.
- The legal focus is not on the out-come per se but on the quality of care and how well it was documented.
- NOTE: The underlined text is a direct quote from the State Operations Manual Guidance to Surveyors!!
- "Legal Eagle Eye Newsletter. September 2013."
Direct Quote

F314

If the lawyers are reading F314 do you think its in your best interest to do the same???

Why Accurate and Consistent Documentation is Critical?

1. Office of Inspector General (OIG) of US Department of Health and Human Services
   - **Providers carry the burden of proving** that care was actually rendered to patients (residents)
   - Health care providers must **prove** they rendered **appropriate care**
   - OIG may conclude that **claims submitted are false**

2. Providers also risk **liability for negligence or malpractice** when they fail to document care provided

3. Critical for quality care related to **caregiver to caregiver communication** and **continuity of care**

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Legal Investigations

- Document-Intensive

Remember!!!

- If you’re involved in a malpractice lawsuit
  - How you document
    - What you document
  & MOST IMPORTANT
  - What you did not document will influence the jury and the outcome of the trial
    - Excellent Documentation is the Best Defense
Documentation Tips

In addition to your facility documentation requirements:

- Document patients assessment at admission, discharge, transfers, and changes in condition
- When in doubt spell it out – i.e. do not use abbreviations that have not been vetted in your care setting
- Never document abnormalities without documenting an intervention and evaluation of the intervention
- Avoid general statements, “Dr. Smith called”
- Put patient statements in quotations
- Do not make accusations, vague expressions or conclusions in your documentation
- Keep your audience in mind: experts, attorneys, jurors
### Actual EMR Documentation

- “Unresponsive and in no distress”
- “Increased worriation”
- “Pt was apprehended and guarded”
- “Pulses are fixed and dilated”
- “MD at bedside attempting to urinate”
- “Pt expired and was dc’d home”
- “Lying comfortably in bed, appears uncomfortable”
- “Reason for leaving AMA, pt wants to live”

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Regulatory Considerations

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State Operations Manual
F314
F309

RAI/MDS 3.0
Section-M

Standards of Practice
Evidenced Based

Guidelines
- NPUAP
- AMDA
- WOCN

Framing Your Wound Prevention & Care Program

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### Pressure Ulcer Resources

- **NPUAP/EPUAP Pressure Ulcer Prevention and Treatment: Clinical Practice Guideline**
  - 2014-2019 (5 year shelf life)
  - NPUAP.org
  - Quick Reference Guide free
  - Full version of Guideline=$75.00

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<th>Suggestion</th>
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<tr>
<td>Compare your facility's wound documentation form with documentation recommendations from current best practices, F314, RAI/MDS-Section M, NPUAP guidelines.</td>
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This form was created specifically for LTC taking into consideration federal mandates (F314, F309 [survey process], and MDS, 3.0-M Section) and current standards of wound care and best practices.
State Operations Manual

- CMS State Operations Manual (SOM) - a guide for what you do in clinical practice
- SOM reflects current evidence based practice
- Provides guidance to surveyors
- Taken from current wound care research and practice
- Prevention of PrUs gets lots of attention from CMS
- Free download at CMS.gov
- Lawyers use it
- Download and create in-services from this document!!!

CMS-Surveyors

- Often times the surveyor sees a facility acquired pressure ulcer as a failure of your systems and care for pressure ulcer prevention
- The ONLY way to show the surveyor differently is in the quality of your documentation
Intent of F314

- Well organized PrU prevention program reduces facility acquired PrU… only unavoidable PrU occur
- Caregivers competent
- Limited exclusively to PrUs
- Other wounds (arterial, venous, diabetic, etc.) are grouped under F309, the regulation for Quality of Care
  - Critical for practitioners to accurately perform a differential diagnosis of chronic wounds
- Recommend review of accepted definitions to prevent confusion between surveyors and clinical staff in terms of documentation

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**Risk Assessment Key for Prevention**

- Identify and document risk factors
- Identify pre-existing signs (skin trauma, DTI)
- Assess and document pain
- Include Resident Assessment Instrument (RAI)
- Identify resident with:
  - multi-system organ failure
  - end-of-life condition
  - refusal of care and treatment
- Address factors that have been identified as having an impact on the development, treatment and/or healing of pressure ulcers... (ex. steroids)
- Document ALL
The implementation and consistent use of a risk assessment tool can reduce the incidence of pressure ulcers by ~60%*

PrU Risk Assessment Tool

Utilized upon admission, weekly thereafter for four weeks, quarterly, and at discharge

Braden

Norton

Risk Factors for Developing Pressure Ulcers

Comorbid conditions (DM)

Drugs (Steroids)

Moisture Exposure (Incontinence)

Previous Stg 3 or 4 PrU

Increased Shear

Decreased Mobility

Nutrition Issues

Refusal of care

Cognitive Impairment

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M0100 Determination of Pressure Ulcer Risk

Reflects multiple approaches for determining a resident’s risk for developing a PrU

A. Presence or indicators of PrUs
B. Assessment using a formal tool
C. Physical examination of skin and/or medical record
D. Z. None of the above

Risk Assessment and POC

- Risk assessment

- Document and address each risk in the resident’s plan of care
Recognize & Document Suspected Deep Tissue Injury

• “This deep tissue damage could lead to unavoidable Stage 3 or 4 PrU or progression of a Stage 1 PrU to an ulcer with eschar within days”

Prevention & Risk Assessment

CMS considers facility acquired PrU to be a sentinel event in a resident who had been assessed as being at low risk for a PrU

• The only residents who are at high risk are those who have
  • impaired transfer or bed mobility
  • are comatose
  • malnourished
• any other resident is at low risk (until proven otherwise)
Risk factors for PrU include, but are not limited to:

