Unavoidable Pressure Injuries, Terminal Ulceration, & Skin Failure: Where were we, where are we and where are we going?
November 16, 2017

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Faculty Disclosures

Elizabeth A. Ayello:
• Was a member of the SCALE panel
• Consultant to CMS on F Tag 314 and MDS 3.0

Jeffrey M. Levine:
• No disclosures

Planning Committee Disclosures

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• Colin Dworak

The planning committee members have listed no financial interest/arrangements that would be considered a conflict of interest.
Today’s Speakers

Elizabeth A. Ayello, PhD, RN, ACNS-BC, CWOCN, ETN, MAPWCA, FAAN

Jeffrey Levine, MD, AGSF, CWSP

Please Note:

• Synonymous terminology: bedsore, decubitus ulcer, pressure sore, pressure ulcer, pressure injury

• Terminology on any particular slide: used in the literature or in CMS guidance at the time of original publication

• This presentation reflects the presenters’ opinions and is not the official position of the NPUAP

• Consult CMS website for official regulations, guidance documents and RAI manuals
Objectives- We will:

- Review the evolution of concepts regarding unavoidable PI, terminal ulcers, and skin failure
- Define current concepts and terminologies as they exist today
- State CMS regulations and guidance regarding these concepts
- Review the evidence for each concept
- Suggest a path for the future

Where were we?
Terminal Ulcers & Unavoidability

The controversy of “Terminal Ulceration” and Pressure Injury avoidability is over 100 years old!

“…if [the patient] has a bed-sore, it is generally the fault not of the disease, but of the nursing.”

Notes on Nursing, 1859

Florence Nightingale
1820-1910
Jean-Martin Charcot
1825-1893

Charcot’s “Neurotrophic Theory”

All Decubitus Ulcers are unavoidable with brain or spinal injury due to disruption of “trophic nerves” that go from the CNS to the skin.
Charcot’s “Decubitus Ominosus”

Certain Decubitus Ulcers, if present, mean that death will soon arrive.
“On guinea pigs… I have found that no ulceration appeared when I took care to prevent … a continued state of compression, and washing them to remove urine and feces.”

Charles-Erward Brown-Sequard
1817-1894

Growth of the Elderly Population
1900 to 2030

Source: U.S. Bureau of the Census
1989: Kennedy Terminal Ulcer (KTU)

The Kennedy Terminal Lesion describes pressure ulcers that are precursors of death.


IOM Report: “To Err is Human”

- 1999: “To Err is Human: Building a Safer Health System” Institute of Medicine (IOM), National Academy Press

- Identified Hospital Acquired Conditions (HAC) caused by medical errors as a leading cause of morbidity and mortality in the United States
21st Century:

PrU Become a Universally Recognized Quality Measure

- Centers for Medicare and Medicare Services (CMS)
- Joint Commission for Accreditation of Healthcare Organizations (JCAHO)
- Agency for Healthcare Research Quality (AHRQ).
- National Quality Forum (NQF)
- Institute for Healthcare Improvement (IHI).

The Era of Value Based Reimbursement (P4P) Begins

2008 CMS Reimbursement Changes: The HAC’s

- Identified a list of hospital acquired conditions (HACs) designated as “reasonably preventable” using clinical practice guidelines

- Applies to Stage 3 and 4 pressure ulcers acquired in hospital

- Brought the spotlight of pressure ulcers as a quality measure into hospitals

2008: SCALE
Skin Changes at Life’s End

2010: Trombley-Brennan
Terminal Tissue Injury (TB-TTI)

2010 Affordable Care Act

• Mandated EHR and Quality Reporting
• Mandated “Meaningful Use” of the EHR
• A key to Meaningful Use is standardization of terminology as it promotes accurate quality reporting
Where are we?

- Rapidly changing healthcare environment shifting from FFS to value based reimbursement
- Mandated EMRs that require standardized terms
- PI linked to quality measurement
- Growing doubts among experts that this should be the case
Where are we?

• High-tech life support technology applied to an increasingly vulnerable population

• Changing epidemiology of PI with increasing numbers from critical care environments

• Lack of universally recognized terminology for wounds that are unavoidable, and mixed messages from authorities and regulators.

Where are we?

A number of classifications for overlapping clinical syndromes:

➢ KTU
➢ SCALE
➢ TB-TTI
➢ Unavoidable pressure injuries
A number of classifications for overlapping clinical syndromes:

- KTU
- SCALE
- TB-TTI
- Unavoidable pressure injuries
What is the relationship among these concepts?

What are these and how are these related to pressure injuries?

Are any of these unavoidable?

