

Critical analysis of the consensus document on current advances in risk assessment, prevention, and treatment of skin tears. A response from ISTAP

Ray Samuriwo^{1,2} PhD, **Samantha Holloway**^{*3,4} MSc, FHEA, CertEd, RN, **Karen Ousey**^{5,6} PhD, RGN, FHEA, CMgr, MCMI, **Kimberly LeBlanc**^{7,8,9} PhD

¹President-Elect, International Skin Tear Advisory Panel

²School of Health and Social Care, Edinburgh Napier University, Scotland, United Kingdom

³Past President, International Skin Tear Advisory Panel.

⁴Centre for Medical Education, School of Medicine, Cardiff University, Wales, United Kingdom

⁵President, International Skin Tear Advisory Panel

⁶Institute of Skin Integrity and Infection Prevention, Department of Nursing, University of Huddersfield, England, United Kingdom

⁷Past-president, International Skin Tear Advisory Panel (2016-2018)

⁸Ingram School of Nursing, Faculty of Medicine, McGill University, Canada. Academic Chair, Nurses, Specialized in Wound, Ostomy, and Continence, Canada

⁹Academic Chair, Nurses, Specialized in Wound, Ostomy and Continence, Canada

*Corresponding author email holloways1@cardiff.ac.uk

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INTRODUCTION

Diagnostic errors are harmful and can cause death, but they can be difficult to detect and define because of their complexity.^{1,2} These errors are a recurring issue in clinical practice where skin tears (STs) and other wounds are often misdiagnosed or misclassified,³⁻⁵ undermining ongoing efforts to improve the quality and safety of care. Given the high prevalence of STs among aging populations, the accurate assessment and diagnosis of STs is a key global priority for improvement.^{3,6} A robust evidence-based classification system is fundamental to any efforts to improve ST care in different contexts throughout the world.^{3,6} Classification enables healthcare professionals to engage in communication in a common language.⁶ By using common and appropriate descriptors for various types of wounds, including STs, healthcare professionals can more effectively communicate with other healthcare professionals, policy makers, researchers, and patients.³ The correct use of a robust classification tool or system is essential to efforts and interventions to improve the quality of care for different types of wounds such as STs,^{3,6} diabetic foot ulcers,⁷ pressure ulcers,⁸ and surgical wounds.^{5,9}

A good classification system in healthcare, has a high level of reliability, and validity with low measurement error.⁸ The ISTAP ST classification system has been validated and based on robust research evidence pertaining to its validity and reliability in different countries and different languages.¹⁰⁻¹² Van Tiggelein et al¹⁰ reported an overall interrater agreement of 80%, with specificity of 92%, and sensitivity of 88% when the ISTAP ST classification system was used by participants from 44 different countries. A recent paper,¹³ argues that the ISTAP consensus document ST definitions are incomplete because it omits the hypodermis. Instead, the authors¹³ state that ISTAP skin tear definitions must be revised to include subcutaneous

cellular tissue. Our peers¹³ assert that a change in definitions would contribute to a more detailed understanding of the extent of ST damage with due awareness of any associated adverse events, such as bleeding and haematoma formation. The views expressed by Henao and Gómez¹³ are in sharp contrast to the views of Budri⁶ who contends that the ISTAP ST classification system^{11,12} provides an evidence-based, effective, and efficient tool that can be used by clinicians to diagnose, assess, and treat STs across the world.

Definitions and classification systems matter because they determine how care is prioritised organised and delivered. Accurate classification facilitates correct diagnosis, assessment, treatment as well as effective communication between healthcare professionals with differing levels of knowledge, skills, and expertise.^{3,7,8,14} The correct use of evidence-based classification is integral to benchmarking quality and standards, while also ensuring that healthcare professionals are making the most appropriate decisions about the care of their patients.^{3,7,8,14} There are some specific reasons why clarity and consensus about evidence-based ST definitions is important. Professionals in clinical practice often find it difficult to accurately diagnose STs due to physiological variations in the morphology and structure of the skin, which may be age related.^{6,14,15} Misclassification and misdiagnosis of STs causes delays in the implementation of correct treatment, which often undermines quality and safety of care delivered.^{6,14} For example, if a ST with a viable skin flap is accurately classified early enough, and the wound is cleansed correctly then the flap can be reapproximated with the wound edges to facilitate healing by primary intention, which leads to better, more cost effective outcomes, thus enhancing patient comfort.^{6,14}

Given the key role that classification systems play in assessment, diagnosis, and treatment of skin tears, it is vital

to examine the Henao and Gómez¹³ critique of the ISTAP ST classification system. The best, scientific advances, decisions, improvements, and innovations occur in healthcare when all opinions are considered with due reference to the best available evidence. Human history demonstrates that often views and opinions that are initially overlooked or ignored have subsequently been shown to be correct, as new evidence has emerged. With this in mind, we respond on behalf of ISTAP to the points put forward in the critical analysis,¹³ with due reference to the underpinning evidence and rationale for the decisions made. We welcome this critique of the ISTAP definitions of skin tears as it provides an important opportunity to focus on this often-overlooked aspect of wound care and to clarify our position for an international readership.

