Disclaimer

The information presented herein is provided for the general well-being and benefit of the public, and is for educational and informational purposes only. It is for the attendees’ general knowledge and is not a substitute for legal or medical advice.

Although every effort has been made to provide accurate information herein, laws change frequently and vary from state to state. The material provided herein is not comprehensive for all legal and medical developments and may contain errors or omissions.

If you need advice regarding a specific medical or legal situation, please consult a medical or legal professional. Gordian Medical, Inc. dba American Medical Technologies shall not be liable for any errors or omissions in this information.
Objectives

At the end of this presentation participants will be able to:

- Recognize the different terms for patient/resident compromised physiology leading to failure of skin integrity as defined by CMS and wound prevention and care research/best practices.
- Verbalize CMS regulatory guidelines related to the unavoidable failure of skin integrity aka the Unavoidable Pressure Ulcer/Kennedy Terminal Ulcer.
- Describe signs of physiological changes in skin integrity when there is chronic organ failure.
- List goals for treatment when failure of skin integrity is “unavoidable”.

Introduction

- Skin is largest organ of the body
- Fails same as other organs: heart, kidneys, liver, etc.
- With acute and chronic illnesses body systems can fail, sometimes suddenly
- Skin failure is an **unavoidable condition**
- Older adults have higher risk for skin failure due to more fragile overall organ physiology, including the skin
- When patients/residents are deteriorating physically, particularly in the presence of multi-organ failure, skin failure may not be preventable
### Difficult to Tell the Difference Between PU/PI and Skin Failure

<table>
<thead>
<tr>
<th>Pressure Ulcer/Injury</th>
<th>Skin Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Necrosis</td>
<td>□ Necrosis</td>
</tr>
<tr>
<td>□ Ulceration</td>
<td>□ Ulceration</td>
</tr>
<tr>
<td>□ Blistering</td>
<td>□ Blistering</td>
</tr>
<tr>
<td>□ Usually over bony prominences</td>
<td>□ Mottling</td>
</tr>
<tr>
<td></td>
<td>□ Gangrene</td>
</tr>
<tr>
<td></td>
<td>□ Anywhere on the body</td>
</tr>
</tbody>
</table>

Skin Mottling. Pt. in respiratory failure and hypotension

### Avoidability/Unavoidability of Skin Breakdown

- □ Terminal (end of life) ulceration is NOT a new concept
- □ Concept over 100 years old and documented in historical medical literature
- □ Lack of complete understanding of skin failure
- □ Some people think, erroneously, that ALL PU/PIs are avoidable
- □ CMS agrees not all PU/PIs are avoidable
- □ Research needed on topic of terminal skin failure/ulcerations
- □ Shared terminology needed that defines process of skin failure/KTU/unavoidable PU/PI
Terms to Describe Unavoidable Skin Changes

- Several classifications/terms for similar/overlapping clinical syndromes
  - Kennedy Terminal Ulcer (CMS recently recognized-F686)
  - Trombley-Brennan Terminal Tissue Injury
  - Skin Changes at Life’s End
  - Skin Failure
  - Unavoidable pressure ulcer/injuries (CMS SOM F686)

- All of these terms may be a component of multi-organ failure where the skin is failing in concert with other body systems.
- Similar meaning of these different terms creates confusion for clinicians trying to communicate and design plans of care that are appropriate for end of life skin deterioration

Decubitus Ominousus

Skin breakdown heralding impending death of the patient decubitus ominosus.
- This nomenclature (name) was forgotten until the late 20th century when Karen Kennedy recognized and published information on the what became known as the Kennedy Terminal Ulcer in 1980s.
The Kennedy Terminal Ulcer (KTU)