KTU  TB-TTI
SCALE  SKIN FAILURE

What the regulations & literature says about these concepts

Definitions exist:
* CMS
* NPUAP
* WOCN
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Changes at Life’s End SCALE (2008)</td>
<td>“Physiological changes that occur as a result of the dying process may affect the skin and soft tissues and may manifest as observable (objective) changes in skin color, turgor, or integrity, or as subjective symptoms such as localized pain.” p. 226</td>
</tr>
</tbody>
</table>
Definitions

<table>
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</thead>
<tbody>
<tr>
<td>Trombley Brennan TB-TTI (2010)</td>
<td>Spontaneously appearing skin alterations (rapid evolution, speed of enlargement and progression, appearance in areas of little to no pressure such as skin, thighs, and mirror imaging) found in patients at the end of life.</td>
</tr>
</tbody>
</table>

The Evidence Base

Kennedy Terminal Ulcer (KTU) - 1989

- 1 retrospective case review in LTC after clinical observation of these skin changes 1983--1988
  - 51 patients who died with total of 95 pressure ulcers
  - Life expectancy
    - 55.7% died within 6 weeks
    - Range from 2 weeks to several months
  - Location
    - coccyx (23.4%)
    - hip (17.4%)
    - heel (14%)
    - buttocks (11.6%)
    - ischium (6.2%)

The Evidence Base

Skin Changes at Life’s End (SCALE)

- Modified 3 phase Delphi process international interdisciplinary group

- Ten Consensus Statements:
  - Unavoidable
  - Includes wounds of many underlying etiologies that accompany dying process
  - Reflection of compromised skin
    - reduced soft-tissue perfusion
    - decreased tolerance to external insults
    - impaired removal of metabolic wastes.

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The Evidence Base

Trombley-Brennan Terminal Tissue Injury (TB-TTI) - 2010

2 published descriptive studies after clinical observation of skin changes

- Retrospective chart reviews from 10 bed Palliative care unit

N=22 (2010)

N= 80 (2012)

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The Evidence Base - TB-TTI

Summary

- Occurs suddenly- hours to days before death
- Location
  - May or may not be over bony prominences
  - Sacrum (butterfly), trunk, lower extremities, bilateral and/or “mirror image”
- Bruised like appearance; can be confused with DTPI
  - Pink, purple or maroon color
  - Deep purple had core devoid of color (“white centered”)
- Skin remains intact

“Aggressive turning/positioning and strict attention to wound prevention protocols had absolutely no impact on the prevention of these wounds.”


What CMS says about Terminal Ulcers

LTCH Version 3.0 p. M-3
(Long Term Care Hospital)

- Skin ulcers at the end of life (a.k.a. Kennedy or terminal ulcers) are not captured in Section M of the LTCH CARE Data Set.
  - Do assess, stage, document in clinical record
  - Address in care planning
- Etiology
  - related to tissue perfusion issues at end of life due to organ and skin failure.
- Evolution not that of a typical pressure ulcer.
  - develop and evolve rapidly
  - generally appear from 6 weeks to 2 to 3 days before death
  - pear-shaped purple areas of skin with irregular borders
  - often found in the sacral and coccygeal regions in terminal/dying patients.

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What CMS says about Terminal Ulcers

Inpatient Rehabilitation Facility – Patient Assessment Instrument

August 2016- Following statement was in IRF-PAI Version 1.4  p. M-3

• “When an ulcer has been determined to be a Kennedy Ulcer, it should not be coded as a pressure ulcer.”

IRF-PAI Version 1.5 Effective October 1, 2017 no longer has this or any statement about Kennedy Ulcer


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What CMS says about Terminal Ulcers in acute care and LTC (MDS 3.0) RAI Manual

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What CMS says in LTC- F686
§ 483.25(b) Skin Integrity
§ 483.25(b)(1) Pressure ulcers.

• Resident’s Written directives
  – Pressure ulcers
  – End of life
  – Terminal stages of an illness
  – Multiple system failures

• “The facility’s care must reflect the resident’s goals for care and wishes as expressed in a valid Advance Directive, if one was formulated, in accordance with State law.

• However, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the resident’s Advance Directive.”


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What CMS says in LTC- F686
§ 483.25(b) Skin Integrity
§ 483.25(b)(1) Pressure ulcers.

• “It is important for surveyors to understand that when a facility has implemented individualized approaches for end-of-life care in accordance with the resident’s wishes, the development, continuation, or worsening of a PU/PI may be considered unavoidable.

• If the facility has implemented appropriate efforts to stabilize the resident’s condition (or indicted why the condition cannot or should not be stabilized) and has provided care to prevent or treat existing PU/PIs (including pertinent, routine, lesser aggressive approaches, such as, cleaning, turning, repositioning), the PU/PI may be considered unavoidable and consistent with regulatory requirements.”

* bolding, color and size of font by Ayello for emphasis


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What CMS says in LTC- F686
§ 483.25(b) Skin Integrity
§ 483.25(b)(1) Pressure ulcers.

