



Terminal Ulcers, SCALE, Skin Failure, and Unavoidable Pressure Injuries: Results of the 2019 Terminology Survey

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1.5 Contact Hours

GENERAL PURPOSE: To present the results of the 2019 study of healthcare professionals' consensus and opinions regarding terminology for terminal ulcers, Skin Changes At Life's End, skin failure, and unavoidable pressure injuries to improve clinical care and to foster research into current criteria for unavoidable skin changes at the end of life.

TARGET AUDIENCE: This continuing education activity is intended for physicians, physician assistants, NPs, and nurses with an interest in skin and wound care.

LEARNING OBJECTIVES/OUTCOMES: After completing this continuing education activity, the participant should be better able to:

1. Explain the survey methodology and identify the consensus statements.
2. Synthesize the open-ended questions and respondent comments and their implications for clinical care and research.

ABSTRACT

This article reports the results of a global wound care community survey on Kennedy terminal ulcers, Skin Changes At Life's End, Trombley-Brennan terminal tissue injuries, skin failure, and unavoidable pressure injury terminology. The survey consisted of 10 respondent-ranked statements to determine their level of agreement. There were 505 respondents documented. Each statement required 80% of respondents to agree (either "strongly agree" or "somewhat agree") for the statement to reach consensus. Nine of the 10 statements reached consensus. Comments from two additional open-ended questions were grouped by theme. Conclusions and suggested recommendations for next steps are discussed. This summary is designed to improve clinical care and foster research into current criteria for unavoidable skin changes at the end of life.

KEYWORDS: pressure injuries, Kennedy terminal ulcer, SCALE, Skin Changes At Life's End, skin failure, survey, terminal ulcers, terminology, Trombley-Brennan terminal tissue injury

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INTRODUCTION

In March 2019, an article was published in *Advances in Skin & Wound Care* entitled "Reexamining the Literature on Terminal Ulcers, SCALE, Skin Failure, and Unavoidable Pressure Injuries."¹ It summarized and proposed relationships among terminal ulcers, skin failure, Skin Changes At Life's End (SCALE), and unavoidable pressure injuries (PIs) based in part on sessions hosted at the 2017 National Pressure Ulcer Advisory Panel conference.¹ This article presents the results of a survey that was partially based on that article and designed to assess healthcare professionals' opinions about relevant terminology to determine their levels of agreement and consensus.

METHODS

Evidence-based medicine is a combination of the scientific evidence, expert opinion/knowledge, and patient preference.² This survey was designed to solicit expert knowledge/opinion on this terminology. The survey was created by the study authors in January and February

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2019 and implemented with the SurveyMonkey platform (San Mateo, California). It contained seven demographic questions about respondents' clinical experience and background, as well as one question on whether the respondent had read the original CE/CME article.¹ The instructions stated that it was not necessary to have read the article to complete the survey, and the questions were designed to stand alone from it.

In the second section of the survey, participants were asked to indicate their level of agreement with 10 consensus statements. The options were strongly agree, somewhat agree, somewhat disagree, and strongly disagree. Participants could also elaborate by appending narrative comments to any of the survey questions. The consensus statements included four questions concerning skin failure, two questions on Kennedy terminal lesions (now known as Kennedy terminal ulcers [KTUs]), and a single question for each of the following: SCALE, Trombley-Brennan terminal tissue injury, avoidability of terminal ulceration, and the CMS definition of PI. A final open-ended question asked participants to comment on what they believe is needed to provide a better conceptual framework for end-of-life skin changes.

Respondents were informed at the start of the survey that results were anonymous and completion implied permission to participate. As an incentive, participants could enter their name and email at the end of the survey for a chance to win one of five \$100 American Express gift cards or a print copy of a wound care textbook. This information was stored separately

from survey results, and only deidentified results were shared with these authors.

The survey was open from March 1 to June 30, 2019. To publicize the survey, notices were placed in the March through June issues of *Advances in Skin & Wound Care*, as well as in one issue of *Nursing2019*. In addition, emails were sent to members of relevant organizations that agreed to disseminate notification about the survey, including the American Professional Wound Care Association, the World Union of Wound Healing Societies, the World Council of Enterostomal Therapists, the International Interprofessional Wound Care Group, and attendees of the International Interprofessional Wound Care Course. Notices were also displayed on the journal website (www.woundcarejournal.com) and social media platforms, as well as in professional presentations by the survey coauthors.