- Unavoidable skin breakdown or skin failure that occurs as part of the dying process
- Not a cause of a patient’s death
- Occurs in spite of good quality care
- Appears quickly and progresses rapidly…sometimes within hours
- May start out superficially as a blister or what appears to be a Stage 2
- May have early characteristics of a DTPI
<table>
<thead>
<tr>
<th>Kennedy Terminal Ulcer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Described as pear-butterfly-horseshoe or irregular-shaped red/yellow/black ulcer</td>
</tr>
<tr>
<td>Described as an abrasion with small black almost vasculitic spots</td>
</tr>
<tr>
<td>Often appear on the sacrum/coccyx area, but have been reported in other anatomical areas (eg. calf/thigh)</td>
</tr>
<tr>
<td>Rapidly progresses to a full-thickness ulcer</td>
</tr>
<tr>
<td>Instructed by CMS to call this a Stage 3 or Stage 4 PrU per the SOM and report as a PU/PI on the MDS</td>
</tr>
</tbody>
</table>

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.
Kennedy’s Terminal Ulcer: Pressure Ulcer

- Kennedy Terminal Ulcers are considered PRESSURE ULCER/INJURY per CMS.
- Pressure ulcers that generally occur at the end of life.
- For concerns related to Kennedy Terminal Ulcers, refer to F686, 483.25(b) Pressure Ulcers.

**NOTE:** From Presenter…not CMS statement, but reality.
- These skin changes are not pressure ulcers…they are the result of skin failure due to the dying process or during multi-organ failure.
- The resident is in the dying process and the skin…largest organ of the body begins to also fail.
- If you recognize this situation and your MDs/NPs documents accordingly, then you can at least document them as unavoidable pressure ulcer/injuries.

**Characteristic of Kennedy Terminal Ulcers - F686**

**Know When to Use This Designation!!!**

- “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.”
Currently Pressure Ulcers Considered a Quality Measure

- Centers for Medicare and Medicaid 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)
**INTENT of F686 Related to PU/PIs**

“The intent of this requirement is that the resident does not develop pressure ulcers/injuries (PU/PIs) unless clinically unavoidable and that the facility provides care and services consistent with professional standards of practice to:

- Promote the prevention of pressure ulcer/injury development;
- Promote the healing of existing pressure ulcers/injuries (including prevention of infection to the extent possible); and
- Prevent development of additional pressure ulcer/injury.”

**Pressure Ulcer/Injury Development**

- More than 100 risk factors have been cited in the literature related to PU/PI development
- Affirms the multifactorial etiology of PU/PI development
- Braden captures **SOME** of these factors, certainly not all
- Comorbidities listed as contributory include:
  - Diabetes, infection, PAD, cardiovascular disease, anemia, hypotension, advancing age, vasopressor medications, and many more...
- The research, literature, and experience of clinician over the decades agree that ALL pressure ulcer/injuries are NOT preventable
- Delmore, Cox, Rolnitzky, Chu, Stolfi, 2015
F686
§483.25(b) Skin Integrity
§483.25(b)(1) Pressure ulcers.
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; 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.

“Avoidable” means that 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 resident needs, resident goals, and professional standards of practice;
- monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.
Unavoidable Pressure Ulcer/Injury per CMS pg 261-11/22/17 SOM

☐ “Unavoidable” means that 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 resident needs, goals, and professional standards of practice;
  ☐ monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

KEY ELEMENTS OF NONCOMPLIANCE To Cite Deficient Practice at F686

☐ Surveyor’s investigation will generally show that the facility failed to do one or more of the following:
  ☐ Provide preventive care, consistent with professional standards of practice, to residents who may be at risk for development of pressure injuries; or
  ☐ Provide treatment, consistent with professional standards of practice, to an existing pressure injury; or
  ☐ Ensure that a resident did not develop an avoidable PU/PI.
Trombley-Brennan Terminal Tissue Injury (TB-TTI)

- Purple maroon discoloration that may appear suddenly at end of life
- Further description: Patient will exhibit these skin changes on bony and non-bony prominences
- These injuries do not evolve into full thickness wounds with non viable tissue
- Frequently characterized by an increase in surface area
- No drainage present
- Linear and mirror images may appear on lower extremities
- No complaints of discomfort
- Do not follow the same course as the KTU
Trombley-Brennan Terminal Tissue Injury (TB-TTI)

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

Skin Failure and Skin Changes at Life’s End
“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 indicated 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.”