METHODS

In this commentary we critically reflect on each of the points made by Henao and Gómez,¹³ with due reference to ISTAP documents, wider evidence, and principles of the scientific method which inform and underpin every aspect of improvement in healthcare quality and safety. The transparent evidence-based approach we have taken is important because all arguments, assertions, or hypotheses that are put forward in relation to healthcare must be subject to proper scientific scrutiny to avoid causing harm to patients, no matter how well intentioned. In other words, we have taken great care in this paper to adopt principles of the scientific method in which we respond to each of the points made in the critique¹³ of the ISTAP ST classification system. We refer directly to the evidence on which they are based and being transparent and clear about the rationale for the definitions therein.

DISCUSSION

Healthcare is a dynamic field where knowledge and understanding continually evolve. Therefore, we appreciate that there is merit in revisiting the existing ISTAP ST classification system, to determine whether it still captures emerging insights or advancements in research and clinical practice. We welcome the opportunity to engage in a critical discussion.

ANATOMY AND PHYSIOLOGY OF THE SKIN

The skin is made up of three layers, the epidermis (which has five sub-layers), dermis (papillary and reticular), and the hypodermis (subcutaneous tissue) which connects the skin to the fascia. The hypodermis is not strictly a part of the skin, although the border between the hypodermis and dermis can be difficult to distinguish. ISTAP's most recent definition of a skin tear reflects the involvement of subcutaneous tissue³ but importantly states that a ST does not *extend through* the subcutaneous tissue to the fascia below. This distinguishes it from a laceration (cut) in which, unlike an abrasion, none of the skin is missing. A laceration is typically thought of as a wound caused by a sharp object. Importantly ISTAP 2018 guidance³ makes it clear that pre-tibial lacerations are a specific type of wound that requires a different approach to management i.e. requiring surgery and grafting.

DEFINITION OF A SKIN TEAR

It has been hypothesised that the use of multiple different ST

definitions coupled with the relative youth of the validated ISTAP definition, is in-part, a reason why skin tears do not have a specific category code in the World Health Organization's International Classification of Diseases (ICD) 10 codes.^{16,17,18} This lack of specific ICD coding by the WHO may partially explain why STs are often trivialised by healthcare professionals.^{17,18} While the inclusion of STs as a child code within the parent code of 'laceration' in the ICD-10 was a step forward it may only serve to cause further confusion. This is something the ISTAP is trying to address as part of a wider strategy to support accurate classification.

ISTAP's original definition stated that STs were,

"traumatic wounds caused by mechanical forces, including removal of adhesives, that results in separation of skin layers. A skin tear can be partial-thickness (separation of the epidermis from the dermis) or full-thickness (separation of both the epidermis and the dermis from underlying structures)"

(LeBlanc et al 2011, pg. 6)¹⁹

This definition was developed as part of a robust Delphi study and emphasises the aetiology of skin tears, attributing them to mechanical forces such as shear, friction, or blunt trauma.¹⁹ It also highlighted the potential severity of skin tears by distinguishing between partial-thickness and full-thickness injuries. Additionally, the inclusion of adhesive removal as a common cause of STs underscores the importance of preventive measures in clinical practice. Overall, the ISTAP definition provided a clear and comprehensive description of STs, facilitating their recognition, assessment, and management by healthcare professionals.

In 2018 the ISTAP definition of a ST was updated to help differentiate STs from other types of injuries, for example pre-tibial lacerations. This led to the following revised definition,

"A skin tear is a traumatic wound caused by mechanical forces, including removal of adhesives. Severity may vary by depth (not extending through the subcutaneous layer)"

(LeBlanc et al 2018, pg. 2)³

Reference to 'extending through' implies that the subcutaneous tissue may be involved in a ST, but the injury will not extend through to the fascia overlying the muscle.

Subsequently Van Tiggelen et al¹⁰ suggested an extension to the ISTAP classification system by incorporating a definition for a "skin flap." To refine this definition, an expert panel comprising 17 international key opinion leaders was convened. In the initial Delphi round, these experts were invited to offer feedback on the proposed definition. The feedback was collated and used to formulate a revised proposal. In the second round, the experts were invited to provide their approval and any further comments on the refined definition. Consensus was reached following the second Delphi round.¹⁰

The revised ST definition included the following definition of a flap for clarity,

'A flap in skin tears is defined as a portion of the skin (epidermis/dermis) that is unintentionally separated (partially or fully) from its original place due to shear, friction, and/or blunt force. This concept is not to be confused with tissue that is intentionally detached from its place of origin for therapeutic use e.g. surgical skin grafting'. pg. 150¹⁰