DEMOGRAPHIC RESULTS

A total of 505 responses were received, but not all respondents answered every question. Most completed surveys were from North America, with global respondents from Europe, South America, the Middle East, Asia, and Australia. Fewer than half of the participants ($n = 208$, 42.89%) stated they had read the article the survey was based on; 20 respondents did not answer this question. Table 1 summarizes the participant demographics. Table 2 reports on their responses by level of agreement or disagreement. Each statement required 80% of respondents to agree (either strongly agree or somewhat

Table 1. SUMMARY OF RESPONSES

Question	Response, n (%)						No Response/ Response
1. Years of wound care experience	>2 y, 26 (5.39%)	2–5 y, 73 (15.15%)	5–10 y, 77 (15.98%)	10–20 y, 125 (25.93%)	>20 y, 181 (37.55%)		23/482
2. Profession	Nursing, 347 (71.84%)	Physician, 45 (8.91%)	Podiatrist, 36 (7.25%)	Rehabilitation, 27 (5.59%)	Allied health, 2 (0.41%)	Other, 26 (5.38%)	22/483
3. Wound care % of clinical practice	>60%, 237 (49.17%)	41%–60%, 65 (13.49%)	21%–40%, 67 (13.90%)	6%–20%, 73 (15.15%)	≤5%, 40 (8.30%)		23/482
4. Practice includes PI, LU, FU, and/or other	PI + LU + FU, 320 (66.12%)	Other + PI, 62 (12.81%) Other—PI, 23 (4.75%)	PI + LU, 8 (1.65%) PI + FU, 8 (1.65%)	PI only, 39 (8.06%)	FU only, 18 (3.72%)	LU only, 8 (0.165%)	21/484
5. I work in ^a	Community home care, 69 (14.37%)	Acute hospital care, 191 (39.79%)	Long-term/chronic care, 62 (12.92%)	Nursing home, 87 (18.13%)	Outpatient wound clinic, 128 (26.67%)	Other, 95 (19.79%)	25/480
6. Certifications include ^a	CWOCN, 53 (12.80%) CWON, 32 (7.73%)	CWCN, 13 (3.14%) CWS, 91 (21.98%)	WCC, 112 (27.05%)	ABWM, 28 (67.63%)	CWSS, 13 (3.14%)	Other, 172 (41.54%)	91/414

Abbreviations: ABWM, American Board of Wound Healing; CWCN, Certified Wound Continence Nurse; CWOCN, Certified in Wound Ostomy Continence Nursing; CWON, Certified Wound Ostomy Nurse; CWSS, Certified Wound and Skin Specialist; FU, foot ulcer; LU, leg ulcer; PI, pressure injury; WCC, Wound Care Certified.

^aCheck all that apply.

**Table 2. RESULTS BY STATEMENT**

Statement	Strongly Agree	Somewhat Agree	Combined Agree	Somewhat Disagree	Strongly Disagree	Combined Disagree	Total Responses
1. Kennedy terminal lesions are attributable to local ischemia and are less likely to be a primary pressure injury.	125 (47.89)	95 (36.40)	220 (84.29)	30 (11.49)	11 (4.21)	41 (15.70)	261
2. Kennedy terminal lesions are prognostic of impending death (within a 6-wk period and up to 55.7% as documented in Karen Lou Kennedy data).	148 (57.14)	95 (36.68)	243 (93.82)	9 (3.47)	7 (2.70)	16 (6.18)	259
3. Trombley-Brennan terminal tissue injuries may represent hypoperfusion and leaky superficial vessels resulting in all three of the following: a) Pink purple maroon bruise like butterfly skin alterations. b) Vertical-linear striations particularly on the legs or horizontal striations with purpura on the abdomen. c) These changes do not ulcer or break down.	64 (26.23)	133 (54.51)	197 (80.74)	41 (16.80)	6 (2.46)	47 (19.26)	244
4. The concept of skin failure does not include pressure injuries.	51 (19.62)	52 (20.00)	103 (39.62)	75 (28.85)	82 (31.54)	157 (60.38)	260
5. Skin failure can occur with acute illness, chronic illness, and at end of life.	208 (79.09)	50 (19.01)	258 (98.10)	3 (1.14)	2 (0.76)	5 (1.90)	263
6. Skin failure is an event in which the skin and underlying tissue dies because of hypoperfusion and occurs concurrently with severe failure of other organ systems (two or more).	172 (65.90)	76 (29.12)	248 (95.02)	10 (3.83)	3 (1.15)	13 (4.98)	261
7. The definition of skin failure at the end of life should include a description of the degree of skin injury and the area involved.	176 (67.43)	68 (26.05)	244 (93.48)	12 (4.69)	5 (1.92)	17 (6.51)	261
8. Kennedy terminal ulcer (KTU), Trombley-Brennan terminal tissue injury (TB-TTI), Skin Changes At Life's Ends (SCALE), and skin failure at the end of life are unavoidable and not attributable to substandard care.	159 (60.92)	67 (25.67)	226 (86.59)	23 (8.81)	12 (4.60)	35 (13.41)	261
9. The changes outlined in the SCALE statements can occur in the absence of skin failure.	66 (26.51)	136 (54.62)	202 (81.12)	39 (15.66)	8 (3.21)	47 (18.88)	249
10. How much do you agree with the Centers for Medicare & Medicaid Services' definition of avoidable/unavoidable pressure injury?	112 (42.42)	128 (48.48)	240 (90.91)	15 (5.68)	9 (3.41)	24 (9.09)	264