Skin Failure Definition

“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” (Langemo, 2005, Langemo & Brown, 2006)

“Skin Failure and pressure ulcers are 2 distinct, yet related clinical phenomena” (Delmore, Cox, Rolnitzky et al, 2015)
Physical Manifestations of Skin Failure

- Hemodynamic changes
  - Hypoperfusion of skin – shunting of blood to vital organs to preserve life
- Impaired thermoregulatory control
- Metabolic abnormalities of toxic metabolites from catabolism

Abstract
An expert panel was established to formulate a consensus statement on Skin Changes at Life’s End (SCALE). The panel consisted of 14 internationally-recognized key opinion leaders including clinicians, surgeons, medical researchers, legal experts, academicians, a medical writer, and leaders of professional organizations. The inaugural forum was held on April 2-6, 2019 in Chicago, IL, and was made possible by an unrestricted educational grant from Genzyme Corporation Inc. The panel discussed the issues of SCALE, including the proposed concepts of the Kennedy Terminal Unit (KTU) and skin failure along with other end of life changes. The final consensus document and statements were edited and reviewed by the panel after the meeting. The document and statements were initially externally reviewed by 41 international distinguished reviewers. A modified Delphi process was used to determine the final statements and 51 international distinguished reviewers reached consensus on the final statements.

The skin is the body's largest organ and is one of the essential organs subject to a loss of autonomy. It has an increased risk for injury due to both internal and external causes. The panel concluded that not current comprehensive of skin changes that can occur at life’s end is limited, and additional research and expert consensus is necessary and a new paradigm is needed. Specific aims requiring research and consensus include: 1) the identification of clinical, biological, and pathophysiologic features involved in SCALE, 2) clinical and diagnostic criteria for describing conditions identified with SCALE, and 3) recommendations for evidenced-based pathways of care.

The statements from this consensus document are designed to facilitate the implementation of knowledge, standards, best-practice techniques, and quality indicators for clinical teams. This implementation process should include multidisciplinary teams (clinicians, legal and policy makers) concerned with the care of individuals at life’s end to adequately address the medical, social, legal, and financial ramifications of SCALE.
Physiologic changes that occur as a result of the dying process (days to weeks) 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. These changes can be unavoidable and may occur with the application of appropriate interventions that meet or exceed the standard of care.

Skin changes at life’s end are a reflection of compromised skin (reduced soft tissue perfusion, decreased tolerance to external insults, and impaired removal of metabolic wastes).
Skin Failure

- Based on the SCALE document (2008) and NPUAP position statements (2011, 2014), two conditions necessary for establishing the diagnosis of skin failure are skin hypoperfusion and severe organ dysfunction or failure (White-Chu & Lagemo, 2012).

- ICD-10 diagnosis of skin failure: L98.9 Disorders of the skin

- When it appears skin failure/KTU involved in failing skin integrity have practitioner collaboration a.s.a.p.

Organ Failure Stratification

- Acute
- End-Stage
- Chronic

Skin Barrier Failure
Types of Skin Failure (Langemo & Brown, 2006)

- **Acute Skin Failure**: “an event in which skin and underlying tissue die due to hypoperfusion concurrent with a critical illness” (e.g., MI, sepsis, etc.)

- **Chronic Skin Failure**: “an event in which skin and underlying tissue die due to hypoperfusion with a chronic disease state” (e.g., PAD, MS, neuropathy, kidney disease)

- **End-Stage Skin Failure**: “an event in which skin and underlying tissue dies due to hypoperfusion concurrent with the end of life” (e.g., cancer, MS)

---

End of Life Considerations

- May involve short periods of overwhelming illness (acute)
- Or slow deterioration lasting months to years (chronic)
- In both cases, the skin becomes particularly vulnerable to breakdown