“The Kennedy Terminal Ulcer (KTU)
- The facility is responsible for accurately assessing and classifying an ulcer as a KTU or other type of PU/PI and demonstrate that appropriate preventative measures were in place to prevent non-KTU pressure ulcers.
- KTUs have certain characteristics which differentiate them from pressure ulcers such as the following:
  • KTUs appear suddenly and within hours
  • Usually appear on the sacrum and coccyx but can appear on the heels, posterior calf muscles, arms and elbows;
  • Edges are usually irregular and are red, yellow, and black as the ulcer progresses, often described as pear, butterfly or horseshoe shaped; and
  • Often appear as an abrasion, blister, or darkened area and may develop rapidly to a Stage 2, Stage 3, or Stage 4 injury.”

* Color, size and bolding emphasis by Ayello


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What is the relationship among these concepts?

What are these and how are these related to pressure injuries?

Are any of these unavoidable?

KTU  TB-TTI
SCALE  SKIN FAILURE

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What the regulations & literature says about Unavoidable pressure injury (PI)

Definitions exist:
* CMS
* NPUAP
* WOCN

CMS F 314

(Rev. 4, Issued 11-12-2004, Effective: 11-12-2004, Implementation: 11-12-2004
§ 483.25(c) Pressure Sores

“Based on the comprehensive assessment of a resident, the facility must ensure that--
(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual’s clinical condition demonstrates that they were unavoidable*; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.”

* BOLD and increased font size by Ayello for emphasis
Based on the comprehensive assessment of a resident, the facility must ensure that—

(i) A resident receives care consistent with professional standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual’s clinical condition demonstrates that they were unavoidable*

Red color are changes from CMS

Blue color changes, bold and increased font size by Ayello for emphasis

* Red color are changes from CMS


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And (ii) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice to promote healing, prevent infection and prevent new ulcers from developing.”*

Red Color changes are new changes from CMS; bold and increased font size by Ayello for emphasis


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Are Pressure Injuries…

Avoidable or Unavoidable?

“Means that the 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, resident goals and recognized standards of practice
- Monitor and evaluate the impact of the interventions or
- Revise the interventions as appropriate

Even though the Facility had:

- Evaluated the resident’s clinical condition and pressure ulcer 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 and
- Revised the approaches as appropriate”

Avoidable or Unavoidable?

Source: F Tag 314 November 2004
Definitions: Unavoidable Pressure Injuries

<table>
<thead>
<tr>
<th>NPUAP &amp; WOCN</th>
<th>CMS</th>
</tr>
</thead>
</table>
| “Can develop even though the **Provider**:  
  - Evaluated the **individual’s** clinical condition and pressure ulcer risk factors  
  - Defined and implemented interventions that are consistent with **individual** needs, goals and recognized standards of practice  
  - Monitored and evaluated the impact of the interventions and  
  - **Revised the interventions as appropriate”** | “Means that the **Resident** developed a pressure ulcer even though the **Facility had**:  
  - Evaluated the resident’s clinical condition and pressure ulcer 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 and  
  - **Revised the approaches as appropriate”** |


Wound, Ostomy and Continence Nurses Society. WOCN Society position paper: Avoidable versus unavoidable pressure ulcers injuries. Mt Laurel, NJ: Author; 2017

Source: CMS F Tag 314 November 2004

F686 § 483.25(b) Skin Integrity  
§ 483.25(b)(1) Pressure ulcers

**“Avoidable”**

means the resident developed a pressure ulcer/injury and that the facility did not do one or more of the following:

- Evaluate the resident’s clinical condition and risk factors;
- Define and implement interventions that are consistent with residents needs, resident goals, and **professional** standards of practice;
- Monitor and evaluate the impact of the interventions; or
- **Revise the interventions as appropriate.**

**“Unavoidable”**

means the resident developed a pressure ulcer/injury even though the facility had:

- Evaluated the resident’s clinical condition and risk factors;
- Defined and implemented interventions that are consistent with residents needs, resident goals, and **professional** standards of practice;
- Monitored and evaluated the impact of the interventions; and
- **Revised the approaches as appropriate.**


LTC Effective  
November 28, 2017

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What the regulations & literature says about Unavoidable pressure injury (PI)

• Definition exists-
  CMS, NPUAP, WOCN

• Research needed-
  to determine which are unavoidable

What the literature says: Summary

• CMS
  – KTU guidance in RAI Manual in LTCH ONLY!

• Real clinical phenomena or care failure?

• Unavoidable?; not a pressure injury?