The statement that did not receive consensus is highlighted. All responses are n (%).

agree) to reach consensus; 9 of the 10 statements reached consensus. A total of 119 comments T3 were received, and the open-ended responses are grouped by theme in Table 3. Some of the responses are listed more than once if they fit more than one theme.

Survey respondents were experienced in skin and wound care, with the largest group (n = 181, 37.55%) having more than 20 years of experience and 125 (25.93%) stating they had 10 to 20 years' experience (Table 1). Of the 505 respondents, 483 identified their profession. Most were nurses (n = 347, 71.84%) who, primarily identified as direct care providers, NPs, or nurse educators. Responding physicians (n = 45, 8.91%) were primarily specialists with identified specialties including plastic or general surgery, emergency medicine, and dermatology. Almost half of the respondents (n = 237, 49.17%) estimated that wound care comprised greater than 60% of their clinical practice. Pressure injuries were a part of clinical care for 90.2% of respondents (n = 437). Two-thirds of the respondents (n = 320, 66.12%) took care of patients with all three of the following: leg ulcers, foot ulcers, and PIs. The majority worked in acute

hospital care (n = 191, 39.79%), followed by outpatient wound care clinics (n = 128, 26.67%).

One question in the demographic section of the survey asked about participant certifications. Seven common certifications and an "other" category were provided as responses, and respondents could check all that applied. In total, the respondents held 342 individual certifications, but some individuals held more than one. Most of the "other" responses (n = 172) were advanced degrees and not formal wound care certifications.

CONSENSUS STATEMENTS

The following section details each consensus statement and the reported results. To help contextualize the responses, a summary of some of the concepts is included. For a more in-depth overview, refer to the summary article and/or the primary sources of related terms.

All of the statements reached consensus except for the proposed association of PIs as part of skin failure. High-quality research is needed to validate the clinical observations and proposed mechanisms of these injuries.

Table 3. SELECTED WRITTEN COMMENTS GROUPED BY THEME

Need for expert consensus

- A more definitive document
- Consensus on terminology, education, and guidance re: documentation, guidelines
- Consensus or Taskforce to established criteria and impetus on the need to implement it as a third classification of PI (outside unavoidable)
- Policies and guidelines
- We need consensus in all age groups; this is NOT a geriatric problem
- A framework that brings all these concepts together and shows how they relate to a terminal ulcer or not.
- Time and better distribution of information, NPUAP to agree and publish white paper
- A review by a group of respected wound care specialized personnel and development of a consensus statement
- Tough call. More discussions

Is it a pressure injury—yes or no?