SKIN TEAR CLASSIFICATION SYSTEM

The ISTAP classification system was developed following an international cross-sectional survey (n=1127 health care providers from 16 countries). Health care providers reported problems using other classification methods for the assessment and documentation of STs (69.6%, n=695). An overwhelming majority (89.5%, n=891) favoured the development of a simplified, user friendly and validated method for skin tear assessment.²⁰ In response to the survey, ISTAP used a Delphi method to develop the ISTAP ST classification system.¹⁷ Building on previous classification systems, ISTAP collapsed the sub-categories, allowing for three simple categories with no requirement for estimations. The three distinct categories include type 1 (no skin loss), type 2 (partial skin loss) and type 3 (complete skin loss). The rationale for collapsing the categories was that estimating percentage of skin loss is often subjective. The presence or absence of haematoma and ischaemia was felt to have a greater link to predictability of potential ST risk and healing time and, therefore, was not incorporated into the classification system.^{11,17}

The ISTAP system underwent test-re-test reliability with the expert ISTAP panel and inter-rater reliability testing with 339 healthcare professionals. They reported a level of agreement sufficient to indicate they had met their objective of developing a reliable and valid ST classification system. Interrater reliability based on wound care expertise was established using Fleiss *k* statistic. The level of agreement was substantial (Fleiss $k=0.619$; two month follow-up= 0.653). Test-re-test or Intra-rater reliability was high (Cohen $k=0.877$). Interrater reliability was moderate (Fleiss $k = 0.555$) for healthcare professionals (n=303) and fair for non-health professionals (Fleiss $k=0.338$; n=24).

Study results were replicated in a second study involving inter-rater reliability testing with 270 healthcare professionals.²¹ A moderate level of agreement was demonstrated for both the Registered Nurse group and the non-Registered Nurse group (Fleiss' Kappa=0.464 and 0.443, respectively) (<0=less than chance agreement, 0.01-0.20=slight agreement, 0.21-0.40=fair agreement, 0.41-0.60=moderate agreement, 0.61-0.80=substantial agreement, 0.81-0.99=almost perfect agreement).²¹

More recently Van Tiggelen et al,¹⁰ undertook an international validation study of the ISTAP ST Classification system among healthcare professionals (n=1601) from 44 countries. The overall agreement with the reference standard was 0.79 [95% confidence interval (CI) 0.79–0.80] and sensitivity ranged from 0.74 (95% CI 0.73–0.75) to 0.88 (95% CI 0.87–0.88). The inter-rater reliability was 0.57 (95% CI 0.57–0.57). Cohen's Kappa measuring intra-rater reliability was 0.74 (95% CI 0.73–0.75). This robust validation of the ISTAP classification system among a wide range of healthcare professionals increases the generalisability of the classification system and its utility in practice. Currently the ISTAP ST classification system has been translated into 14 other languages including Arabic, Chinese, Czech, Danish, Dutch, French, German, Hebrew, Italian, Japanese, Portuguese, Spanish, Swedish and Turkish. This supports the external validity, acceptability, and user friendliness of the Skin Tear classification system.

CONCLUSION

In this paper, we have sought to answer the questions raised by Henao and Gómez with regards to the ISTAP definitions of STs. We are grateful for comments and feedback provided but are disappointed by the fact that the points made in the critique do not mention any of the ISTAP documents where we explain the reasons for the definitions that we have published. While we disagree with many of the points that are made by colleagues in their critique, we respect and value their right to critique our ST definitions. In our opinion, discussion, and debate are non-negotiable aspects of the scientific method which underpins improvement and in healthcare. The critique of the ISTAP definitions of STs made by Henao and Gómez contained some new and unexpected, but important arguments. The views expressed in this critique provide us with a timely opportunity to clearly explain the rationale and evidence that underpins the ISTAP consensus document and the definitions of STs.

Intellectual and scientific advances that improve the quality and safety of healthcare are not static but are continually evolving in response to new evidence and innovation. In this spirit of continuous improvement with adaptation, innovation, and innovation in the complex adaptive context of healthcare, ISTAP maintains an agile and pragmatic focus. To put it simply, ISTAP continually seeks to improve the quality of care to prevent and treat STs through the best available evidence. ISTAP will be updating all its documents over the next 12 months and will give due consideration to all views and opinions throughout this process. Improvement in science and healthcare requires an openness to new evidence, humility to change and needs to adapt when new evidence emerges or circumstances. ISTAP remains committed to changing and evolving the definitions of skin tears as new evidence emerges and wider knowledge in this aspect of healthcare appears. We remain committed to providing guidance, recommendations, and information that are based on the best available evidence. We will continue to highlight the quality of evidence that underpins our work with due acknowledgement to gaps in knowledge, and what is based on expert opinion.

In conclusion, we have explained why we disagree with the points made by our counterparts and explained the basis for the ISTAP definitions of STs with due reference to the best available evidence. ISTAP welcomes all views, perspectives, and evidence because they are vital to ensuring ST definitions are continually improved. We encourage our colleagues and others to share their thoughts, feedback, criticisms, as they will enable us all to get a step closer towards the shared goal of 'a world without skin tears'.

CONFLICT OF INTEREST

The authors have all been or are currently on the ISTAP board.

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