Understanding
Types of Research

Meta Analysis and Systematic Review
Summarizes the clinical research that has been performed by independent investigators and researchers. This is critical assessment of all the research that looks at a specific topic.

Randomized Controlled Trials (RCT)
Subjects that have a specific condition are randomly (by chance) assigned to one of two groups, either a treatment or a control group. While at baseline both groups are similar, the control group receives the standard treatment/ intervention and the treatment group receives the treatment/intervention newly created.

Cohort Study
Groups of people that have a certain condition or receive a specific treatment are followed over time. This group is compared to a similar group of people that do not have the condition or receive the treatment of interest.

Case Control Studies
Compares two groups, one with a condition of interest to a similar group that is free from the condition of interest.

Cross Sectional Studies
This type of study looks at specific populations at a given point in time to measure the occurrence of a clinical risk factor, outcome, or unique result.

Case Reports / Case Series
Case reports are published accounts of clinical observations. This is a retrospective description of a distinct case that presents differently than projected. A case series is a retrospective report of the outcomes of a group of patients with the condition of interest that are treated in a similar fashion.

References:
• Aslam S, Georgiev H, Mehta K, Kumar A. Matching research design to clinical research questions. Indian J Sex Transm Dis 2012;33:49-53
• Kumar R. Research Methodology. APH Publishing, 2012. ISBN 8131304221 9788131304228
• Titler MG. The Evidence for Evidence-Based Practice Implementation. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 7. Available from: http://www.ncbi.nlm.nih.gov/books/NBK2659/

NATIONAL PRESSURE ULCER ADVISORY PANEL

epuap

PAN PACIFIC Pressure Injury Alliance

LEVELS OF EVIDENCE

Full explanation of the methodology is available in the full Clinical Practice Guideline. Individual studies were assigned a 'level of evidence' based on study design and quality, using a classification system adapted from Sackett (1989).

	INTERVENTION STUDIES	DIAGNOSTIC STUDIES	PROGNOSTIC STUDIES
1	Randomized trial(s) with clearcut results and low risk of error or systematic literature review or meta-analysis according to the Cochrane methodology or meeting at least 9 out of 11 quality criteria according to AMSTAR appraisal tool.	Systematic review of high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding.	Systematic review of high quality (longitudinal) prospective cohort studies according to the quality assessment tools.
2	Randomized trial(s) with uncertain results and moderate to high risk of error.	Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.	A prospective cohort study.
3	Non randomized trial(s) with concurrent or contemporaneous controls.	Non-consecutive studies, or studies without consistently applied reference standards.	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
4	Non randomized trial(s) with historical controls.	Case-control studies, or poor/ non-independent reference standard.	Case-series or case-control studies, or poor quality prognostic cohort study, retrospective cohort study.
5	Case series with no controls. Specify number of subjects.	Mechanism-based reasoning, study of diagnostic yield (no reference standard).	Not applicable.

The full body of evidence supporting each recommendation was given a 'strength of evidence'. A consensus voting process (GRADE) involving all the experts formally engaged in the guideline development was used to assign a 'strength of recommendation' that indicates the confidence the health professional can have that the recommended practice will improve patient outcomes (i.e., do more good than harm). The overall aim of the 'strength of recommendation' is to help health professionals to prioritize interventions.

STRENGTHS OF EVIDENCE

The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at risk for pressure ulcers), providing statistical results that consistently support the recommendation. (Level 1 studies required)

The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or humans at risk for pressure ulcers) providing statistical results that consistently support the recommendation. (Level 2, 3, 4, 5 studies)

The recommendation is supported by indirect evidence (e.g., studies in healthy humans, humans with other types of chronic wounds, animal models) and/ or expert opinion.

STRENGTHS OF RECOMMENDATION