- Clarification that KTU not a pressure injury
- Harmonize these with Pressure injury
- TBTTI is not a PI while KTU is
- Skin failure, life's end, KTU should be excluded in the incidence rate of PU's
- The etiology of these wounds does not all regularly indicate PRESSURE INJURY

Definition clarification

- The definitions need to be explained to non WOC trained health care professionals. Medical doctors need to understand how the skin fails at end of life and document appropriately.
- We must address the hierarchy of needs, if they patient is unstable it is better to sacrifice the skin to maintain perfusion to brain and other vital organs, I have seen necrotic toes due to events from hypotension during dialysis. Necrosis of skin due to TTP (thrombotic thrombocytopenic purpura), patients unable to breathe unless in a high fowler position. These show that we cannot make a narrow designation for end of life skin failure to strictly include just KTU or TB-TTI, we need a time frame to death and a list of disease processes which contribute to skin failure: dialysis, heart failure, hypotensive crisis, hypoxia, etc.
- Identify and differentiating standards between end of life category, high risk patients and routine impaired skin
- Need one accepted definition instead of multiple descriptions of end of life skin changes
- Defined as part of multiorgan failure acute or chronic
- Consistent publication of the above on a routine i.e. monthly basis so clinicians can consistently see the language and document according to patient records so it becomes common language and understanding
- Better ontological definitions
- Evidence based definitions
- At this point Langemo and Brown's definition should be used for skin failure which includes acute, chronic and end stage. KTU, SCALE and TB-TTI should be included in the end stage or end of life skin failure. More research is needed BUT until that time, all the research done to date assists us in going forward. To eliminate anything at this point is not necessary or wise.
- Satisfactory as is

More research

- Evidence and research. Databanks. TBTTI is not a PI while KTU is
- Study with statistics and documentations of observations
- I think the science base to distinguish the etiological differences behind these phenomena is in need of strengthening. At this point it is all observational in nature.
- Tissue sampling from an RCT to provide clear guidelines and diagnostic criteria for Skin failure to influence policy, regulatory and billing practices
- I think if it was authenticated and researched
- For over a decade we have been addressing these issues with consensus statements and polls. It's time for some real science in order that we can have evidence-based practice
- Use science to drive definition, not process
- More research in the area of skin changes in the dying patient
- It's obvious that more research needs to be done I believe prealbumin and I'm biopsy on the skin with hypoperfusion specifically the leak out of platelets from the vascular system because of lack of albumin into the skin staining it
- More research, education of health care professionals at all level
- Primary tissue research
- More studies, training and documentation by hospice nurses.
- More research

(continues)

Table 3. SELECTED WRITTEN COMMENTS GROUPED BY THEME, CONTINUED

More education

- More education on skin failure in general x17 -onset, community, nursing + physician, all disciplines, patients + families, novice, support staff – not their fault, validation of education, improve knowledge base, guidelines for careers & staff
- Have a decision tree to guide staff.
- Providing comfortable positions as per the patient's preference/protective dressings/air mattress
- Education of lack of oxygen
- Facilities needs more training and visual training aids. Also, the communities, family members with little knowledge can sometimes be very harsh with staff when these skin changes occur, blaming them for maltreatment
- In order to distinguish these changes from PU/PIs, clinicians need to be educated about the underlying causes of each problem. Ischemia underlies SCALE. Inflammation due to injury underlies PU/PIs.
- The education is lacking In the long-term care facilities, primary care, and when family members Receive a diagnosis that have terminal outcomes that could result in skin failures The family members also need educated as well
- Medicare needs to be educated
- Offering of educational experiences either online or on conferences for long term care facility nurses.
- Federal healthcare agencies must be educated-they do not know there medicine at this point regarding this topic
- More articles on these issues, More patient photos in text

Skin failure

- Better awareness of the skin failure concept
- Would like the international guideline to include more definitive statements on skin failure so we are all talking the same language, even if it's broad, so that we can be guided from the same document. This would help us enormously in Australia as many still use our outdated Australian guideline. The international guideline should be our gold standard that we can all agree on and support each other globally to better care for these patients. As previously stated, I believe we should also look at skin failure that is not at life's end. It is too varied to define but it exists. Conceptually we tend to box everything up, skin is bigger than that, people live with skin failure long before they are in their last 6 weeks of life.
- Skin is an organ that can fail just like other organs fail at end of life
- Better understanding of overall decline in multiple system failure and end of life
- Include all of these terms as skin failure in terminally ill persons. Don't differentiate. It is only confusing. End of life skin failure is the overarching concept.
- What is skin failure? Is it visible? Is it systemic meaning all over the skin surface and not just over bony prominences. Yes, skin more easily breaks down toward end of life for many reasons. Certainly hypo perfusion makes the skin more susceptible to pressure. Emaciation, immobility, etc. add to making pressure relief more difficult. The dermatology definition of skin failure is different than the wound care community. We need consistency

End of life/SCALE

- Maintenance, pain management, drainage control, and comfort. End of life means just that for every organ in the body. Skin the largest organ should not be treated any differently
- Often times at end of life it is more stressful for the patient to be rolled and repositioned when they are so close to death.
- Maybe better to lump them all into SCALE in order to alleviate confusion.