- *Witkowski and Parish concluded that skin breakdown is often unavoidable at this point*
INTERVENTIONS
to Mitigate Chronic Skin Failure

Well documented multidisciplinary interventions
- Nutritional support
- Hydration
- Medical management
- Hygiene
- Functional rehabilitation
- Pressure redistributing surface selection

End-Stage Skin Failure

- Skin and underlying tissue die due to hypoperfusion concurrent with end of life
- Challenges to maintaining skin integrity
- Transition from acute to chronic to end-stage - not easily observable continuum
End-Stage Organ Decompensation and Failure

- Large and unusual presentations of skin failure
- Body shunts blood to vital organs
- Widespread and deep tissue destruction over stressed areas can appear in a matter of hours or less
  - Sacrum
  - Heels
  - Posterior calf muscles
  - Arms
  - Elbows

Conclusions from SCALE Expert Panel

- Current Understanding Limited
- Additional Research Needed
- Observable Changes
- SCALE (2009)
- Education: Clinicians, Laypeople, Policy Makers
End of Life

- **Phase of life when a person is living with an illness that will often worsen and may eventually cause death**

- Occurrence of skin failure in the chronically ill is a time to establish dialogue with:
  - Patient/resident
  - Family
  - Caregivers

- **Time to discuss Pros and cons of future aggressive medical interventions; write POC that meets resident/caregivers goals for care**

Clinicians should strive to distinguish the difference between:

<table>
<thead>
<tr>
<th>Healable Wounds</th>
<th>Maintenance Wounds</th>
</tr>
</thead>
</table>
| • Have adequate blood supply | • Healing potential  
  • Can heal if underlying causes addressed  
  • Patient/resident or health system barriers compromising healing  
  • Patient/residents may be nonadherent to treatment  
  • Patients/residents may have resource limitations |
| Nonhealable Wounds       | • Includes palliative wounds  
  • Cannot heal due to irreversible causes/illnesses  
  • Critical ischemia  
  • Non treatable malignancy |
1. Focus on Preventing and Relieving Suffering

- Focused on preventing and relieving suffering of the individual with life-threatening illness and his or her significant others through:
  - Identification, assessment and relief of distressing physical, psychosocial and spiritual issues, and pain while neither hastening nor prolonging death
2. Goals of care

- Goals of care should be established in collaboration with the individual and his or her significant others.
- To the extent possible, allow the individual to direct care.

3. NOT Lack of Care

- Palliative pressure ulcer care is not ‘lack of care’, but care focus on comfort and limiting the extent or impact of the wound
- Prevention of new pressure ulcers remains important; however, during the period of active dying, comfort and/or the individual’s preference may override implementation of active prevention strategies.
Suggested Goals for Palliative Wound Care

- Prevent wound from getting larger
- Prevent new wounds as possible by patients physiology
- Prevent infection
- Manage odor & exudate
- Assess & treat pain/discomfort

General Principles
End of Life Skin Failure/KTU/Unavoidable PU/PIs Management

- Manage and control individual’s symptoms
- Promote best quality of life
- Neither hasten nor prolong death process
- Collaborative goals for care with individual & family
- Where possible allow individual to direct care
- Focus on comfort
- Limit impact of wound on quality of life
Hospice and Palliative Care

- Good skin care and palliative wound care for the what may be termed an unavoidable pressure ulcer, or skin failure should continue even if a person is on hospice.
- With appropriate and adequate documentation, the surveyor will be able to follow the resident's decline.
- Should an unavoidable pressure ulcer appear, the facility should not get an F686 tag, or, if an F686 tag is given, documentation should be able to provide clear info that skin failure was unavoidable and perhaps have the tag removed.

Palliative Care
When Healing Wounds is NOT the Goal

- Individual receiving palliative care whose body systems are shutting down often lacks the physiological resources necessary for complete healing of the pressure ulcer.
- As such, the goal of care may be to maintain or improve the status of the pressure ulcer rather than heal it.
Repositioning and Early Mobilization for Individuals Receiving Palliative Care

- Pre-medicate the individual 20 to 30 minutes prior to a scheduled position change for individuals who experience significant pain on movement.
- Consider the individual’s choices in turning, including whether she/he has a position of comfort, after explaining the rationale for turning.
- Consider changing the support surface to improve pressure redistribution and comfort.