• Multiple terms—same phenomena in terminal persons?
  – KTU, SCALE, TB-TTI

• Understanding of pathophysiology incomplete

• Description of location & shape varies
  – Pear/butterfly (KTU), Butterfly/ deep purple white centered (TB-TTI)
  – Sacrum, heels, hip (KTU), Sacrum, trunk, or extremities (TB-TTI & SCALE)
  – Rapid evolution: Open (KTU), closed (TB-TTI), maybe open, not fully elucidated (SCALE)
“Skin Failure”

- Has been in the literature for last 2 decades
- Came to the forefront with the work of Langemo et al. Advances (2006) 19: 206-211.
- Primary pathophysiology related to hypoperfusion
- Still no universally agreed upon definition or agreement on clinical manifestations
Clinical Manifestations of Skin Failure as Described in the Literature

<table>
<thead>
<tr>
<th>Clinical Features</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin failure includes dermatologic conditions such as Stevens-Johnson Syndrome; no mention of pressure ulcers.</td>
<td>Irvine C (1991), Inamadar AC, Palit A (2005)</td>
</tr>
<tr>
<td>Skin failure is a separate entity from pressure ulcers.</td>
<td>White-Chu EF, Langemo D (2012); Delmore (2016); Olshansky (2016)</td>
</tr>
<tr>
<td>Pressure ulcers are a manifestation of skin failure in the setting of multiple organ system failure.</td>
<td>Witkowski JA, Parish LC (2000); Levine (2017)</td>
</tr>
</tbody>
</table>

Skin Failure: First Proposed Definition (2006)

“An event in which the skin and underlying tissue die due to hypoperfusion that occurs concurrent with severe dysfunction or failure of other organ systems.”

Skin Failure: Expanded Definition (2017)

“Skin failure is the state in which tissue tolerance is so compromised that cells can no longer survive in zones of physiological impairment that includes hypoxia, local mechanical stresses, impaired delivery of nutrients, and buildup of toxic metabolic byproducts.”


Skin Failure: Risk Factors

- SIRS (Systemic Inflammatory Response Syndrome)
- Multiple Organ System Failure
- Severe anemia
- Severe edema/anasarca
- Severe hypoalbuminemia
- Respiratory failure/life support measures
- Severe nutritional depletion/Wt loss
- Pharmacologic (steroids, vasopressors, immunosuppressants)
- Hypoperfusion/hypoxia from whatever cause (Severe CHF, atherosclerosis, shock, blood loss, lung disease, etc)
- Pre-existing skin damage (RT, age-related changes)
- The dying process

Levine et al JCOM 2009
Edsberg et al. JWOCN 2014
Skin Failure: Risk Factors

- SIRS (Systemic Inflammatory Response Syndrome)
- Multiple Organ System Failure
- Severe:
  - anemia
  - edema/anasarca
  - hypoalbuminemia
  - nutritional depletion/Wt loss
- Respiratory failure/life support measures
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- Pre-existing skin damage (RT, age-related changes)
- The dying process

Levine et al JCOM 2009
Edsberg et al. JWOCN 2014

RESEARCH GAP!

- Scoring systems to assess multiple organ dysfunction do not include skin! (APACHE, SOFA, MODS, etc)
- There are no reliable clinical algorithms to determine unavoidability
- There are no biomarkers for skin failure
- We cannot rely on “dying” as a criteria for the diagnosis
What’s stopping us from recognizing Skin Failure?

- Multiple stakeholders with different interests and opinions
- Lack of a biochemical marker for skin failure
- Limited evidence for common underlying mechanisms
- Lack of a universally accepted definition

Where are we going?
**Lets Fill in the Gaps!**

- Need to recognize and legitimize the unavoidable pressure injury, whatever its cause.
- Even the best clinicians are poor at predicting death. Is it appropriate for “impending death” to be a requirement for a diagnosis? Therefore we should delete this requirement from the definition.
- Need to develop algorithms and identify biomarkers to determine unavoidability.
- Need to recognize common terminology that covers KTU, SCALE, TB-TTI and unavoidable Pressure Injuries that occur in all settings. **This might be under the name “Skin Failure.”**

**A Path to the Future**

- Recognize Skin Failure as an entity.
- Unify vocabulary to accommodate realities of EMR requirements, QMs, coding.
- Identify common mechanisms of skin failure shared with other organ systems, such as oxidative stress, endothelial dysfunction, mitochondrial dysfunction.
- Common vision of unavoidable skin breakdown inclusive of other mechanisms of injuries including terminal ulceration.
Bibliography

Reference list for this webinar is available at:
http://www.npuap.org/pi-prevention-day-2017-webinar-handouts/

Objectives- We have:

- Reviewed the evolution of concepts regarding unavoidable PI, terminal ulcers, and skin failure
- Defined current concepts and terminologies as they exist today
- Stated CMS regulations and guidance regarding these concepts
- Reviewed the evidence for each concept
- Suggested a path for the future
Thank you!

Questions

Comments

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