Accountability

- Less emphasis on fear of accountability. We should make PIs simpler instead of more complicated to diagnose and therefore prevent
- I wish common sense and accountability could also be considered
- The NEVER event did not take into consideration that the skin is the largest organ of the body. Like kidneys, lungs, hearts that fail and we do not get penalized for those failures, "they" have decided to penalize if skin failure happens at end of life. I understand why the initiatives were put into place because as a 35 year nurse I have seen horrific wounds on patients due to poor care but now we need to sort this out. Look at what events took place in the weeks prior to these skin issues showing up...code blue, placed on pressors, multiorgan failure etc. need to be taken into consideration.
- Not attributed to poor care. CMS classification
- Maintenance, pain management, drainage control, and comfort. End of life means just that for every organ in the body. Skin the largest organ should not be treated any differently
- If the standard of care is met and documented and comorbidities and organ failure are documented as part of diagnosis then it is skin condition life's end.

(continues)

Table 3. SELECTED WRITTEN COMMENTS GROUPED BY THEME, CONTINUED

Diagnosis

- Clinicians should be aware and know where to find the information when they need it to make a diagnosis
- Stronger definition. Probable progression with timeline?
- A tool like the Braden Scale that can quantify the skin changes that occur at the end of life.
- Better markers of multiorgan failure, documentation of skin failure and what it looks like, lab tests that indicate skin failure, etc.
- Such changes need to also be coordinated with patient's cognitive condition and ability to comply with self protective measures
- We need look toward causes just like we learned Pr I vs MASD
- It is multifactorial so may need a checklist to determine if it is SCALE vs a HAPI
- Checklists that aid in diagnosis and prognosis
- Need better diagnostic criteria

Unavoidable

- Unavoidable pressure injury has to be excluded from incidence total number at the end of each month
- An appreciation that the skin is an organ and as with other organs can fail despite all medical interventions.
- Avoidable definition requires an out for clinicians that do everything "reasonable" to maintain the skins integrity in whatever setting they find themselves

Miscellaneous

- Better staffing
- Less emphasis on fear of accountability. We should make PI's simpler instead of more complicated to diagnose and therefore prevent
- Recognition of patient and family denial of processes
- Work with other specialties to individual the care
- Better support surfaces
- You simply do not have enough space here for me to pontificate

Abbreviations: KTU, Kennedy terminal ulcer; HAPI, hospital-acquired pressure injury; MASD, moisture-associated skin damage; NPUAP, National Pressure Ulcer Advisory Panel; PI, pressure injury; PrI, pressure injury; PU, pressure ulcer; RCT, randomized controlled trial; SCALE, Skin Changes at Life's End; TB-TTI, Trombley-Brennan terminal tissue injury; WOC, wound ostomy continence.

Statements 1 and 2: Kennedy Terminal Ulcers

Statement 1, "Kennedy terminal lesions are attributable to local ischemia and are less likely to be a primary pressure injury," reached 84.29% agreement. In Statement 2, "Kennedy terminal lesions are prognostic of impending death," there was 93.82% agreement.

The KTU was one of the first terminal ulcers reported in modern literature.³ Therefore, it is possible that respondents were familiar with this lesion. Similar to Charcot's ulcer ominous, it is most common over the sacrum or coccyx. It is described as a red, yellow, and/or black pear-shaped lesion that appears suddenly. It may be on intact skin or form an erosion (ie, loss of epidermis with an epidermal base) or an ulcer (ie, loss of epidermis with a dermal or deeper base).³

The majority of respondents agreed that ischemia probably played a greater role than pressure in KTUs (84.29%; Statement 1). The sacrum does not have good collateral circulation and is prone to injury. When the heart or brain is compromised, circulation from the skin, kidneys, liver, lungs, or gastrointestinal tract is often shunted to preserve vital functions. Blood is shifted—literally squeezed—by vasoconstriction, first from skin and soft tissues toward the heart and brain, and then from visceral organs because of the ingenious adrenergic distribution that makes the brain the most protected organ.⁴ It is hypothesized that when the capillaries become

leaky, local hemorrhage can cause a red color on the surface of the skin. As a bruise resolves, it can evolve to a yellow-brown color. If local ischemia is complete and the blood supply shuts down, a black color can result. The color changes can vary in the KTU depending on the relative amount of ischemia.