Skin Failure in Individuals with Advanced or Terminal Diseases

- These patients are at significant risk for KTU/Skin Failure
- Full-thickness (appearance of Stage 3 and 4 pressure injuries common; but in reality are KTUs/Skin Failure)
- Majority of skin failure in hospice occur ~2 weeks before death
- Correlates with physiological shut down of body systems 10-14 days before death
Wounds at Life’s End

- Affect up to 35% of patients at life’s end

- ~ 50% of these wounds are pressure injuries

- ~ 20% are ischemic wounds (PAD)

Wounds at Life’s End (con’t.)

- ~ 30% mixture of various wound etiologies
  - Malignant fungating wounds
  - Fistulae
  - Radiotherapy skin reactions
  - Surgical wounds turned to chronic wounds
  - Venous insufficiency/lymphedema
  - Diabetic neuropathic wounds
  - Skin tears

- ~ 2 million patients in hospice care

- Approximately 700,000 people need palliative wound care each year
End of Life Considerations

- May involve short periods of overwhelming illness (acute)
- Or slow deterioration lasting months to years (chronic)
- In both cases, the skin becomes particularly vulnerable to breakdown

Witkowski and Parish concluded that skin breakdown is often unavoidable at this point

Goals for Treatment of KTU/Skin Failure Wounds

- Prevent wound deterioration as much as possible using current wound care practices
- Conservative interventions often more appropriate (e.g. collagenase/Santyl for debridement instead of sharp/surgical)
- Pain assessment and management – do NOT undertreat pain unless requested by resident
- Odor control
- Infection prevention
- Maximize ADLs to resident’s tolerance and wishes
- POC should enhance QoL even though the wound may not improve or heal
Importance of Having A Consistent Shared Terminology
Levine (2017)

- “Consistency of terminology is important for communication among the interprofessional team and constituents in various healthcare settings.
- Standardization of terms may assist regulatory bodies, including CMS, to locate appropriate evidence-based research for decision-making.”

Summary

- Skin failure is a subset of multiple organ dysfunction syndrome (MODS) (Bone et al, 1992)
- These skin disruptions are NOT pressure ulcers (Langemo & Brown, 2006, White-Chu & Langemo, 2012, Delmore et al. 2015)
- Skin failure and PU/PI are 2 distinct phenomena, yet interrelated & may occur simultaneously
- Skin Failure occurs without the presence of pressure and/or shear. (White-Chu & Langemo, 2012)
- PU/PI can occur in people not chronically ill or at life’s end (e.g. paraplegics/quadriplegics)
- Skin failure can occur acutely, in chronically ill residents, or at life’s end (Langemo 2006)
- Respiratory failure significantly associates with skin failure (Curry et al, 2012, Levine et al, 2009)
- Curry et al also found 2 or more failed organ systems resulted in skin failure
THANK YOU!!!

References

- State Operations Manual. Appendix PP-Guidance to Surveyors for Long Term Care Facilities. Rev. 11-22-17
- [http://www.kennedyterminalulcer.com/#Q1](http://www.kennedyterminalulcer.com/#Q1), Accessed 1/21/18
References


References

- Alvarez O, Brindle CT, Langemo D, Kennedy-Evans, KL, Krasner DL, Brennan MR, Levine JM. The VCU Pressure Ulcer Summit. The search for a clearer understanding and more precise clinical definition of the unavoidable pressure injury. JWOCN. 2016; 43(5);455-463.
- Ayello EA. CMS MDS 3.0 Section M
- Black JM, Edsberg LE, Baharestani MM et al. Pressure ulcers: avoidable or unavoidable? Results of the National Pressure Ulcer Advisory Panel consensus conference. OWM. 2011;57(2); 24-37.