- Comorbid conditions (e.g. DM, end-stage renal disease, thyroid disease)
- Drugs that may affect ulcer healing (e.g. steroids)
- Exposure of skin to urinary or fecal incontinence
- History of a healed Stage III or IV PrU****
- Impaired or decreased mobility or functional ability
- Increase in friction or shear
- Moderate to severe cognitive impairment
- Resident refusal of some aspects of care & treatment
- Undernutrition, malnutrition, & hydration deficits

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**Immobility**
- Offloading/positioning /heel elevation
- Pressure redistribution and support surfaces (bed /wheelchair)
- Rehab Consult to improve functional mobility

**Decreased Activity**

**Nutrition Impairments**
- Nutrition & hydration interventions
- Dietary consult or re-consult
- Consider resident food preferences, social & cultural differences
Nutrition
F314 Triggers F327 Nutrition Tag

- Adequate nutrition and hydration assessment and provided
- Weight loss monitoring
- Nutritional goals for prevention and healing of PrU
- Protein - 1.2-1.5 gm/kg body weight daily

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F314 & Repositioning

- Repositioning:
  - Common, effective intervention
    - person with PrU
    - person at risk for developing PrU
  - Critical for immobile residents (or those dependent upon staff for repositioning)
  - Resident care plan for those at risk of friction/shearing with repositioning may require the use of lifting devices
  - Positioning the resident on an existing pressure ulcer should be avoided
    - Adds pressure to compromised tissue
    - May impede healing

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CMS & Heels

- Important to reduce pressure over heel and elbows
- Pillows used to support the entire lower leg may effectively raise the heel from contact with the bed

F314 & Support Surfaces; Pressure Redistribution

Match a device's potential therapeutic benefit with the resident's specific situation
- Multiple ulcers
- Limited turning surfaces
- Ability to maintain position

Effectiveness is based on their potential to address
- Individual resident's risk
- Resident's response to the product
- The characteristics and condition of the product

Examples of these surfaces or devices include:
- 4-inch convoluted foam pads
- Gel pads
- Air fluidized beds
- Low loss air mattresses
CMS: **Unavoidable Pressure Ulcers**

F314

- Resident developed a pressure ulcer *even though* the facility:
  - Evaluated the resident’s clinical condition and risk factors
  - Defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice
  - Monitored and evaluated the impact of the interventions
  - Revised interventions as appropriate

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CMS: **Avoidable Pressure Ulcers**

F314

- Resident developed a pressure ulcer and the facility *DID NOT DO* one or more of the following:
  - Evaluate the resident’s clinical condition and pressure ulcer risk factors
  - Define and implement interventions that are consistent with resident needs, goals, and recognized standards of practice
  - Monitor and evaluate the impact of the interventions
  - Revise the interventions if appropriate
If the Facility is Given an F314…

- Other Tags and Care Areas for surveyor instructed to consider:
  - Notification of Change-F155,
  - Abuse-F157,
  - Choices -F223, F224, F226, F242,
  - General Pathway-F155, F242, F246, F271, F274, F278, F281, F309
  - Behavioral/Emotional Status F309, F319, F320
  - Nutrition F325
  - Hydration F327
  - Sufficient Staffing F353, F354, F385, F498, F501,
  - Infection Control F441
  - QA&A F520

MDS/CAAs, Pressure Ulcers and the Surveyor
Guidance to Surveyors
Pressure Ulcer Critical Element Pathway

☐ Document that guides surveyor through the pressure ulcer review process of the facilities care for prevention and treatment of pressure ulcers

☐ Instructions to surveyors

☐ “Use this pathway for a sampled resident having, or at risk of developing, a pressure ulcer (PU) to determine if facility practices are in place to identify, evaluate, and intervene to prevent and/or heal pressure ulcers.”

Review the following to guide your observations and interviews:

☐ “Review the most current comprehensive MDS/CAAS for cognitive status, mobility status, functional mobility, bowel and bladder status, pain, nutritional status, skin conditions (including history of a pressure ulcers), and pressure relieving devices,

☐ Physician’s orders (e.g., wound treatment) and treatment record (TAR),

☐ Pertinent diagnosis, and

☐ Care plan (e.g., pressure relief devices, repositioning schedule, treatment, scheduled skin/wound inspection, or pressure ulcer history).”
Interviews by Surveyor

- As part of the investigation, surveyors should attempt to initially interview the most appropriate direct care staff member.
- Your interview question should be specific to the investigation at hand and based on findings from the record review and observations.
- Interview the treatment or wound care nurse.
- Consider interviewing the DON, MD, CNP or PA to complete the investigation.
- If further guidance is needed, surveyors should refer to the regulation, IG, and investigative protocol as they conduct the investigation.

Record Review

- You may need to return to the record to corroborate information from the observations and interviews.
- Potential pertinent items in the record are listed below.
- If further guidance is needed, surveyors should refer to the regulation, IG, and investigative protocol as they conduct the investigation.
Note

- Survey results are public record
- Families have a right to your survey results
- Lawyers can access your survey results

Recommendations from the OIG

- Work with States and patient advocacy associations to promote public awareness that nursing home survey results are available for review by any member of the public.
- Include, in HCFA's Guide to Choosing a Nursing Home, language that explains simply what constitutes a nursing home survey and the availability and location of survey results.
- Work with interested public and private entities to promote public knowledge about how and where to access HCFA survey reports on nursing homes.
- **NOTE:** one easy location to access Survey and other measured items: Nursing Home Compare
$10.00
LTC SOM
F tags
$ for Q tags IJ