Knight and colleagues⁵ measured sacral local tensions of oxygen and carbon dioxide, along with sweat lactate and urea, for indirect measures of ischemia in 14 healthy volunteers. With varying external applied pressures, they concluded that oxygen levels were lowered in soft tissues subjected to higher pressures and that this decrease is generally associated with an increase in carbon dioxide levels "well above the normal basal levels (with) considerable increases, in some cases up to twofold, in the concentrations of both sweat lactate and urea at the loaded site compared with the unloaded control."⁵ The investigators also stated "...it is well established that prolonged-pressure ischemia will affect the viability of soft tissues, leading to their eventual breakdown." Therefore, the KTU may represent local ischemia partly from shunted cutaneous circulation subject to a much lower-than-usual pressure, contributing to the local lesion.

Although more than 90% of the respondents agreed that KTUs are prognostic of impending death, one of the comments noted that according to Kennedy's data 44.3% of patients did not die in the 6-week period

following the lesion's appearance. There is only one published data-based article about KTUs.³ Future research should include prospective databases, case series, and cohort-based studies. These lesions are most likely unavoidable and should not be included in PI incidence and prevalence studies.⁶

According to the CMS's *State Operations Manual: Guidance to Surveyors* (F686), KTUs need to be differentiated from other ulcers/injuries:⁶

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.*

However, there is no statement regarding KTUs in the Resident Assessment Instrument User's Manual for long-term care.⁷

Statement 3: Trombley-Brennan Terminal Tissue Injuries

The third survey statement reached 80.74% agreement. In examining the etiology of these injuries, the pink color would again come from hemorrhage of the superficial vessels, and the purple-maroon color could arise from deeper vessels and mature into a bruise type of evolution. Vertical striations on the legs and horizontal areas on the abdomen may follow skin folds, edema patterns, or the vascular plexus structure of the skin.⁸

In the original report, none of the lesions lost their skin integrity or broke down to form an ulcer. However, the survey authors received seven respondent comments about these injuries breaking down with ulcer formation.

Statements 4 to 7: Skin Failure

Of all the concepts in the survey, skin failure has the most related articles in the literature.⁹⁻¹³ Skin failure may be acute or chronic and occur at the end of life or with acute and chronic illnesses.⁹⁻¹³ All but one of the statements on skin failure achieved consensus. In Statement 7, "The definition of skin failure at the end of life should include a description of the degree of skin injury and the area involved," there was 93.4% agreement. Statement 6, "Skin failure is an event in which the skin and underlying tissue die because of hypoperfusion and occurs concurrently with severe failure of other organ systems (two or more)," achieved 95.62% agreement. Similarly, statement 5, "Skin failure can

occur with acute illness, chronic illness, and at end of life," achieved an even greater 98.1% agreement. However, consensus was not reached for Statement 4, "The concept of skin failure does not include pressure injuries;" 60.38% of respondents disagreed with this statement.

In defining skin failure, Langemo and Brown⁹ state: "Skin failure is 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." Levine has also published commentaries on skin failure^{10,11} that include proposed definitions such as "the state in which tissue tolerance is so compromised that cells can no longer survive in zones of physiologic impairment such as hypoxia, local mechanical stresses, impaired delivery of nutrients, and buildup of toxic metabolic byproducts. In this schema, skin failure can occur over bony prominences where skin and underlying tissues, including muscle, are stretched and subjected to external pressure."¹¹ These criteria for skin failure with hypoperfusion and compromise of two or more other organs can occur with an acute illness, chronic illness, or at the end of life.

What continues to need clarity is whether skin failure involves one or more organs. The survey featured a number of written comments concerning the desire for more evidence to clarify whether one severe organ failure is enough (eg, cardiac arrest) or if two internal organs must fail.

It is important to distinguish skin failure from other dermatologic disease processes that cause skin compromise from mechanisms other than hypoperfusion (eg, erythroderma with hyperperfusion compromise of the skin where >90% of the skin is red). The extent of skin compromise is an important component in describing ischemic injury associated with skin failure. Specific descriptions of skin changes should also be documented. Some written comments from the survey suggest that the severity of skin injury (erythema, erosion, ulcer, necrosis, bruising) and extent of the injury (percent of body surface area) may be a better documentation base to define treatment than the degree of skin injury.

The respondents agreed that skin failure can occur at the end of life and also with acute and chronic illnesses. There are two data-based articles on skin failure associated with acute illnesses from Delmore and colleagues.^{12,13} In 2015, they defined acute skin failure as "hypoperfusion of the skin resulting in tissue death in the setting of critical illness"¹² and later revised the definition as "the hypoperfusion state that leads to tissue death that occurs simultaneously to a critical illness."¹³

There is evidence that, with ischemia, the threshold pressure for a PI is lower and may occur even with an acceptable standard of care.⁶ There were 15 open-ended comments stating that PIs occur more readily with skin failure or are part of the concept of skin failure.

Statement 9: SCALE

For the statement “The changes outlined in the SCALE statements can occur in the absence of skin failure,” there was 81.42% agreement and thus consensus. Skin Changes At Life’s End^{14,15} can occur as patients are dying without two internal organs failing, although many of the SCALE criteria may be present within the definition of skin failure. Further, SCALE includes changes in skin color, turgor, or integrity (involving factors such as medical devices, incontinence, chemical irritants, chronic exposure to body fluids, skin tears, shear, friction, and infection). Suboptimal nutrition can result in weight loss, wasting, and skin changes with dehydration. Diminished tissue perfusion may cause a local decrease in skin temperature, mottled vasculature, and skin necrosis or gangrene. Pressure injuries are also a component of SCALE. Most of these changes may be unavoidable.

Statements 8 and 10: Unavoidable Skin Changes

For Statement 8, “Kennedy terminal ulcer (KTU), Trombley-Brennan terminal tissue injury (TB-TTI), Skin Changes At Life’s End (SCALE), and skin failure at the end of life are unavoidable and not attributable to substandard care,” there was 86.59% agreement and thus consensus. Similarly, in Statement 10, “How much do you agree with the Centers for Medicare and Medicaid Services’ definition of avoidable/unavoidable pressure injury?” there was 90.91% agreement and consensus.

The most current CMS definitions (effective November 28, 2017) provided to distinguish avoidable and unavoidable PIs are as follows:⁶

“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” means that the resident developed a pressure ulcer/injury even though the facility has 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.

The CMS also provides some clarification regarding PIs at the end of life. Even if a resident has an advance directive, the facility still needs to provide the resident with supportive and pertinent care as long as it is not prohibited by the directive.⁶ Further, statements about whether a PI is avoidable or unavoidable are also provided.⁶

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.

Some of the written responses expressed concern about how to define “substandard care.” Perhaps the elements of the process that CMS describes in the “avoidable” definition could be used to define what survey respondents called “substandard care.”

Open-Ended Question

At the end of the survey, survey authors asked for write-in comments; some of these have been organized by theme in Table 3. Many survey participants stated they would like a more definitive statement on skin failure/end-of-life skin changes (eg, from a task force or consensus group). They also requested definitions that are more closely aligned with evidence. Clearly, there is a need for more scientific evidence through research using an improved conceptual framework for end-of-life skin failure. Specific ideas about diagnostic criteria need to be validated, and enhanced definitions require further research. Clinicians want to know more about how to describe these wounds, how they impact funding, and how to relate these issues to patients and families. The need for more focused education for clinicians is a future opportunity.

CONCLUSIONS

This study represents a first step in exploring the global skin and wound care community’s opinions about terminal ulcers/injuries, skin failure, and SCALE in a structured way. It was clear respondents want clarified terminology and hope for a global consensus. Importantly, there was a lack of consensus as to whether skin failure includes PIs. The need for more research in this area, including clear diagnostic criteria, was repeatedly expressed by survey participants. The next steps could include a knowledge translation task force or a global consensus conference to explore terminology and propose scientific validation studies. This research may be facilitated by the development of databases through sponsoring national or international professional organizations.

PRACTICE PEARLS

- KTU and TB-TTI are believed to be terminal ulcers observed in patients at end of life.



- Survey results reveal that there is no current consensus as to whether the concept of skin failure includes pressure injuries.
- Skin failure (acute, chronic, and/or end of life) criteria must be further defined and the validated.
- Although definitions for unavoidable and avoidable pressure injuries exist from the CMS and other regulatory bodies, global criteria for determining when a pressure injury is avoidable or unavoidable should be validated and agreed upon. ●

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